BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
SUMMARY SHEET

November 9, 2023

(X) ACTION/DECISION
( ) INFORMATION

I. TITLE: MUHA Community Hospital requests Board approval for a second Board extension of CON SC-20-25.

II. SUBJECT:

Medical University Hospital Authority d/b/a MUHA Community Hospital requests the Board's approval for the second Board extension of Certificate of Need (CON) SC-20-25, for the Construction of a 128-bed general acute hospital in Berkeley County. Department staff recommends the Board finds that MUHA Community Hospital has demonstrated extenuating circumstances beyond its control, which has prevented the Project from advancing, and a 9-month extension of CON SC-20-25 be granted.

III. FACTS:

After the South Carolina Administrative Law Court's (ALC) affirmation of the Department's approval of the project, CON SC-20-25 was issued to Medical University Hospital Authority d/b/a MUHA Community Hospital on September 29, 2020, for the construction of a 128-bed general acute hospital in Berkeley County at a total project cost of $325,000,000. The original CON had an expiration date of September 29, 2021.

MUHA requested a first staff extension of the CON on August 27, 2021, which was more than 30 days prior to expiration. MUHA's CON SC-20-25 EXT-1 was valid until June 29,2022, a period of nine months from original expiration of the CON. On May 3, 2022, the Department received a letter from MUHA requesting a second staff extension of the CON. The Department issued the second staff extension, CON SC-20-25-EXT-2 to MUHA, which was valid until March 29, 2023. MUHA submitted a third extension request to the Department on December 21, 2022, approved by the Board on March 9, 2023. On August 28, 2023, the Department received a letter from MUHA requesting a fourth extension request of the CON. Trident Health appealed the decision of the South Carolina Administrative Law Court (ALC) to the South Carolina Supreme Court. The South Carolina Supreme Court heard the case on October 4, 2023, and the decision is still pending.

IV. ANALYSIS:

Department staff have reviewed all relevant information concerning this fourth extension request and finds that circumstances beyond the control of MUHA, specifically the delays experienced due to pending litigation, have contributed to the need for further extension of CON SC-20-25.

MUHA provided in its extension request an updated timeline for the project, which Department staff believe is achievable.

V. RECOMMENDATION:

Department staff recommend the Board finds that MUHA Community Hospital has demonstrated extenuating circumstances beyond its control which have prevented the Project from advancing. The Department staff recommend the Board grant the 9- month extension.

Approved by:

Gwendolyn C. Thompson

Gwen C. Thompson
Deputy Director
Healthcare Quality

Attachments:

A) CON SC-20-25
B) MUHA First Extension Request
C) MUHA First Extension Issuance of CON
D) MUHA Second Extension Request
E) MUHA Second Extension Issuance of CON
F) MUHA Third Extension Request and Quarterly Report
G) MUHA Third Extension Issuance of CON
H) MUHA Fourth Extension Request

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-20-25

FACILITY NAME: MUHA Community Hospital

LOCATION: Berkeley County

LICENSEE: Medical University Hospital Authority

FOR: Construction of a 128-bed general acute hospital in Berkeley County.

TOTAL PROJECT COST: $325,000,000.

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 *et seq*. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until September 29, 2021 which is a period of twelve (12) months from the date of issuance unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 29th day of September 2020.

Louis W. Eubank, Chief
Bureau of Healthcare Planning and Construction

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

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Sarah Bacik, MHA
Chief Strategy Officer
Medical University of South Carolina
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MUSC Health
MEDICAL UNIVERSITY of SOUTH CAROLINA

August 27, 2021

Ms. Margaret (Maggie) Murdock
SC Department of Health and Environmental Control
2600 Bull Street
Columbia SC 29201

RE: MUHA Community Hospital Certificate of Need 1st Extension Request (SC-20-25)

Dear Ms. Murdock:

This letter on behalf of MUHA, is to provide the first extension request for a nine month period on the MUHA Community Hospital CON (SC-20-25) in accordance with the State "Certification of Need and Health Facility Licensure Act" S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15 "Certification of Need for Health Facilities and Services."

After a protracted appeal process, the Certificate of Need was ultimately issued on September 30, 2020. MUHA is requesting the first extension, more than 30 calendar days prior to the current expiration on September 30, 2021. The new expiration date for the CON would be June 30, 2022.

Planning is underway for this project. An architect has been secured, but the building design is still in the development phase. Site studies have been conducted. Progress has occurred on the project; however, most activities have been suspended or slowed due to the current COVID-19 pandemic. To date, approximately $150,000 in A/E fees have been incurred.

The ability to efficiently plan and design the new hospital under current conditions are impossible and beyond the control of MUHA, and therefore requires a CON extension. This delay will make implementation of the project impossible to achieve prior to the September 30, 2020 deadline. Once some "normalcy" is restored to our operations, we will submit a revised project timeline for the project. Currently, we are unable to accurately predict when productive activities in earnest can resume.

We appreciate your attention to this matter. Please contact me at (843) 792-9917 if you have any questions regarding this information.

Sincerely,

Sarah Bacik, MHA
Chief Strategy Officer
The Medical University of South Carolina

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Article #: 9214896900999790142235732 8

October 7, 2022

VIA EMAIL AND CERTIFIED MAIL
Patrick J. Cawley, MD
Medical University Hospital Authority
169 Ashley Avenue
Charleston, SC 29425

Re: **CON SC-20-25 EXT-1**
Applicant: Medical University Hospital Authority d/b/a MUHA Community Hospital
Project: Construction of a 128-bed general acute hospital in Berkeley County at a total project cost of $325,000,000.
Application No.: 2520

Dear Dr. Cawley:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you have provided in support of your request, it is the decision of the Department to **grant you a nine (9) month initial extension** for Certificate No. SC-20-25. The Department's decision is based on the following findings:

- You have provided the Department with reasonable assurance that the Project will be implemented within the requested extension period.

As required by Regulation No. 61-15, Section 607, you must continue to submit quarterly progress reports from the date of issuance of the original Certificate of Need (September 29, 2020). You must continue to report on, if applicable:

a. Costs incurred on the project;
b. Construction activity;
c. Program or service activity; and
d. Any deviations from the submitted application with supporting documentation.

The mandated due dates for these reports are as follows:

5th Quarterly Report: **12/29/2021**
6th Quarterly Report: **3/29/2022**
7th Quarterly Report: **6/29/2022**

Failure to adhere to the reporting schedule and format may result in enforcement action, which may be inclusive of the voidance of the Certificate of Need and a monetary penalty pursuant to Regulation No. 61-15, Section 701.

Should the length of your project exceed the nine month period of this extension, you are required to file a second extension request with the Department pursuant to Regulation No. 61-15, Sections 602 and 603. The due date for the second extension request, if one is needed, is **May 30, 2022.** Extension requests received after this date will not receive consideration from the Department.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing, or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Ms. Susan Jenkins, (803) 545-0530; Division of Health Facilities Construction, Mr. Graham Cormack, (803) 727-3576; and Bureau of Healthcare Systems and Services, Ms. Charlene Bell, (803) 545-4223.

If this office can be of further service to you or if you have any questions concerning the above, feel free to contact me at (803) 545-3028.

Sincerely,

Ashley C. Grant

Ashley C. Grant, MBA
Project Coordinator
Certificate of Need Program

Enclosures: Certificate of Need SC-20-25 EXT-1
cc: Sarah Bacik (Via email)

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-20-25 EXT-1

FACILITY NAME: MUHA Community Hospital

LOCATION: Charleston County

LICENSEE: Medical University Hospital Authority

FOR: Construction of a 128-bed general acute hospital in Berkeley County.

TOTAL PROJECT COST: $325,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. Section 44-7-110 *et seq.* and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until June 29, 2022, which is a period of nine (9) months from the date of CON expiration, unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this Day 7th day of October 2022.

Trenessa K. Jones, DSL, Bureau Director
Healthcare Planning and Construction

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Chief Strategy Officer
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May 3, 2022

Ms. Jennifer Hyman
SC Department of Health and Environmental Control
2600 Bull Street
Columbia SC 29201

RE: MUHA Community Hospital Certificate of Need 2nd Extension Request (SC-20-25)

Dear Ms. Hyman:

This letter is submitted on behalf of MUHA to request a second nine-month extension of the MUHA Community Hospital CON (SC-20-25) in accordance with the State "Certification of Need and Health Facility Licensure Act," S.C. Code Ann. §§44-7-110 et seq. and Regulation 61-15 "Certification of Need for Health Facilities and Services."

After a protracted litigation process, the Certificate of Need was ultimately issued on September 30, 2020, although the appeal challenging this CON continues. Issuance of the CON occurred during the middle phase of the COVID-19 pandemic and approximately nine months after the Public Health Emergency was declared. MUHA appreciates the Department's granting of the First Extension Request made in August 2021 as the hospital community continued to field, staff, and devote significant resources to the ever-changing COVID-19 pandemic environment.

Since receiving its First CON Extension, MUHA has continued to engage in as much planning activities as practical under the pandemic conditions. Internal planning groups continue to work towards developing a general building design, planning for site development and other related activities. To date, approximately $8,650,000 in land costs and A/E fees have been incurred. However, current pandemic conditions and operational impacts have made it impossible for MUHA to meet the current implementation deadline of June 30, 2022. Given the uncertainty related to the continuation of the Public Health Emergency and its ramifications, MUHA is unable to accurately estimate when it can fully resume its implementation efforts despite the acknowledged need of our community. As we continue to emerge from the pandemic, we will submit a revised project timeline to the Department.

Based on the above, MUHA is requesting this second extension more than 30 calendar days prior to the current expiration date of June 30, 2022. If this Second Extension Request is granted, the new expiration date for the CON would be March 30, 2023.

We appreciate your attention to this matter. Please contact me at (843) 792-9917 if you have any questions regarding this information.

Sincerely,

Sarah Bacik, MHA
Chief Strategy Officer
The Medical University of South Carolina

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Article #: 9214896900999790142235738O

October 7, 2022

VIA CERTIFIED MAIL
Patrick J. Cawley, MD
Medical University Hospital Authority
169 Ashley Avenue
Charleston, SC 29425

Re: **CON SC-20-25 EXT-2**
Applicant: Medical University Hospital Authority d/b/a MUHA Community Hospital
Project: Construction of a 128-bed general acute hospital in Berkeley County at a total project cost of $325,000,000.
Application No.: 2520

Dear Dr. Cawley:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you have provided in support of your request, it is the decision of the Department to **grant you a second nine (9) month extension** for Certificate No. SC-20-25. The Department's decision is based on the following findings:

- You have provided the Department with reasonable assurance that the Project will be implemented within the requested extension period.

As required by Regulation No. 61-15, Section 607, you must continue to submit quarterly progress reports from the date of issuance of the original Certificate of Need (September 29, 2020). You must continue to report on, if applicable:

a. Costs incurred on the project;
b. Construction activity;
c. Program or service activity; and
d. Any deviations from the submitted application with supporting documentation.

The mandated due dates for these reports are as follows:

8th Quarterly Report: **9/29/2022**
9th Quarterly Report: **12/29/2022**
10th Quarterly Report: **3/29/2023**

Failure to adhere to the reporting schedule and format may result in enforcement action, which may be inclusive of the voidance of the Certificate of Need and a monetary penalty pursuant to Regulation No. 61-15, Section 701.

Should the length of your project exceed the nine month period of this extension, you are required to file a DHEC Board extension request with the Department pursuant to Regulation No. 61-15, Sections 602 and 603. The due date for the Board extension request, if one is needed, is **December 31, 2022**. Extension requests received after this date will not receive consideration from the Department.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing, or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Ms. Susan Jenkins, (803) 545-0530; Division of Health Facilities Construction, Mr. Graham Cormack, (803) 727-3576; and Bureau of Healthcare Systems and Services, Ms. Charlene Bell, (803) 545-4223.

If this office can be of further service to you or if you have any questions concerning the above, feel free to contact me at (803) 545-3028.

Sincerely,

Ashley C. Grant, MBA
Project Coordinator
Certificate of Need Program

Enclosures: Certificate of Need SC-20-25 EXT-2
cc: Sarah Bacik (Via Email)

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-20-25 EXT-2

FACILITY NAME: MUHA Community Hospital

LOCATION: Charleston County

LICENSEE: Medical University Hospital Authority

FOR: Construction of a 128-bed general acute hospital in Berkeley County.

TOTAL PROJECT COST: $325,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. Section 44-7-110 *et seq*. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until March 29, 2023, which is a period of nine (9) months from the date of CON EXT-1 expiration, unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this Day 7th day of October 2022.

Trenessa K. Jones, DSL, Bureau Director
Healthcare Planning and Construction

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

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Patrick Cawley, MD
Chief Executive Officer, MUSC Health
Vice President for Health Affairs, University
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Charleston, SC 29407
Tel 843 792 0599
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December 21, 2022

DHEC CON Staff
SC Department of Health and Environmental Control
2600 Bull Street
Columbia SC 29201

RE: MUHA Community Hospital Certificate of Need 3rd Extension Request and 9th Quarterly Update (SC-20-25)

Dear DHEC CON Staff:

This letter is submitted on behalf of MUHA is to request a third nine-month extension of the MUHA Community Hospital CON (SC-20-25) in accordance with the State "Certification of Need and Health Facility Licensure Act," S.C. Code Ann. §§44-7-110 et seq. and Regulation 61-15 "Certification of Need for Health Facilities and Services." This letter also provides the ninth quarterly update on the project.

After a protracted litigation process, the Certificate of Need (CON) was ultimately issued on September 30, 2020, although the opposition challenging this CON continues. The S.C. Administrative Law Court (ALC) heard the case and in September 2020 affirmed the Department's approval of the project. However, Trident Health has appealed that decision to the South Carolina Court of Appeals. Until Trident Health either withdraws its challenge or exhausts the appeals process in favor of MUHA, the entire project is subject to cancellation. If MUHA were to proceed with material development activities or expenditures on the project, all activities and a substantial portion of the expenditures would be "at risk" if the S.C. Court of Appeals reversed the previous approval and the S.C. Supreme Court either affirmed or allowed the Court of Appeals' decision to stand. Adding to this uncertainty is the timeline for the appeals process, namely, that all written briefings were submitted to the Court of Appeals as of April 2021 but no hearing dates for oral arguments have been scheduled.

Despite the above, since receiving its Second CON Extension, MUHA has continued to engage in planning activities as practical under the market conditions and with pending litigation overshadowing the project. Internal planning groups continue to work towards developing a general building design, planning for site development and other related activities demonstrating architectural progress. To date, approximately $8,650,000 in land costs and A/E fees have been incurred.

In consideration of these uncontrollable delays and the rather unique situation MUHA finds itself in, an updated project timeline was developed (Attachment I), which reflects over $2,000,000 in expenditures during the next several months related to design services alone. This timeline assumes MUHA prevails in the litigation and that the appellate proceedings are exhausted relatively soon, but as noted above, the timeline for the appellate proceedings remains uncertain.

Based on the above, MUHA is requesting this third extension more than three months prior to the current expiration date of March 29, 2023. If this request is granted, the new expiration date for the CON would be December 29, 2023. Attached are the first and second extension approvals and supporting documents.

We appreciate your attention to this matter. Please contact me at (843) 792-0599 if you have any questions regarding this information.

Sincerely,

DocuSigned by:
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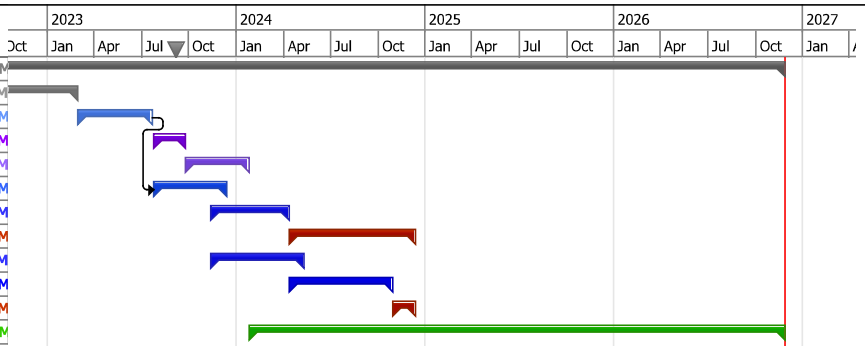
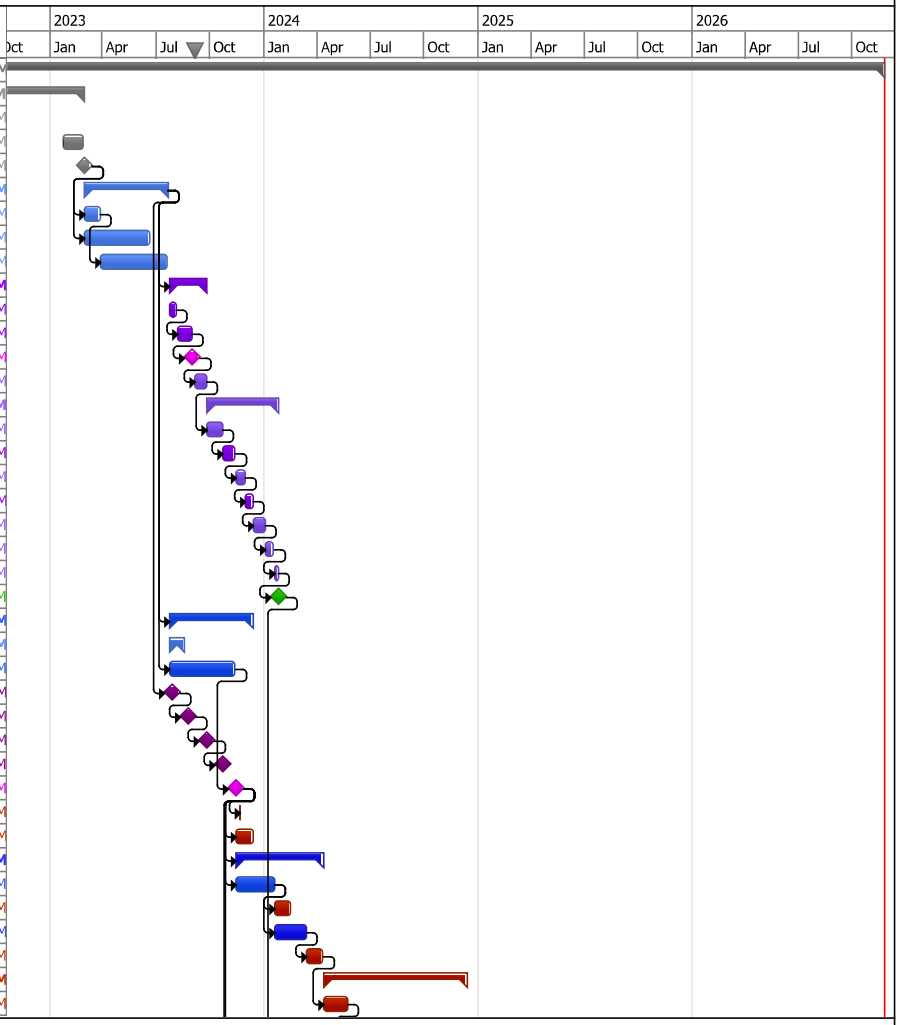
Patrick Cawley, MD
Chief Executive Officer, MUSC Health
Cc: Rebecca Felice
Attachments

ATTACHMENT I
REVISED TIMELINE

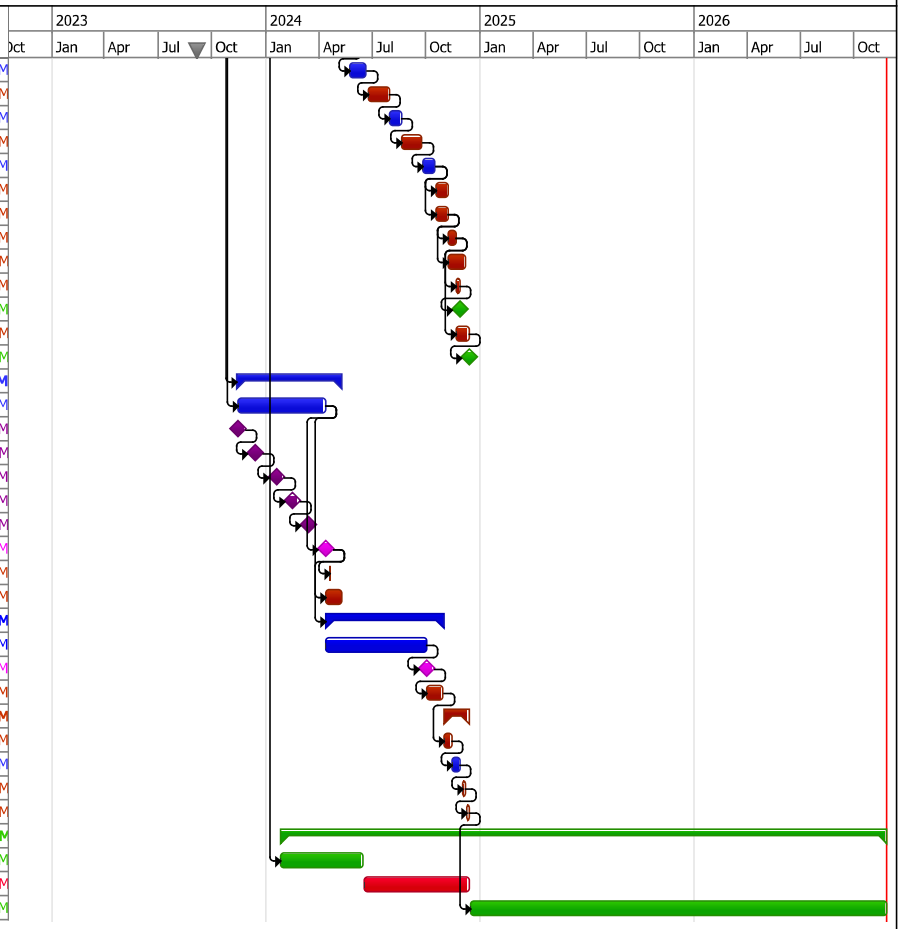
Task Name	Duration	Pre...	Start	End
MUSC Health - Nexton Community Hospital	1,394d		May 20, 2021 8:00 AM	Nov 26, 2026 5:00 PM
Basis of Design Development	22.20mo		May 20, 2021 8:00 AM	Mar 1, 2023 8:00 AM
Predesign	5mo		Mar 1, 2023 8:00 AM	Jul 21, 2023 5:00 PM
Early Clearing and Grading Package	2.25mo		Jul 24, 2023 8:00 AM	Sep 25, 2023 5:00 PM
Clearing and Grading Package Permitting	16w		Sep 26, 2023 8:00 AM	Jan 25, 2024 5:00 PM
Schematic Design	5mo	5	Jul 24, 2023 8:00 AM	Dec 13, 2023 5:00 PM
Full Site Package	5mo	32	Nov 14, 2023 8:00 AM	Apr 11, 2024 5:00 PM
Full Site Package Permitting	8.50mo		Apr 12, 2024 8:00 AM	Dec 13, 2024 5:00 PM
Design Development	6mo	32	Nov 13, 2023 5:00 PM	May 9, 2024 5:00 PM
Construction Documents	7mo	56	Apr 12, 2024 8:00 AM	Oct 30, 2024 5:00 PM
Building Permitting	6w		Oct 31, 2024 8:00 AM	Dec 13, 2024 5:00 PM
Construction	36.25mo		Jan 26, 2024 8:00 AM	Nov 26, 2026 5:00 PM



Task Name	Duration	Pre...	Start	End
MUSC Health - Nexton Community Hospital	**1,394d**		**May 20, 2021 8:00 AM**	**Nov 26, 2026 5:00 PM**
Basis of Design Development	**22.20mo**		**May 20, 2021 8:00 AM**	**Mar 1, 2023 8:00 AM**
BOD Narrative Development	57d		May 20, 2021 8:00 AM	Aug 6, 2021 5:00 PM
Cost Validation	25d		Jan 25, 2023 8:00 AM	Feb 28, 2023 5:00 PM
Design Team Notice to Proceed	0d		Mar 1, 2023 8:00 AM	Mar 1, 2023 8:00 AM
Predesign	**5mo**		**Mar 1, 2023 8:00 AM**	**Jul 21, 2023 5:00 PM**
Strategic Programming	4w	4	Mar 1, 2023 8:00 AM	Mar 28, 2023 5:00 PM
Campus Master Planning	16w	4	Mar 1, 2023 8:00 AM	Jun 21, 2023 5:00 PM
Detailed Space Programming	16w	6	Mar 29, 2023 8:00 AM	Jul 21, 2023 5:00 PM
Clearing and Grading Design	**45d**	**5**	**Jul 24, 2023 8:00 AM**	**Sep 25, 2023 5:00 PM**
Civil Early Sitwork Design Development	2w		Jul 24, 2023 8:00 AM	Aug 4, 2023 5:00 PM
Civil Early Sitework Construction Documents	4w	10	Aug 7, 2023 8:00 AM	Sep 1, 2023 5:00 PM
Submit Early Sitework Package	0d	11	Sep 1, 2023 5:00 PM	Sep 1, 2023 5:00 PM
Site Package Nexton Design Committee Review	3w	12	Sep 5, 2023 8:00 AM	Sep 25, 2023 5:00 PM
Clearing and Grading Package Permitting	**16w**		**Sep 26, 2023 8:00 AM**	**Jan 25, 2024 5:00 PM**
Berkeley County and OCRM Initial Review	4w	13	Sep 26, 2023 8:00 AM	Oct 23, 2023 5:00 PM
Address BC Comments	3w	15	Oct 24, 2023 8:00 AM	Nov 13, 2023 5:00 PM
Berkeley County 2nd Review	2w	16	Nov 14, 2023 8:00 AM	Nov 29, 2023 5:00 PM
Address BC 2nd Round Comment	2w	17	Nov 30, 2023 8:00 AM	Dec 13, 2023 5:00 PM
Berkely County Issues MS4 Permit	2w	18	Dec 14, 2023 8:00 AM	Jan 4, 2024 5:00 PM
OCRM issues NPDES Permit	2w	19	Jan 5, 2024 8:00 AM	Jan 18, 2024 5:00 PM
Berkely County Issues CAA	1w	20	Jan 19, 2024 8:00 AM	Jan 25, 2024 5:00 PM
Clearing and Grading can begin	0d	21	Jan 25, 2024 5:00 PM	Jan 25, 2024 5:00 PM
Schematic Design	**5mo**	**5**	**Jul 24, 2023 8:00 AM**	**Dec 13, 2023 5:00 PM**
Community Engagement	**4w**		**Jul 24, 2023 8:00 AM**	**Aug 18, 2023 5:00 PM**
Schematic Design Document Production	16w	5	Jul 24, 2023 8:00 AM	Nov 13, 2023 5:00 PM
User Meeting #1	0d	5FS...	Jul 28, 2023 5:00 PM	Jul 28, 2023 5:00 PM
User Meeting #2	0d	27F...	Aug 25, 2023 5:00 PM	Aug 25, 2023 5:00 PM
User Meeting #3	0d	28F...	Sep 25, 2023 5:00 PM	Sep 25, 2023 5:00 PM
User Meeting #4	0d	29F...	Oct 23, 2023 5:00 PM	Oct 23, 2023 5:00 PM
Submit Schematic Design to MUSC	0d	26	Nov 13, 2023 5:00 PM	Nov 13, 2023 5:00 PM
SD DHEC Review Session	1d	31F...	Nov 21, 2023 8:00 AM	Nov 21, 2023 5:00 PM
SD Nexton Design Comittee Review	4w	31	Nov 14, 2023 8:00 AM	Dec 13, 2023 5:00 PM
Full Site Package	**5mo**	**31**	**Nov 14, 2023 8:00 AM**	**Apr 11, 2024 5:00 PM**
Site Design Development	8w	31	Nov 14, 2023 8:00 AM	Jan 18, 2024 5:00 PM
Site DD Nexton Design Comittee Review	4w	35	Jan 19, 2024 8:00 AM	Feb 15, 2024 5:00 PM
Site Construction Documents	8w	35	Jan 19, 2024 8:00 AM	Mar 14, 2024 5:00 PM
Full Site Nexton Design Committee Review	4w	37	Mar 15, 2024 8:00 AM	Apr 11, 2024 5:00 PM
Full Site Package Permitting	**8.50mo**		**Apr 12, 2024 8:00 AM**	**Dec 13, 2024 5:00 PM**
Berkeley County, OCRM, and BCWS Initial Review	6w	38	Apr 12, 2024 8:00 AM	May 23, 2024 5:00 PM



Task Name	Duration	Pre...	Start	End
Address BC and BCWS Comments	4w	40	May 24, 2024 8:00 AM	Jun 21, 2024 5:00 PM
Berkeley County and BCWS 2nd Review	5w	41	Jun 24, 2024 8:00 AM	Jul 30, 2024 5:00 PM
Address BC and BCWS Comments	3w	42	Jul 31, 2024 8:00 AM	Aug 20, 2024 5:00 PM
Berkeley County and BCWS 3rd Review	5w	43	Aug 21, 2024 8:00 AM	Sep 25, 2024 5:00 PM
Address BC and BCWS Comments	3w	44	Sep 26, 2024 8:00 AM	Oct 16, 2024 5:00 PM
Berkeley County Issues MS4 permit	3w	45	Oct 17, 2024 8:00 AM	Nov 6, 2024 5:00 PM
BCWS Issues verbal plan approval	3w	45	Oct 17, 2024 8:00 AM	Nov 6, 2024 5:00 PM
OCRM issues NPDES permit	2w	47	Nov 7, 2024 8:00 AM	Nov 20, 2024 5:00 PM
BCWS issues water and sewer contracts	4w	47	Nov 7, 2024 8:00 AM	Dec 6, 2024 5:00 PM
Berkely County Issues CAA	1w	48	Nov 21, 2024 8:00 AM	Nov 27, 2024 5:00 PM
Sitework can begin	0d	50	Nov 27, 2024 5:00 PM	Nov 27, 2024 5:00 PM
DHEC issues permit for water and sewer	3w	48	Nov 21, 2024 8:00 AM	Dec 13, 2024 5:00 PM
Water and sewer construction can begin	0d	52	Dec 13, 2024 5:00 PM	Dec 13, 2024 5:00 PM
Design Development	**6mo**	**31**	**Nov 13, 2023 5:00 PM**	**May 9, 2024 5:00 PM**
Design Development Document Production	20w	31	Nov 14, 2023 8:00 AM	Apr 11, 2024 5:00 PM
DD User Meeting #1	0d		Nov 13, 2023 5:00 PM	Nov 13, 2023 5:00 PM
DD User Meeting #2	0d	56F...	Dec 13, 2023 5:00 PM	Dec 13, 2023 5:00 PM
DD User Meeting #3	0d	57F...	Jan 18, 2024 5:00 PM	Jan 18, 2024 5:00 PM
DD User Meeting #4	0d	58F...	Feb 15, 2024 5:00 PM	Feb 15, 2024 5:00 PM
DD User Meeting #5	0d	59F...	Mar 14, 2024 5:00 PM	Mar 14, 2024 5:00 PM
Submit Design Development	0d	55	Apr 11, 2024 5:00 PM	Apr 11, 2024 5:00 PM
DD DHEC Review Session	1d	61F...	Apr 19, 2024 8:00 AM	Apr 19, 2024 5:00 PM
DD Nexton Design Committee Review	4w	61	Apr 12, 2024 8:00 AM	May 9, 2024 5:00 PM
Construction Documents	**7mo**	**55**	**Apr 12, 2024 8:00 AM**	**Oct 30, 2024 5:00 PM**
Construction Documents Production	24w		Apr 12, 2024 8:00 AM	Oct 2, 2024 5:00 PM
Submit Construction Documents	0d	65	Oct 2, 2024 5:00 PM	Oct 2, 2024 5:00 PM
CD Final Nexton Design Committee Review	4w	66	Oct 3, 2024 8:00 AM	Oct 30, 2024 5:00 PM
Building Permitting	**6w**		**Oct 31, 2024 8:00 AM**	**Dec 13, 2024 5:00 PM**
Berkeley County Initial Review	2w	67	Oct 31, 2024 8:00 AM	Nov 13, 2024 5:00 PM
Address BC Comments	2w	69	Nov 14, 2024 8:00 AM	Nov 27, 2024 5:00 PM
Berkeley County 2nd Review	1w	70	Dec 2, 2024 8:00 AM	Dec 6, 2024 5:00 PM
Berkeley County Issues Building Permit	1w	71	Dec 9, 2024 8:00 AM	Dec 13, 2024 5:00 PM
Construction	**36.25mo**		**Jan 26, 2024 8:00 AM**	**Nov 26, 2026 5:00 PM**
Clearing and Grading	5mo	22	Jan 26, 2024 8:00 AM	Jun 14, 2024 5:00 PM
Construction Gap to Fill	25w		Jun 17, 2024 8:00 AM	Dec 13, 2024 5:00 PM
Full Building Construction	25mo	72	Dec 16, 2024 8:00 AM	Nov 26, 2026 5:00 PM



ATTACHMENT II
FIRST EXTENSION APPROVAL

Healthy People. Healthy Communities.

Article #: 9214896900999790142235732 8

October 7, 2022

VIA EMAIL AND CERTIFIED MAIL
Patrick J. Cawley, MD
Medical University Hospital Authority
169 Ashley Avenue
Charleston, SC 29425

Re: **CON SC-20-25 EXT-1**
Applicant: Medical University Hospital Authority d/b/a MUHA Community Hospital
Project: Construction of a 128-bed general acute hospital in Berkeley County at a total project cost of $325,000,000.
Application No.: 2520

Dear Dr. Cawley:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you have provided in support of your request, it is the decision of the Department to **grant you a nine (9) month initial extension** for Certificate No. SC-20-25. The Department's decision is based on the following findings:

- You have provided the Department with reasonable assurance that the Project will be implemented within the requested extension period.

As required by Regulation No. 61-15, Section 607, you must continue to submit quarterly progress reports from the date of issuance of the original Certificate of Need (September 29, 2020). You must continue to report on, if applicable:

a. Costs incurred on the project;
b. Construction activity;
c. Program or service activity; and
d. Any deviations from the submitted application with supporting documentation.

The mandated due dates for these reports are as follows:

5th Quarterly Report: **12/29/2021**
6th Quarterly Report: **3/29/2022**
7th Quarterly Report: **6/29/2022**

Failure to adhere to the reporting schedule and format may result in enforcement action, which may be inclusive of the voidance of the Certificate of Need and a monetary penalty pursuant to Regulation No. 61-15, Section 701.

Should the length of your project exceed the nine month period of this extension, you are required to file a second extension request with the Department pursuant to Regulation No. 61-15, Sections 602 and 603. The due date for the second extension request, if one is needed, is **May 30, 2022.** Extension requests received after this date will not receive consideration from the Department.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing, or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Ms. Susan Jenkins, (803) 545-0530; Division of Health Facilities Construction, Mr. Graham Cormack, (803) 727-3576; and Bureau of Healthcare Systems and Services, Ms. Charlene Bell, (803) 545-4223.

If this office can be of further service to you or if you have any questions concerning the above, feel free to contact me at (803) 545-3028.

Sincerely,

Ashley C. Grant, MBA
Project Coordinator
Certificate of Need Program

Enclosures: Certificate of Need SC-20-25 EXT-1
cc: Sarah Bacik (Via email)

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-20-25 EXT-1

FACILITY NAME: MUHA Community Hospital

LOCATION: Charleston County

LICENSEE: Medical University Hospital Authority

FOR: Construction of a 128-bed general acute hospital in Berkeley County.

TOTAL PROJECT COST: $325,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. Section 44-7-110 *et seq.* and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until June 29, 2022, which is a period of nine (9) months from the date of CON expiration, unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this Day 7th day of October 2022.

Trenessa K. Jones, DSL, Bureau Director
Healthcare Planning and Construction

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

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Healthy People. Healthy Communities

ATTACHMENT III
SECOND EXTENSION APPROVAL

Healthy People. Healthy Communities.

Article #: 9214896900999790142235738O

October 7, 2022

VIA CERTIFIED MAIL
Patrick J. Cawley, MD
Medical University Hospital Authority
169 Ashley Avenue
Charleston, SC 29425

Re: **CON SC-20-25 EXT-2**
Applicant: Medical University Hospital Authority d/b/a MUHA Community Hospital
Project: Construction of a 128-bed general acute hospital in Berkeley County at a total project cost of $325,000,000.
Application No.: 2520

Dear Dr. Cawley:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you have provided in support of your request, it is the decision of the Department to **grant you a second nine (9) month extension** for Certificate No. SC-20-25. The Department's decision is based on the following findings:

- You have provided the Department with reasonable assurance that the Project will be implemented within the requested extension period.

As required by Regulation No. 61-15, Section 607, you must continue to submit quarterly progress reports from the date of issuance of the original Certificate of Need (September 29, 2020). You must continue to report on, if applicable:

a. Costs incurred on the project;
b. Construction activity;
c. Program or service activity; and
d. Any deviations from the submitted application with supporting documentation.

The mandated due dates for these reports are as follows:

8th Quarterly Report: **9/29/2022**
9th Quarterly Report: **12/29/2022**
10th Quarterly Report: **3/29/2023**

Failure to adhere to the reporting schedule and format may result in enforcement action, which may be inclusive of the voidance of the Certificate of Need and a monetary penalty pursuant to Regulation No. 61-15, Section 701.

Should the length of your project exceed the nine month period of this extension, you are required to file a DHEC Board extension request with the Department pursuant to Regulation No. 61-15, Sections 602 and 603. The due date for the Board extension request, if one is needed, is **December 31, 2022**. Extension requests received after this date will not receive consideration from the Department.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing, or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Ms. Susan Jenkins, (803) 545-0530; Division of Health Facilities Construction, Mr. Graham Cormack, (803) 727-3576; and Bureau of Healthcare Systems and Services, Ms. Charlene Bell, (803) 545-4223.

If this office can be of further service to you or if you have any questions concerning the above, feel free to contact me at (803) 545-3028.

Sincerely,

Ashley C. Grant, MBA
Project Coordinator
Certificate of Need Program

Enclosures: Certificate of Need SC-20-25 EXT-2
cc: Sarah Bacik (Via Email)

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-20-25 EXT-2

FACILITY NAME: MUHA Community Hospital

LOCATION: Charleston County

LICENSEE: Medical University Hospital Authority

FOR: Construction of a 128-bed general acute hospital in Berkeley County.

TOTAL PROJECT COST: $325,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. Section 44-7-110 *et seq*. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until March 29, 2023, which is a period of nine (9) months from the date of CON EXT-1 expiration, unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this Day 7th day of October 2022.

Trenessa K. Jones, DSL, Bureau Director
Healthcare Planning and Construction

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

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THE ENCLOSED LETTER CONTAINS VITAL INFORMATION. PLEASE REVIEW IT CAREFULLY AND COMPLETELY TO ENSURE COMPLIANCE WITH RELEVANT LAWS AND REGULATIONS.

Article #: 9214896900999790142316562 5

March 28, 2023

VIA CERTIFIED MAIL
Patrick J. Cawley, MD
CEO, MUSC Health
Medical University Hospital Authority
22 Westedge Street, Suite 300
Charleston, SC 29407

Re: **Request for Board Approval and 3rd Extension of Certificate of Need No. SC-20-25**
Applicant: Medical University Hospital Authority d/b/a MUHA Community Hospital
Project: Construction of a 128-bed general acute hospital in Berkeley County at a total project cost of $325,000,000.
Application No.: 2520

Dear Dr. Cawley:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of nine months a piece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to **grant you a nine (9) month Board extension** for Certificate No. **SC-20-25**. The Department's decision is based on the following findings:

- You have submitted sufficient documentation that extenuating circumstances beyond the Applicant's control have prevented compliance with the timetable; and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

As required by Reg. No. 61-15, Section 607, you must continue to submit quarterly progress reports from the date of issuance of the original Certificate of Need (September 29,2020). You must continue to report on, if applicable:

a. Costs incurred on the project;
b. Construction activity;
c. Program or service activity; and
d. Any deviations from the submitted application with supporting documentation.

The mandated due dates for these reports are as follows:

9th Quarterly Report: **6/29/2023**
10th Quarterly Report: **9/29/2023**
11th Quarterly Report: **12/29/2023**

Failure to adhere to the reporting schedule and format may result in enforcement action, which may be inclusive of the voidance of the Certificate of Need and a monetary penalty pursuant to Reg. No. 61-15, Section 701.

Please note that all subsequent requests for extension of **SC-20-25** are subject to approval by the Department Board. Requests for such extension must be received 90-days prior to expiration of the current extension pursuant to Regulation No. 61-15, Sections 601 through 603. The due date for the next Department Board extension request, if one is needed, is **September 29,2023.** Extension requests received after this date will not receive consideration from the Department.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing, or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Ms. Susan Jenkins (803-545-0530); Division of Health Facilities Construction, Mr. Graham Cormack (803-727-3576); and Bureau of Healthcare Systems and Services, Mr. Eric McFarland (803-545-4240).

A copy of the Department's Guide to Board Review is enclosed for your convenience. If this office can be of further service to you or if you have any questions concerning the above, feel free to contact me at (803) 545-3028.

Sincerely,

Ashley C. Grant

Ashley C. Grant, MBA
Senior Consultant, Certificate of Need Program

Enclosures: Certificate of Need SC-20-25-EXT-3
Department's Guide to Board Review

CC: Rebecca Felice (Via Email)
M. Elizabeth Crum, Esq. (Via Email)
David Levitt (Via Email)

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-20-25-EXT-3

FACILITY NAME: MUHA Community Hospital

LOCATION: Charleston County

LICENSEE: Medical University Hospital Authority

FOR: Construction of a 128-bed general acute hospital in Berkeley County.

TOTAL PROJECT COST: $325,000,000.

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. Section 44-7-110 *et seq*. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until December 29, 2023, which is a period of nine (9) months from the date of CON expiration, unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 28th day of March 2023.

Trenessa K. Jones, DSL, Bureau Director
Healthcare Planning and Construction

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

dhec
Healthy People. Healthy Communities.

Patrick Cawley, MD
Chief Executive Officer, MUSC Health
Vice President for Health Affairs, University
22 Westedge Street, Suite 300
Charleston, SC 29407
Tel 843 792 0599
www.muschealth.com

MUSC Health
MEDICAL UNIVERSITY of SOUTH CAROLINA

September 28, 2023

SC Department of Health and Environmental Control
2600 Bull Street
Columbia SC 29201

RE: MUHA Community Hospital Certificate of Need 4th Extension Request (SC-20-25)

Dear DHEC Board Clerk:

This letter is submitted on behalf of the Medical University Hospital Authority ("MUHA") to request a fourth nine-month extension of the MUHA Community Hospital CON (SC-20-25) in accordance with the State "Certification of Need and Health Facility Licensure Act," S.C. Code Ann. §§44-7-110 et seq. and Regulation 61-15 "Certification of Need for Health Facilities and Services."

After a protracted litigation process, the Certificate of Need ("CON") was ultimately issued on September 30, 2020, although the opposition by HCA facilities (Trident, Summerville, and Colleton Medical Centers) challenging this CON continues. The administrative law court (ALC) heard the case and affirmed the Department's approval of the project. However, HCA appealed that decision to the South Carolina Court of Appeals, which in turn recently transferred the case to the South Carolina Supreme Court ("Supreme Court") as a result of Act No. 20. The appeal now is scheduled to be heard by the Supreme Court on October 4, 2023 and the Court will issue a decision thereafter. Until that decision is issued, the entire project is subject to cancellation. Thus, if MUHA were to proceed with material development activities or expenditures on the project, all activities and expenditures would be "at risk" if the Supreme Court reverses MUHA's CON approval.

In spite of these uncontrollable delays and the rather unique situation MUHA finds itself in, MUHA continues to make substantial progress toward implementing the project. An architect and contractor have been secured. Internal planning groups continue to work towards developing the general building design, planning for site development and other related activities. The site concept has been approved and work continues on further operational planning through bi-weekly work group meetings. Revised hospital programming has been vetted internally, development of updated financial feasibility projections has been initiated, and planning and programming specific to Imaging Services has commenced. Collaborative meetings with the Nexton Architectural and Review bodies are on-going to start initial communication of the project, scope, and design parameters to align with development agreement/design guidelines. Based on receiving a favorable decision from the Supreme Court and thus the CON is no longer subject to appeal, **Attachment I** contains a revised schedule.

As of August 2023, the project has incurred a total project cost of $8,753,763.

Finally, as the Board is well aware, since the last approval of MUHA's Third Extension Request in March 2023, significant changes to the CON Program have occurred. Act No. 20 became effective May 16, 2023 and, as MUHA and the MUSC Health System has stated in recent submissions to the Department, we appreciate the General Assembly's sweeping changes to healthcare's competitive landscape in South Carolina as a result. However, the impact of Act 20

has, thankfully, sped up the appeal timeline but also has forced MUHA to require additional time to adjust its planning horizon and expenditure rate if the Supreme Court issues a favorable decision.

Based on the above, MUHA is requesting this fourth extension more than 90 calendar days prior to the current expiration date of December 30, 2023. If this request is granted, the new expiration date for the CON would be September 30, 2024. Attached are the previous extension approvals and supporting documents.

We appreciate your attention to this matter. Please contact me at (843) 792-9917 if you have any questions regarding this information.

Sincerely,

DocuSigned by:

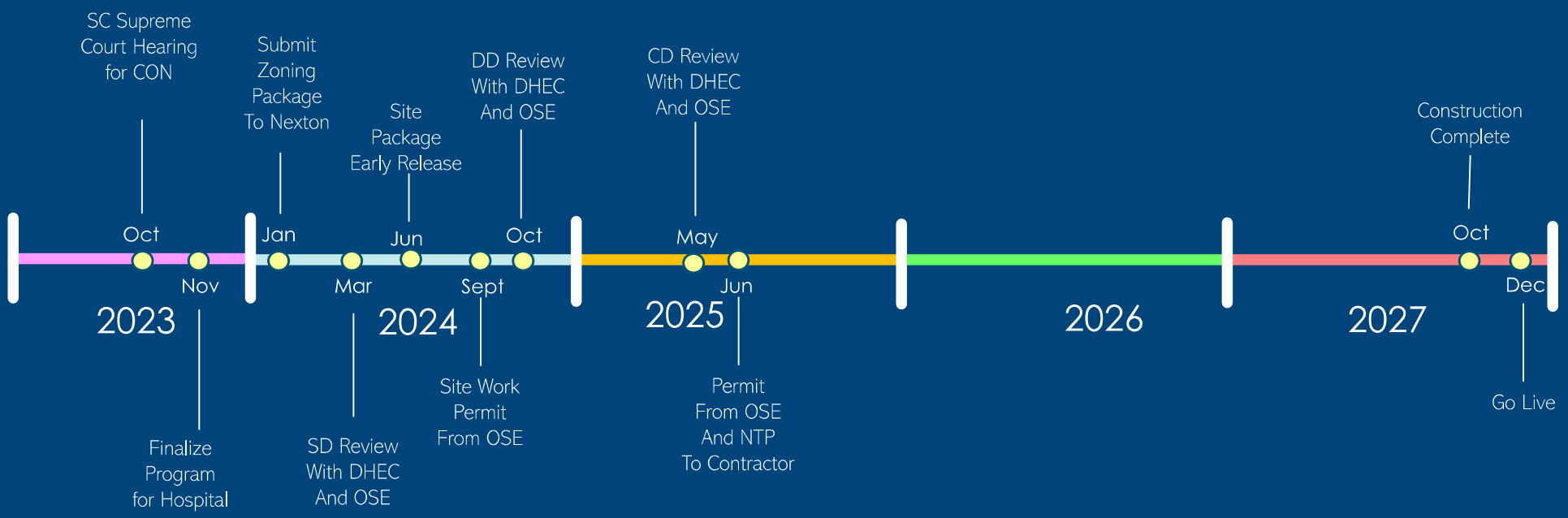
F9BB7C7D6CE24F6...

Patrick Cawley, MD
Chief Executive Officer, MUSC Health

Cc: Rebecca Felice
Attachments

ATTACHMENT I
REVISED TIMELINE

MUHA Community Hospital



ATTACHMENT II
FIRST EXTENSION APPROVAL

Healthy People. Healthy Communities.

Article #: 9214896900999790142235732 8

October 7, 2022

VIA EMAIL AND CERTIFIED MAIL
Patrick J. Cawley, MD
Medical University Hospital Authority
169 Ashley Avenue
Charleston, SC 29425

Re: **CON SC-20-25 EXT-1**
Applicant: Medical University Hospital Authority d/b/a MUHA Community Hospital
Project: Construction of a 128-bed general acute hospital in Berkeley County at a total project cost of $325,000,000.
Application No.: 2520

Dear Dr. Cawley:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you have provided in support of your request, it is the decision of the Department to **grant you a nine (9) month initial extension** for Certificate No. SC-20-25. The Department's decision is based on the following findings:

- You have provided the Department with reasonable assurance that the Project will be implemented within the requested extension period.

As required by Regulation No. 61-15, Section 607, you must continue to submit quarterly progress reports from the date of issuance of the original Certificate of Need (September 29, 2020). You must continue to report on, if applicable:

a. Costs incurred on the project;
b. Construction activity;
c. Program or service activity; and
d. Any deviations from the submitted application with supporting documentation.

The mandated due dates for these reports are as follows:

5th Quarterly Report: **12/29/2021**
6th Quarterly Report: **3/29/2022**
7th Quarterly Report: **6/29/2022**

Failure to adhere to the reporting schedule and format may result in enforcement action, which may be inclusive of the voidance of the Certificate of Need and a monetary penalty pursuant to Regulation No. 61-15, Section 701.

Should the length of your project exceed the nine month period of this extension, you are required to file a second extension request with the Department pursuant to Regulation No. 61-15, Sections 602 and 603. The due date for the second extension request, if one is needed, is **May 30, 2022.** Extension requests received after this date will not receive consideration from the Department.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing, or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Ms. Susan Jenkins, (803) 545-0530; Division of Health Facilities Construction, Mr. Graham Cormack, (803) 727-3576; and Bureau of Healthcare Systems and Services, Ms. Charlene Bell, (803) 545-4223.

If this office can be of further service to you or if you have any questions concerning the above, feel free to contact me at (803) 545-3028.

Sincerely,

Ashley C. Grant

Ashley C. Grant, MBA
Project Coordinator
Certificate of Need Program

Enclosures: Certificate of Need SC-20-25 EXT-1
cc: Sarah Bacik (Via email)

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-20-25 EXT-1

FACILITY NAME: MUHA Community Hospital

LOCATION: Charleston County

LICENSEE: Medical University Hospital Authority

FOR: Construction of a 128-bed general acute hospital in Berkeley County.

TOTAL PROJECT COST: $325,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. Section 44-7-110 *et seq.* and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until June 29, 2022, which is a period of nine (9) months from the date of CON expiration, unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this Day 7th day of October 2022.

Trenessa K. Jones, DSL, Bureau Director
Healthcare Planning and Construction

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

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ATTACHMENT III
SECOND EXTENSION APPROVAL

dhec
Healthy People. Healthy Communities.

Article #: 9214896900999790142235738O

October 7, 2022

VIA CERTIFIED MAIL
Patrick J. Cawley, MD
Medical University Hospital Authority
169 Ashley Avenue
Charleston, SC 29425

Re: **CON SC-20-25 EXT-2**
Applicant: Medical University Hospital Authority d/b/a MUHA Community Hospital
Project: Construction of a 128-bed general acute hospital in Berkeley County at a total project cost of $325,000,000.
Application No.: 2520

Dear Dr. Cawley:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you have provided in support of your request, it is the decision of the Department to **grant you a second nine (9) month extension** for Certificate No. SC-20-25. The Department's decision is based on the following findings:

- You have provided the Department with reasonable assurance that the Project will be implemented within the requested extension period.

As required by Regulation No. 61-15, Section 607, you must continue to submit quarterly progress reports from the date of issuance of the original Certificate of Need (September 29, 2020). You must continue to report on, if applicable:

a. Costs incurred on the project;
b. Construction activity;
c. Program or service activity; and
d. Any deviations from the submitted application with supporting documentation.

The mandated due dates for these reports are as follows:

8th Quarterly Report: **9/29/2022**
9th Quarterly Report: **12/29/2022**
10th Quarterly Report: **3/29/2023**

Failure to adhere to the reporting schedule and format may result in enforcement action, which may be inclusive of the voidance of the Certificate of Need and a monetary penalty pursuant to Regulation No. 61-15, Section 701.

Should the length of your project exceed the nine month period of this extension, you are required to file a DHEC Board extension request with the Department pursuant to Regulation No. 61-15, Sections 602 and 603. The due date for the Board extension request, if one is needed, is **December 31, 2022**. Extension requests received after this date will not receive consideration from the Department.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing, or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Ms. Susan Jenkins, (803) 545-0530; Division of Health Facilities Construction, Mr. Graham Cormack, (803) 727-3576; and Bureau of Healthcare Systems and Services, Ms. Charlene Bell, (803) 545-4223.

If this office can be of further service to you or if you have any questions concerning the above, feel free to contact me at (803) 545-3028.

Sincerely,

Ashley C. Grant, MBA
Project Coordinator
Certificate of Need Program

Enclosures: Certificate of Need SC-20-25 EXT-2
cc: Sarah Bacik (Via Email)

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-20-25 EXT-2

FACILITY NAME: MUHA Community Hospital

LOCATION: Charleston County

LICENSEE: Medical University Hospital Authority

FOR: Construction of a 128-bed general acute hospital in Berkeley County.

TOTAL PROJECT COST: $325,000,000

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. Section 44-7-110 *et seq*. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until March 29, 2023, which is a period of nine (9) months from the date of CON EXT-1 expiration, unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this Day 7th day of October 2022.

Trenessa K. Jones, DSL, Bureau Director
Healthcare Planning and Construction

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

dhec
Healthy People. Healthy Communities

ATTACHMENT IV
THIRD EXTENSION APPROVAL

Article #: 9214896900999790142316562 5

March 28, 2023

VIA CERTIFIED MAIL
Patrick J. Cawley, MD
CEO, MUSC Health
Medical University Hospital Authority
22 Westedge Street, Suite 300
Charleston, SC 29407

Re: **Request for Board Approval and 3rd Extension of Certificate of Need No. SC-20-25**
Applicant: Medical University Hospital Authority d/b/a MUHA Community Hospital
Project: Construction of a 128-bed general acute hospital in Berkeley County at a total project cost of $325,000,000.
Application No.: 2520

Dear Dr. Cawley:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of nine months a piece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to **grant you a nine (9) month Board extension** for Certificate No. **SC-20-25**. The Department's decision is based on the following findings:

- You have submitted sufficient documentation that extenuating circumstances beyond the Applicant's control have prevented compliance with the timetable; and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

As required by Reg. No. 61-15, Section 607, you must continue to submit quarterly progress reports from the date of issuance of the original Certificate of Need (September 29,2020). You must continue to report on, if applicable:

a. Costs incurred on the project;
b. Construction activity;
c. Program or service activity; and
d. Any deviations from the submitted application with supporting documentation.

The mandated due dates for these reports are as follows:

9th Quarterly Report: **6/29/2023**
10th Quarterly Report: **9/29/2023**
11th Quarterly Report: **12/29/2023**

Failure to adhere to the reporting schedule and format may result in enforcement action, which may be inclusive of the voidance of the Certificate of Need and a monetary penalty pursuant to Reg. No. 61-15, Section 701.

Please note that all subsequent requests for extension of **SC-20-25** are subject to approval by the Department Board. Requests for such extension must be received 90-days prior to expiration of the current extension pursuant to Regulation No. 61-15, Sections 601 through 603. The due date for the next Department Board extension request, if one is needed, is **September 29,2023.** Extension requests received after this date will not receive consideration from the Department.

The issuance of a Certificate of Need does not constitute approval for any proposed construction, licensing, or certification changes. You should contact the following individuals for information concerning these related issues: Bureau of Radiological Health, Ms. Susan Jenkins (803-545-0530); Division of Health Facilities Construction, Mr. Graham Cormack (803-727-3576); and Bureau of Healthcare Systems and Services, Mr. Eric McFarland (803-545-4240).

A copy of the Department's Guide to Board Review is enclosed for your convenience. If this office can be of further service to you or if you have any questions concerning the above, feel free to contact me at (803) 545-3028.

Sincerely,

Ashley C. Grant

Ashley C. Grant, MBA
Senior Consultant, Certificate of Need Program

Enclosures: Certificate of Need SC-20-25-EXT-3
Department's Guide to Board Review

CC: Rebecca Felice (Via Email)
M. Elizabeth Crum, Esq. (Via Email)
David Levitt (Via Email)

South Carolina Department of Health and Environmental Control

Certificate of Need

SC-20-25-EXT-3

FACILITY NAME: MUHA Community Hospital

LOCATION: Charleston County

LICENSEE: Medical University Hospital Authority

FOR: Construction of a 128-bed general acute hospital in Berkeley County.

TOTAL PROJECT COST: $325,000,000.

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. Section 44-7-110 *et seq*. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until December 29, 2023, which is a period of nine (9) months from the date of CON expiration, unless the applicant receives an extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 28th day of March 2023.

Trenessa K. Jones, DSL, Bureau Director
Healthcare Planning and Construction

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

dhec
Healthy People. Healthy Communities.

Date: November 9, 2023

To: S.C. Board of Health and Environmental Control

From: Bureau of Land and Waste

Re: Public Hearing for Notice of Final Regulation Amending R.61-83, Transportation of Radioactive Waste Into and Within South Carolina, Document No. 5226

I. Introduction

The Bureau of Land and Waste Management ("Bureau") proposes the attached Notice of Final Regulation amending R.61-83, Transportation of Radioactive Waste Into and Within South Carolina. Legal authority resides in S.C. Code Ann., Sections 13-7-10 et seq., which directs the State to maintain appropriate liaison with agencies of the Federal Government, the United States Congress, certain national foundations and associations, and with other states and regional groups active in nuclear energy affairs.

II. Facts

1. The Department requires compliance with all applicable provisions and current revisions of Title 10, Part 71 of the Code of Federal Regulations (10 CFR 71), and any disposal facility's radioactive material license requirements and site disposal criteria regarding the packaging, transportation, disposal, storage, or delivery of radioactive materials. The Department proposes amending R.61-83 to incorporate 10 CFR 71 regulations promulgated in 2018, provide clarification for conformance with disposal site criteria, include an exemption allowance for consistency with R.61-63, *Radioactive Materials (Title A)*, and update forms to the current Department documents in use.

2. The Department had a Notice of Drafting published in the April 28, 2023, *State Register*.

3. Appropriate Department staff conducted an internal review of the proposed amendments on July 20, 2023.

4. The Bureau held a stakeholder meeting on August 2, 2023, to discuss the schedule and implementation process for the proposed amendments.

5. Upon receiving approval during the August 10, 2023, Board meeting, the Bureau had a Notice of Proposed Regulation published in the August 25, 2023, *State Register*. The Department received no comments by September 25, 2023, close of public comment period.

III. Request for Approval

The Bureau respectfully requests the Board find the need and reasonableness of the attached proposed amendment of R.61-83, Transportation of Radioactive Waste Into and Within South Carolina, for submission to the General Assembly.

Henry J. Porter
Bureau Chief

Myra C. Reece
Director

Attachments:
A. Notice of Final Regulation

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R.61-83, Transportation of Radioactive Waste Into and Within South Carolina

November 9, 2023

Document No. 5226
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 13-7-10 et seq.

61-83. Transportation of Radioactive Waste Into or Within South Carolina.

Synopsis:

Pursuant to S.C. Code Ann., Sections 13-7-10 et seq., the Department of Health and Environmental Control ("Department") requires compliance with all applicable provisions and current revisions of Title 10, Part 71 of the Code of Federal Regulations (10 CFR 71), and any disposal facility's radioactive material license requirements and site disposal criteria regarding the packaging, transportation, disposal, storage or delivery of radioactive materials. The Department proposes amending R.61-83 to incorporate 10 CFR 71 regulations promulgated in 2018, provide clarification for conformance with disposal site criteria, include an exemption allowance to be consistent with R.61-63, *Radioactive Materials (Title A)*, and update forms to the current Department documents in use. The proposed amendments may also include stylistic changes, which may include corrections for clarity and readability, grammar, punctuation, definitions, references, codification, and overall improvement of the text of the regulation.

The Department had a Notice of Drafting published in the April 28, 2023, South Carolina State Register.

Section-by-Section Discussion of Amendment:

Section	**Type of Change**	**Purpose**
Statutory Authority	Addition	Added statutory authority for clarity.
Table of Contents	Reorganization	Updated to reflect proposed amendments to regulatory text.
Section 1		
1.2	Addition/Deletion	Cited Federal regulations adopted by reference.
Section 2		
2.1-2.2	Technical Correction	Corrected for punctuation.
2.11.1-2.11.2	Technical Correction, Revision	Corrected for punctuation and to clarify shipper reference.
Section 3		
3.1	Revision	Revised contact information and revise form number.
3.2, 3.2.3, 3.2.4	Technical Correction	Corrected for punctuation.
3.2.5	Technical Correction, Revision	Corrected for punctuation and to clarify shipper reference.
3.3	Revision	Amended to add criteria type.
3.5.1-3.5.2	Revision	Amended for stylistic clarity.
Section 4		

4.1	Revision	Amended for stylistic clarity.
4.1.1	Revision	Updated form identification number.
4.1.2	Revision	Amended to clarify shipper reference.
4.2	Revision	Updated form identification number.
4.3	Revision	Updated form identification number.
4.4	Revision	Updated form identification number.
Section 5		
5.1	Revision	Updated form identification number.
5.1.1-5.1.2	Technical Correction	Corrected for punctuation.
5.1.3	Revision	Updated form identification number.
5.2	Revision	Updated form identification number.
5.3	Revision	Updated form identification number.
Section 7		
7.1.1	Technical Correction	Corrected for misspelled word.
7.1.2	Revision	Amended for stylistic clarity and to clarify shipper reference.
7.2.1	Technical Correction	Corrected for punctuation.
7.2.2	Revision	Amended for stylistic clarity and to clarify shipper reference.
7.4	Revision	Amended for stylistic clarity.
Section 8 (new)	Addition	Included an exemption for consistency with R.61-63.
Section 9 (previous Section 8)	Technical Correction	Corrected for codification.
Attachments	Deletion	Removed forms from the regulations and indicate by reference source of forms.

~~Indicates Matter Stricken~~
Indicates New Matter

Text:

61-83. Transportation of Radioactive Waste Into or Within South Carolina.

Statutory Authority: S.C. Code Ann. Sections 13-7-10 et seq.

Table of Contents:

Section 1 Scope
Section 2 Definitions

Section 3 Permits
Section 4 Shipper's Requirements
Section 5 Carrier's Requirements
Section 6 Disposal Facility Operator
Section 7 Penalties
Section 8 Exemptions from the Requirements of this Regulation
Section ~~8~~ 9 Severability Clause
~~Attachments:~~
~~Attachment I…..Form RHA-200P "Application for Radioactive Waste Transport Permit"~~
~~Attachment II…..Form RHA-PNC "Radioactive Waste Shipment Prior Notification and Manifest Form"~~
~~Attachment III…..Form RHA-CT "Radioactive Waste Shipment Certification Form"~~

1. SCOPE

1.1 This regulation applies to any shipper, carrier or other person who transports radioactive waste into or within this State, to any persons involved in the generation of radioactive waste within this State, and to any shipper whose radioactive waste is transported into or within this State or is delivered, stored, or disposed of within this State.

1.2 All persons subject to the provisions of this regulation shall comply with all applicable provisions of the Nuclear Regulatory Commission Title 10 CFR Part 71 as revised ~~January 1, 2006~~February 23, 2018, (with the exception of sections 71.2, 71.6, 71.11, 71.14(b), 71.17, 71.19, 71.21, ~~71.24~~, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.52, 71.53, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.70, 71.71, 71.73, 71.74, 71.75, 71.77, 71-85(a)-(c), 71-91(b)-(d), 71.99 and 71.100), 71.101(a), 71.101(b), 71.101(c)(1), 71.101(c)(2), 71.101(d), 71.101(e), ~~71.101(g),~~ 71.103(a), 71.106, 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, 71.125, and 71.135. ~~Regulation 61-83 of the 1976 Code of Laws of South Carolina, and any disposal facility radioactive material license requirements regarding the packaging, transportation, disposal, storage or delivery of radioactive materials.~~

2. DEFINITIONS

2.1 "Carrier" means any person transporting radioactive wastes into or within the State for storage, disposal, or delivery.

2.2 "Department" means the Department of Health and Environmental Control, including personnel authorized to act on behalf of the Department.

2.3 "Disposal facility" means any facility located within the State, which accepts radioactive waste for storage or disposal.

2.4 "Generation" means the act or process of producing radioactive waste.

2.5 "Manifest" means the document used for identifying the quantity, composition, origin, and destination of radioactive waste during its transport to a disposal facility.

2.6 "Operator" means every person who drives or is in actual physical control of a vehicle transporting radioactive waste.

2.7 "Persons" means any individual, public or private corporation, political subdivision, government agency, municipality, industry, partnership or any other entity whatsoever.

2.8 "Permit" means an authorization issued by the Department to any person involved in the generation of radioactive waste, to transport such radioactive wastes or offer such waste for transport.

2.9 “Radioactive waste” means any and all equipment or materials, including irradiated nuclear reactor fuel, which are radioactive or have radioactive contamination and which are required pursuant to any governing laws, regulations, or licenses to be disposed of as radioactive waste.

2.10 “Radiological violation” means radioactive contamination or the emission of radiation in excess of applicable limits.

2.11 “Shipper” means any person, whether a resident of South Carolina or a non-resident:

2.11.1 who transfers radioactive waste to a carrier for transportation into or within the State; or~~,~~

2.11.2 who transports ~~his~~their own radioactive waste into or within the State; or~~,~~

2.11.3 who transfers radioactive waste to another person if such Waste is transported into or within the State.

2.12 “Transport” means the movement of radioactive wastes into or within South Carolina.

3. PERMITS

3.1 Before any shipper transports or causes to be transported radioactive waste into or within the State of South Carolina, the shipper shall purchase an annual radioactive waste transport permit from the Department. An application for a permit shall be submitted on Department Form ~~RHA-200P~~SCDHEC-0800 “Application for Radioactive Waste Transport Permit” together with the necessary fee to: ~~Chief, Bureau of Radiological Health, S.C. Department of Health and Environmental Control~~S.C. Department of Health and Environmental Control (SCDHEC), Bureau of Land and Waste Management/Radioactive Waste Management Section, 2600 Bull Street, Columbia, South Carolina, 2~~0~~9201. These forms are available on the Department website, or by other means the Department may provide.

3.2 Before a permit shall be issued, the shipper must deposit and maintain with the Department a cash or corporate surety bond in the amount of Five Hundred Thousand Dollars ($500,000.00); or~~,~~ provide to the Department satisfactory evidence of liability insurance.

3.2.1 For purposes of this regulation, liability insurance shall mean coverage of Five Hundred Thousand Dollars ($500,000.00) per occurrence and One Million Dollars ($1,000,000.00) aggregate, or as otherwise provided by State law.

3.2.2 Any insurance carried pursuant to Section 2210 of Title 42 of the United States Code and Part 140 of Title 10 of the Code of Federal Regulations shall be sufficient to meet the requirements of this section.

3.2.3 Liability insurance shall be specific to the packaging, transportation, disposal, storage, and delivery of radioactive waste.

3.2.4 Shippers maintaining liability insurance for the purpose of this regulation may provide to the Department a certificate of insurance from their insurer indicating the policy number, limits of liability, policy date, and specific coverage for packaging, transportation, disposal, storage, and delivery of radioactive materials.

3.2.5 A cash or corporate surety bond previously posted will be returned to the shipper upon notification to the Department in writing of his or her intention to cease shipments of radioactive waste into

or within the State. Such bond will be returned after the last such shipment is accepted safely at its destination.

3.3 Each permit application shall include a certification to the Department that the shipper will comply fully with all applicable State or Federal laws, administrative rules and regulations, licenses, or license conditions and waste acceptance criteria of the disposal facility regarding the packaging, transportation, storage, disposal, and delivery of radioactive wastes.

3.4 Each permit application shall include a certification that the shipper will hold the State of South Carolina harmless for all claims, actions, or proceedings in law or equity arising out of radiological injury or damage to persons or property occurring during the transportation of its radioactive waste into or within the State including all costs of defending the same; provided, however, that nothing contained herein shall be construed as a waiver of the State's sovereign immunity; and, further provided, that agencies of the State of South Carolina shall not be subject to the requirements of this provision.

3.5 Permit fees will be annually determined and assessed by the Department based on the following classifications:

3.5.1 Class X—more than an annual total of ~~75~~seventy-five cubic feet (75 ft.^{3}) or more than ~~100~~one hundred curies (100 Ci) of radioactive waste for disposal within the State.

3.5.2 Class Y—an annual total of ~~75~~seventy-five cubic feet (75 ft.^{3}) or less of radioactive waste consisting of ~~100~~one hundred curies (100 Ci) or less total activity for disposal within the State.

3.5.3 Class Z—any shipment of radioactive waste, which is not consigned for storage or disposal within the State, but which is transported into or within the State.

3.6 Permits will be valid from the date of issuance through December 31 of each calendar year. Permit fees are not refundable. Permits may be renewed by filing a new application with the Department.

4. SHIPPER'S REQUIREMENTS

4.1 Before any shipment of radioactive waste may be transported into or within the State, the shipper shall give written notice to the Department not less than seventy-two (72) hours nor more than thirty (30) calendar days before the expected date of arrival of the shipment or departure from the shipper's facility within the State as the case may be, except as provided in paragraph 4.1.3.

4.1.1 All prior notifications shall be filed on a Department form designated as ~~RHA-PNC~~SCDHEC-0802 "Radioactive Waste Shipment Prior Notification and Manifest Form."

4.1.2 The shipper shall immediately notify the Department of any cancellations or significant changes in the prior notification or manifest summary which may occur prior to the shipment departing ~~his~~the facility. For example, such changes include changes in date of arrival, carrier, route, waste description, curie content, volume, or waste classification.

4.1.3 For shipments consisting of ~~75~~seventy-five cubic feet (75 ft.^{3}) or less containing one curie (1 Ci) of radioactive material or less which may be consigned as non-exclusive use shipments according to applicable U.S. Department of Transportation regulations, the requirement for prior notification contained in paragraph 4.1 is waived. Such shipments must otherwise comply with all other applicable requirements regarding the packaging, transportation, storage, disposal, and delivery of radioactive wastes.

4.2. The shipper shall provide to the carrier with each separate shipment a copy of the ~~RHA-PNC~~ SCDHEC-0802 "Radioactive Waste Shipment Prior Notification and Manifest Form" required by

paragraph 4.1. Such copy shall show any changes made pursuant to paragraph 4.1.2 above. Each shipper shall instruct the carrier to comply with the route and schedule contained therein.

4.3 The manifest accompanying each shipment of radioactive waste shall include a copy of the shipper's certification prepared on Department form ~~RHA-CT~~SCDHEC-0803, Part I, "Radioactive Waste Shipment Certification Form," which shall include certification that the shipment has been inspected and complies with all applicable State and Federal laws and administrative rules and regulations, license or license conditions of the disposal facility regarding the packaging, transportation, storage, disposal, and delivery of radioactive wastes.

4.4 Following acceptance of each separate shipment at a disposal facility or at the consignee's facility, it shall be the responsibility of each shipper to provide to the Department for such shipment a copy of the Department form ~~RHA-PNC~~SCDHEC-0802 "Radioactive Waste Shipment Prior Notification and Manifest Form" with the Consignee Acknowledgement properly executed and to provide the Department with the "Radioactive Waste Shipment Certification Form," Department form ~~RHA-CT,~~ SCDHEC-0803 which accompanied that shipment.

5. CARRIER'S REQUIREMENTS

5.1 For each shipment of radioactive waste materials shipped into or within the State, a carrier shall complete Part II: Carrier's Certification on the form ~~RHA-CT~~SCDHEC-0803 provided by the ~~shipper~~generator. The certificate shall be signed by a principal, officer, partner, responsible employee, or other authorized agent of the carrier.

5.1.1 The carrier shall certify that the shipment is properly placarded for transport and that all shipping papers required by law and administrative rules and regulations have been properly executed; and~~,~~

5.1.2 that the transport vehicle has been inspected and meets the applicable requirements of the Federal government and the State of South Carolina, and that all safety and operational components are in good operative condition; and~~,~~

5.1.3 that the carrier has received a copy of the shipper's "Radioactive Waste Shipment Prior Notification and Manifest Form," form SCDHEC-0802 specified in paragraph 4.2 and the "Radioactive Waste Shipment Certification Form," form ~~RHA-CT~~SCDHEC-0803 specified in paragraph 4.3; and~~,~~

5.1.4 that the carrier shall comply fully with all applicable laws and administrative rules and regulations, both State and Federal, regarding the transportation of such waste.

5.2 A carrier shall immediately notify the Department of any variance, occurring after departure, from the primary route and estimated date of arrival of shipment as provided by the shipper on Form ~~RHA-PNC~~ SCDHEC-0802.

5.3 The copies of Forms ~~RHA-CT~~SCDHEC-0803 and ~~RHA-PNC~~SCDHEC-0802 shall accompany the shipment to the destination and shall be presented together with the manifest and other shipping papers.

6. DISPOSAL FACILITY OPERATOR

6.1 Owners and operators of disposal facilities shall permanently record, and report to the Department within twenty-four (24) hours after discovery, all conditions in violation of the requirements of this regulation discovered as a result of inspections required by any license under which the facility is operated.

6.2 Prior to the receipt of radioactive wastes at a disposal facility in this State, the owners and operators of such facility shall notify each shipper of any special requirements, if any, in effect regarding the packaging, transportation, storage, disposal, or delivery of such wastes at that facility.

6.3 No owner or operator of a disposal facility located within this State shall accept radioactive waste for storage or disposal unless the shipper of such waste has a valid, unsuspended permit issued pursuant to this regulation.

7. PENALTIES

7.1 Any person who commits a radiological violation shall:

7.1.1 be fined not less ~~that~~than One Thousand Dollars ($1,000.00) nor more than Five Thousand Dollars ($5,000.00); and~~,~~

7.1.2 if such person is a shipper, have his or her permit suspended for a period of not less than thirty (30) calendar days and until such time as he or she demonstrates to the Department's satisfaction that adequate measures have been taken to prevent reoccurrence of the violation.

7.2. Any person who commits a second radiological violation within twelve (12) months of the first such violation shall:

7.2.1 be fined not less than Five Thousand ($5,000.00) nor more than Twenty-five Thousand Dollars ($25,000.00); and~~,~~

7.2.2 if such person is a shipper, have his or her permit suspended for a period of not more than one (1) year and until such time as he or she demonstrates to the satisfaction of the Department that adequate measures have been taken to prevent reoccurrence of the violations.

7.3 Any person who commits a non-radiological violation of the provisions of this regulation shall be fined not more than One Thousand Dollars ($1,000.00) for each violation; *provided*, that should the Department determine that a series of such violations has occurred, the Department shall suspend or revoke that person's permit for a period of not more than twelve (12) months.

7.4. Any person to whom an order, injunction, suspension, or fine issued under this article is directed shall comply therewith immediately, but on application to the Department, within twenty (20) calendar days after the date of the order, shall be afforded a hearing within thirty (30) calendar days of such application.

8. EXEMPTIONS FROM REQUIRMENTS OF THIS REGULATION

The Department may, upon application thereof or upon its own initiative, grant such exemptions or exceptions from the requirements of this regulation as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

~~8.~~9. SEVERABILITY CLAUSE

~~8.1~~ It is hereby declared that each of the sections and provisions of this regulation are severable, if that any one or more of such sections are declared unconstitutional or invalid, the remaining sections and provisions of this regulation shall remain in effect.

~~ATTACHMENTS~~

Form RHA-200P
(10/80)

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL APPLICATION FOR RADIOACTIVE WASTE TRANSPORT PERMIT

Instructions: Complete Items 1 through 8. Submit original and one copy to Chief, Bureau of Radiological Health, S.C. Dept. of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201. All copies must be signed and dated. Additional sheets may be used if necessary. Upon approval, the Department will return one copy with your transport permit. All permit fees should be made payable to the S.C. Dept. of Health and Environmental Control, Bureau of Finance, 2600 Bull Street, Columbia, S.C. 29201. Please note on remittance, "For Radioactive Waste Transport Permit."

Note: Radioactive Waste Transport Permits may be purchased for more than one facility or location of a company, corporation, etc. However, an application shall be submitted for each facility to include the additional fee and the required certificate of insurance or bond.

1. Name and Address of Applicant (Shipper):	2. Person responsible for Radioactive Waste shipment: (a) Name: (b) Title: (c) Address: (d) Telephone:
3. Locations from which waste will be shipped if application is for more than one facility. (a) (b)	4. NRC or Agreement State Radioactive Material License No. for each location. (a) (b)
5. Estimated Annual Cubic Footage.	6. Amount of permit fee remitted.

Information to be Submitted as Attachment

7. A Certificate of Liability Insurance shall be submitted as evidence of financial ability to protect the State of South Carolina and the public at large from possible radiological injury or damage due to packaging, transportation, disposal, storage, or delivery of radioactive waste. For those applicants not maintaining liability insurance, they must deposit and maintain with the Department a cash or corporate surety bond in the amount of Five Hundred Thousand Dollars ($500,000.00).

CERTIFICATE

8. In compliance with Act No. 429 of 1980, the South Carolina Radioactive Waste Transportation and Disposal Act, I hereby certify on behalf of the above-named applicant (shipper) to the South Carolina Department of Health and Environmental Control that: (A) the above-named applicant (shipper) will comply fully with all applicable laws and administrative rules and regulations, both State and Federal, and any disposal facility radioactive material license requirements regarding the packaging, transportation, storage, disposal, and delivery of such wastes; (B) the above-named applicant (shipper) will hold the State of South Carolina harmless for all claims, actions, proceedings in law or equity arising out of radiological injury or damages to persons or property occurring during the transportation of its radioactive waste into or within the State including all costs defending same; provided, however, that nothing contained herein shall be construed as a waiver of the State's sovereign immunity; (C) the above-named applicant (shipper) has current copies of the Regulations for the Transportation of Radioactive Waste into or within the State of South Carolina, DOT Regulations 49 CFR Parts 171-179, and when applicable, the disposal site radioactive material license and the disposal site waste acceptance criteria; (D) the above-named applicant (shipper) has prepared this application to conform with South Carolina Department of Health and Environmental Control Regulation for Transportation of

Radioactive Waste Into or Within South Carolina, and that all information contained herein, including any required supplements attached hereto, is true and correct to the best of my knowledge and belief.

Date _____ _____

Typed Name and Title of Agent of Applicant
(Shipper)

_____ _____

Signature

DHEC 800
(10/80) Revision

General Instructions and Information

1. This form is to be used to provide the Department with prior notification of radioactive waste shipments transported into or within the State of South Carolina. This notification is to be made 72 hours before the expected date of arrival in the State. All written notices should be mailed to:
Bureau of Radiological Health
Radioactive Waste Management Section
S.C. Dept. of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

2. A separate form shall be submitted for each radioactive waste shipment.

3. Prior notification is required of all radioactive waste shipments as defined in paragraph 2 of Interim Regulations for the Transportation of Radioactive Waste into or within South Carolina except as provided in paragraph 4.1.2 of the Regulation.

4. The "Manifest Summary" portion of this form will satisfy requirements of providing the Department with a shipping manifest, however, it does not satisfy the requirements of shipping documents which shall accompany the shipments as required by DOT Regulations and the disposal facility's license and criteria.

5. A copy of this completed form shall be provided to the carrier and all drivers of the radioactive waste shipment.

6. Upon delivery of the shipment to the consignee, acknowledgment of receipt shall be obtained, and a copy of this form and the shipper/carrier's certification form shall be returned to the Department.

Specific Instructions

Item Number

1. Self Explanatory
2. Self Explanatory
3. This item applies to all shipments of radioactive waste transported to and within the State of South Carolina.
4. Each shipment of radioactive waste shall be identified in some manner by the shipper. This number can be a radioactive shipment record number, bill of lading number, allocation number, etc. The identification number shall only be used once to identify the one shipment for which notification is being made.
5. Self Explanatory

6. Indicate in this item the disposal facility, company, organization, etc., to which this shipment has been consigned.
7. Self Explanatory
8. For through shipments, indicate in this item estimated date shipment will pass through the state.
9. Self Explanatory

10. & 11. Applies only to exclusive use, sole use, and full load shipments.

12. All routing information must be specific. You should check with carrier to insure routes you prescribe are appropriate. The carrier is responsible to inform the Department of any changes of routes in South Carolina after departure.

13 thru 21. Self Explanatory

Certification: To be signed only by an authorized representative or agent of the shipper and carrier.

Form RHA-PHC (5/80)

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Radioactive Waste Shipment Prior Notification and Manifest Form

See Reverse Side for Instructions

1. Name and Address of Shipper:	2. Person Responsible for Radioactive Waste Shipment: (a) Name (b) Title (c) Telephone No. ( )
3. Radioactive Waste Transport Permit No.	4. Shipment Identification No.:
5. Location from which waste will be shipped:	6. Name and Address of Consignee:
7. Scheduled Date of Departure of Shipment:	8. Estimated Date of Arrival of Shipment:

9. Carrier:	10. Type of Transport Vehicle:	11. Trailer No. and Owner (if available)

12. Routes shipment will follow in State of South Carolina (Be Specific):

Manifest Summary

13. Type Container or Cask:	14. Container Spec.	15. Total No. of Containers
16. Waste Description: Physical and Chemical Form	17. Prominent Radionuclides:	
18. Total Curies:	19. Transport Group:	20. Total Cubic Feet:

21. Waste Classification:

		Normal Form	Special Form	Fissile
[ ] Radioactive LSA [ ] Radioactive LSA greater than Type A quantities	[ ] Bulk LSA [ ] Limited quantities and radioactive devices	[ ] Type A quantity [ ] Type B quantity [ ] Large quantity	[ ] Type A quantity [ ] Type B quantity [ ] Large quantity	[ ] Class I [ ] Class II [ ] Class III

CERTIFICATION

I hereby certify on behalf of the above-named shipper to the South Carolina Department of Health and Environmental Control that the information provided herein is complete and correct to the best of my knowledge; and that the shipper has complied with all the provisions as required by Act No. 429 of 1980, the South Carolina Radioactive Waste Transportation and Disposal Act.

Date _____

_____ _____

Typed Name and Title of Agent of Shipper Signature

CONSIGNEE ACKNOWLEDGEMENT

This acknowledges to the South Carolina Department of Health and Environmental Control that the above-described radioactive waste shipment was received.

_____ _____

Date of Delivery Signature of Consignee or authorized Agent

_____

_____

Typed or Printed Name and Title

DHEC 802
(5/80) (Copies of this form may be reproduced locally as needed)

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
Radioactive Waste Shipment Certification Form

General Instructions and Information: This is a two part form to be used by shippers and carriers of radioactive waste. The certifications contained herein satisfy the requirements of Section 13-7-150, of Act No. 429 of 1980, the South Carolina Radioactive Waste Transportation and Disposal Act. This certification along with a copy of the prior notification form shall accompany each shipment of radioactive waste into and within the State of South Carolina. The shipper is to complete his portion of the form and present it to the carrier as part of the shipping documents. Upon receipt, the carrier shall complete his portion of the form. Upon delivery of the shipment to the consignee, a copy of this certification form, and a copy of the Prior Notification and Manifest form with the consignee acknowledgement, shall be returned to the Department.

Part I: Shipper's Certificate of Compliance

1. Name of Shipper and Address: 2. Shipment Identification No.

3. Transport Permit No.

Telephone No. ( )

In compliance with Act No. 429 of 1980, the South Carolina Radioactive Waste Transportation and Disposal Act, I hereby certify on behalf of the above-named shipper to the South Carolina Department of Health and Environmental Control that the above-named shipper has complied with all provisions of Act No. 429 of 1980, and all applicable laws and administrative rules and regulations, both State and Federal, regarding the packaging, transportation, storage, disposal and delivery of such wastes. I further certify that this shipment of radioactive waste has been inspected within 48 hours of the time of departure and that no items of non-compliance with applicable laws, rules or regulations were found.

Date _____

_____ _____

Typed Name and Title of Agent of Shipper Signature

~~Part II: Carrier's Certification~~

~~1. Name of Carrier and Address:~~	~~2. Shipment Identification No.~~ ~~3. Transport Trailer No.~~ ~~Telephone No. ( )~~
~~4. Scheduled Date of Departure of Shipment:~~	~~5. Estimated Date of Arrival of Shipment:~~

~~Certification is hereby made to the South Carolina Department of Health and Environmental Control that: (a) the shipper has provided the carrier with a copy of the shipment manifest, the certificate of compliance, and the routing instructions; (b) the shipment of radioactive waste has been properly placarded for transport according to applicable U.S. Department of Transportation Regulations; (c) all shipping papers originated or reproduced by the carrier have been properly executed; (d) the transport vehicle has been inspected according to applicable State and Federal regulations within the prescribed intervals and that all safety and operational components are in good working order and meet the requirements of regulations; (e) all drivers who will operate the vehicle within the State of South Carolina are qualified to transport hazardous materials as specified by applicable U.S. Department of Transportation regulations; (f) the Department shall be immediately notified of any variance , occurring after departure, from the shipper's notification of primary routes in South Carolina and estimated date of arrival; (g) all applicable laws and administrative rules and regulations, both State and Federal, regarding the transportation of radioactive wastes will be complied with.~~

~~Date~~ _____

_____ _____

~~Typed or Printed Name and Title Signature~~

~~DHEC 803~~
~~(5/80) (Copies of this form may be reproduced locally as needed)~~

Fiscal Impact Statement:

None.

Statement of Need and Reasonableness:

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: R.61-83, Transportation of Radioactive Waste Into or Within South Carolina

Purpose: The Department proposes amending R.61-83, Transportation of Radioactive Waste Into or Within South Carolina, to incorporate the 2018 revisions to 10 CFR 71, and any disposal facility's radioactive material license requirements and site disposal criteria regarding the packaging, transportation, disposal, storage, or delivery of radioactive materials.

Legal Authority: 1976 Code Sections 13-7-10 et seq.

Plan for Implementation: The amendments will take legal effect upon Board approval and upon publication in the State Register. Department personnel will then take appropriate steps to inform the regulated community of the amendment. In Addition, a copy of the regulation will be posted on the Department's

website, accessible at www.scdhec.gov/regulations-table. For a fee, printed copies may also be requested, for a fee, from the Department's Freedom of Information Office.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

Adoption of the proposed amendments of R.61-83 enables compliance with federal regulations and standards.

DETERMINATION OF COSTS AND BENEFITS:

The proposed amendment will potentially relieve the burden to the regulated community by providing the ability to grant exemptions from the requirements of the regulation when authorized by law and when SCDHEC determines it will not result in undue hazard to public health and safety of property.

UNCERTAINTIES OF ESTIMATES:

No known uncertainties.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

These proposed amendments will promote an effective regulatory program for radioactive material users under state jurisdiction, and protection of the public and workers from unnecessary exposure to ionizing radiation. These proposed changes will also provide updates to the transportation safety standards for radioactive materials.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

The State's authority to implement federal requirements, which are believed to be beneficial to the public health and environment, would be compromised if these amendments were not adopted in South Carolina.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Ann., Section 1-23-110(A)(3)(h):

The regulation was promulgated pursuant to Act No. 429 of 1980, the South Carolina Radioactive Waste Transportation and Disposal Act, amending S.C. Code Ann. 13-7-10 *et seq*. of the South Carolina Atomic Energy and Radiation Control Act. The purpose of the regulation is to require written notification to the Department of shipments of radioactive waste by any shipper, carrier, or other person who transports such waste within the State's borders. An additional purpose of the regulation is to require that shippers of waste obtain adequate financial assurance and hold the State harmless in case of radiological injury or damage arising out of the transportation of the waste, and for the enforcement of transportation and disposal requirements of radioactive waste. This regulation applies to generators and shippers of radioactive waste, including, for example, nuclear power plants, waste brokers and processors, educational and government institutions, and research facilities.

(x) ACTION/DECISION
( ) INFORMATION

Date: November 9, 2023

To: S.C. Board of Health and Environmental Control

From: Healthcare Quality

Re: Notice of Proposed Regulation Amending R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*.

I. Introduction

Healthcare Quality proposes the attached Notice of Proposed Regulation amending R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries* for publication in the November 24, 2023 *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Sections 44-7-110 through 44-7-394, which requires the Department of Health and Environmental Control ("Department) to establish and enforce minimum standards for the licensure, maintenance, and operation of hospitals and institutional general infirmaries to ensure the safe and appropriate treatment of persons served in this state. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. Pursuant to S.C. Code Sections 44-7-250 and -260(A)(1), the Department establishes and enforces minimum standards for the licensure, maintenance, and operation of hospitals to ensure the safe and appropriate treatment of persons served in this state. The Department proposes amending R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*, to ensure alignment with current state laws and to update and revise definitions, license requirements and fees, staff and training, reporting, disaster management, accommodations for patients, patient care and services, design and construction, fire protection, prevention and life safety, and policies and procedures.

2. The Department had a Notice of Drafting published in the July 28, 2023 *State Register*. This notice supersedes the Notice of Drafting that was published in South Carolina State Register Volume 47, Issue 3 on March 24, 2023. A copy of the Notice of Drafting appears herein as Attachment B. The Department received public comments from 27 parties by August 28, 2023, close of the public comment period. Attachment C presents a summary of these public comments received and Department responses.

3. Department staff conducted Stakeholder Meetings on August 22, 2023, and October 25, 2023, to discuss the proposed amendments and/or to receive comments on the proposed amendments.

4. Appropriate Department staff conducted an internal review of the proposed amendments on October 9, 2023.

III. Request for Approval

Healthcare Quality respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the November 24, 2023 *State Register*.

Gwen C. Thompson
Deputy Director
Healthcare Quality

Charlene Bell
Director, Hospital and Professional Services
Bureau of Healthcare Systems and Services
Healthcare Quality

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the July 28, 2023 *State Register*
C. Summary of Public Comments Received and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-16, Minimum Standards for Licensing Hospitals and Institutional General Infirmaries

November 9, 2023

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394

61-16. Minimum Standards for Licensing Hospitals and Institutional General Infirmaries

Preamble:

Pursuant to S.C. Code Sections 44-7-250 and -260(A)(1), the Department of Health and Environmental Control ("Department") establishes and enforces minimum standards for the licensure, maintenance, and operation of hospitals to ensure the safe and appropriate treatment of persons served in this state. The Department proposes to amend the R.61-16 for consistency with current statutory requirements, update and revise definitions, licensure requirements, staff and training, reporting, disaster management, accommodations for patients, patient care and services, design and construction, fire protection and life safety, and policies and procedures. It contains a section-by-section discussion and justification for the proposed amendments. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Department had a Notice of Drafting published in the July 28, 2023 *South Carolina State Register*.

Section-by-Section Discussion of Proposed Amendments:

Section	Type of Change	Purpose
Entire Regulation	Technical Corrections	Amended to clarify references to "Facilities" includes both Hospitals and Institutional General Infirmaries and references to "Hospitals" includes only hospitals. Amended to remove "DHEC" from references to certain Regulations – "DHEC Regulation 61-25". See, e.g., Section 1501.
Table of Contents	Technical Correction Reorganization	Amended language and sections to reflect technical corrections and reorganization proposed in regulation text.
101.E.1. Definitions. General Hospital.	Revision	Amended to be consistent with changes from 2023 Act No. 20.
101.E.2. Definitions. Specialized Hospital.	Revision	Amended to be consistent with changes from 2023 Act No. 20.

Section	Type of Change	Purpose
101. Definitions. Privately Owned Educational Institutional Infirmary.	Deletion	Deleted definition.
201. License Requirements. 201.F.	Addition	Added requirement to make payment of all fees prior to issuance of licenses.
201. License Requirements. 201.G.	Revision	Amended to clarify method of fee payment.
201. License Requirements. 201.H.3.	Technical Correction	Amended to delete the language "or replacement".
201. License Requirements. 201.H.4.	Technical Correction	Amended to delete the word "or".
201. License Requirements. 201.H.5.	Technical Correction	Amended to add the word "or".
201. License Requirements. 201.H.6.	Addition/Technical Correction	Added language to clarify an amended license shall be requested for move of a facility.
202.Exemptions to Licensing Standards.	Technical Correction/ Revision	Amended to replace "exemption" with "variance" and to add language to provide clarity regarding variances to licensing standards.
New 300. Enforcing Regulations and Enforcement Actions.	Revision/Deletion/Reorganization	Amended to title section as Enforcing Regulations "and Enforcement Actions." Deleted former 400, Enforcement Actions, and recodified former 401, general, as 304, and former 402, violation classifications, as 305. Deleted former 401.B.
New 400. Policies and Procedures	Addition/Technical Correction/Reorganization	Amended to create section specifically to address policy and procedures.
New 401. General	Addition/Technical Correction/Reorganization	Amended to add clarifying language and to recodify the section.
New 402. Quality of Care	Addition	Added requirements to have quality assessment and performance improvement program.
New 403. Security	Revision/Reorganization	Reorganized to move previous Section 905 to Section 403, with certain minor amendments. .
502. Control	Deletion/Revision	Removed language in section and revised to clarify governing body and control requirements.
503. Chief Executive Officer	Revision	Amended for clarification.

Section	Type of Change	Purpose
504. Medical Staff Appointment. (II)	Revision/ Reorganization	Amended to remove and clarify language; amended to re-letter the section for consistency; amended to add Section 44-7-266(A) requirement .
505. Nursing Services. (II)	Deletion/Revision/ Reorganization/	Amended to remove and add language for clarification; amended to re-letter the section for consistency.
506. Employees. (II)	Deletion/Revision/ Reorganization/	Amended to remove and add language for clarification; amended to re-letter the section for consistency.
507. Job Orientation and In-Service Training	Deletion/Reorganization	Amended and reorganized to remove and clarify language.
508. Plans and Training for Fires and Other Internal Emergencies. (II)	Deletion/ Reorganization	Amended to delete this section and move it to Section 2005.
701. Fire Report	Deletion/Reorganization	Amended to delete this section and move it to new section 2003.
New 701. Incident Reports	Revision/Reorganization	Amended to remove "accident and/or," and add "s" to end of reports in title; amended to add clarifying language and to recodify to section 701; amended to clarify and add reporting obligations to the Department.
New 702. Loss of Essential Services.	Addition	Added new language for reporting losses of essential services.
703. Facility Closure.	Revision	Amended to change lower case "f" in word facility to capital "F;" amended to remove and add language in last paragraph for clarification.
704. Zero Census	Revision	Amended to change lower case "f" in word facility to capital "F;" amended by adding language to clarify numbers in writing; amended by deleting language.
705. Joint Annual Report.	Revision	Amended to clarify language.
706. Hospital Infections Disclosure Act (HIDA) & Reporting Requirements. (I)	Revision	Amended to clarify language.
New 900. Emergency Preparedness	Revision	Amended to re-name section to specifically address hazardous events outside those considered a disaster.

Section	Type of Change	Purpose
New 901. All-Hazards Emergency Operations Plan	Revision/Technical Correction/Reorganization	Amended to change title of section from Emergency Evacuation; amended to remove and clarify language; amended to add language for clarification; amended to re-letter the section for consistency; added subsection F regarding communication with local emergency agencies.
902. Internal Medical Surge	Technical Correction/Revision/ Reorganization	Amended to change lower case "f" in word facility to capital "F;" amended to remove and clarify language; amended to add language for clarification; amended to re-letter the section for consistency.
903. External Medical Surge	Technical Correction/Revision/Reorganization	Amended to remove and clarify language; amended to add language for clarification; amended to re-letter this section for consistency.
904. Emergency Call Data. (I)	Deletion	Amended to remove and clarify language.
905. Security	Technical Correction/Reorganization	Amended to delete this section and move it to Section 403.
1001. Maximum Number of Beds	Addition	Amended to add language for regarding the Facility's ability to setup beds.
1002. Location of Beds	Revision	Amended to add language for clarification.
1105. Contents	Revision/Technical Correction/Reorganization	Amended to remove and clarify language; amended to add language for clarification; amended to re-number this section for consistency.
Section 1200. Patient Care and Services	Revision/Reorganization	Amended Section 1200 to have 1201 addressing basic facility functions and 1202 addressing optional hospital services.
New 1201.A. Pharmaceutical Services.	Revision/Technical Correction/Reorganization	Added pharmaceutical services which incorporates applicable federal Medicare standards; reorganized to delete and relocate some of the provisions in former 1201, Medications, 1204, Pharmacy Services, 1205, Drug Distribution and Control, 1206, Physical Facilities and

Section	Type of Change	Purpose
		Storage, and 1207, labeling of medications.
New 1201.B. Radiological Services.	Revision/Technical Correction/Reorganization	Added radiological services which incorporates applicable federal Medicare standards; deleted former 1203, Radiology.
New 1201.C. Laboratory Services.	Revision/Technical Correction/Reorganization	Added laboratory services which incorporates applicable federal Medicare standards; deleted former 1202, Laboratory.
New 1201.D. Emergency Services.	Revision/Technical Correction/Reorganization	Amended to add language regarding hospitals' provision of emergency services, including classification of such services the provision of off-campus emergency services, and address diversion. Reorganized to delete and relocate some of the standards at former 1214, Emergency Services .
New 1201.E. Central Supply.	Technical Correction/Reorganization	Amended to relocate former 1208, Central Supply, to Section 1201.E; amended to re-number the section for consistency.
New 1202.A. Surgical Services.	Revision/Technical Correction/Reorganization	Added surgical services which incorporates applicable federal Medicare standards and parts of former 1209, surgery; partially relocated former 1211, Equipment, to 1202.A.2.g; deletes former 1210, facilities, and 1216, dental surgery;amended to add language for clarification; amended to re-letter the section for consistency.
New 1202.B. Anesthesia Services.	Revision/Technical Correction/Reorganization	Added anesthesia services which incorporates applicable federal Medicare standards; deleted former 1212, Anesthesia
New 1202.C. Nuclear Medicine Services.	Addition	Added nuclear medicine services which incorporates applicable federal Medicare standards.
New 1202.D. Outpatient Services.	Revision/Technical Correction/Reorganization	Added outpatient services which incorporates applicable federal Medicare standards; deletes former 1213, outpatient services.
New 1202.E. Rehabilitation Services.	Revision/Technical Correction/Reorganization	Added rehabilitation services which incorporates applicable

Section	Type of Change	Purpose
		federal Medicare standards; deletes former 1217, physical therapy, and 1218, occupational therapy.
New 1202.F. Psychiatric Services.	Revision/Technical Correction/Reorganization	Added psychiatric services which incorporates applicable federal Medicare standards; relocates former 1219, psychiatric services, to 1202.F.
New 1202.G. Respiratory Care Services.	Addition	Added respiratory care services which incorporates applicable federal Medicare standards.
New 1202.H. Inpatient Dialysis Services.	Revision/Technical Correction/Reorganization.	Relocated former 1215, inpatient dialysis services, to 1202.H, and adds language regarding quality of care.
New 1202.I. Chemical and Substance Abuse Treatment Services.	Revision/Technical Correction/Reorganization	Relocated former 1220, chemical and substance abuse treatment services, to 1202.I, and adds language regarding quality of care.
New 1202.J. Pediatric Services.	Revision/Technical Correction/Reorganization.	Relocated former 1221, pediatrics, to 1202.J, and adds language regarding quality of care.
1900. Design, Construction, Repairs, Alterations, and Additions.	Revision/Technical Correction	Amended to create new title for section – Design, Construction, Repairs, Alterations, and Additions.
1901. General.	Revision	Amended to delete and add language for clarification.
1902. Codes and Standards.	Revision	Amended to delete and add language for clarification of applicable codes.
1903. Submission of Plans.	Revision/Addition	Amended to delete and add language for clarification of the Department's review of certain construction projects.
1904. Constriction Inspections.	Technical Correction/Revision	Amended to remove inspections and add permits to title; amended to delete and add language for clarification.
1905. Patient Rooms.	Revision	Amended to delete and add language for clarification.
1907. Nurses Station.	Revision	Amended to delete and add language for clarification.
1908. Utility Rooms.	Revision/Addition	Amended to delete and add language for clarification; added

Section	Type of Change	Purpose
		provision regarding nourishment rooms.
1909. Temperature and Humidity.	Deletion	Deleted this section as it is covered under mechanical section.
New 2003. Fire Reports.	Revision/reorganization	Amended to add language from former 701, fire report.
New 2004. Fire Safety.	Addition	Added language regarding compliance with adopted codes concerning fire safety.
New 2005. Plans and Training for Fires.	Revision/reorganization	Amended to add language from former 508, plans and training for fires and other internal emergencies, and clarify certain requirements.
New 2006. Tests and Inspections.	Addition	Added language regarding testing and maintenance of fire systems.
New 2007. Gases.	Addition	Added language regarding safety precautions for administration of oxygen.
New 2008. Furnishings and Equipment.	Addition	Added language regarding maintenance of furnishings/equipment and fire safety.
Section 2100. Preventive Maintenance of Life Support Equipment.	Revision.	Amended for correct grammar/spelling.
Section 2200. General.	Deletion	Deleted section.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments to Healthcare Quality; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; HQRegs@dhec.sc.gov; or the Public Comment Form at https://forms.office.com/g/9VMEXLWtq0. To be considered, the Department must receive the comment(s) by 5:00 p.m. on December 27, 2023, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments during its February 8, 2024, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: http://www.scdhec.gov/Agenda.

The Department publishes a Monthly Regulation Development Update tracking the status of its proposed new regulations, amendments, and repeals and providing links to associated State Register documents at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/.

Preliminary Fiscal Impact Statement

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any requirements of this regulation.

Statement of Need and Reasonableness

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: 61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*

Purpose: The Department proposes to amend R.61-16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*, for consistency with statutory requirements, to update and revise definitions, license requirements and fees, staff and training, reporting, disaster management, accommodations for patients, patient care and services, design and construction, fire protection, prevention and life safety, and policies and procedures. The proposed amendments may also include stylistic changes, which may include corrections for clarity and readability, grammar, punctuation, definitions, references, codification, and overall improvement of the text of the regulation.

Legal Authority: 1976 Code Section(s) 44-7-250 and 44-7-260(A)(1)

Plan for Implementation: The amendments will take legal effect upon General Assembly approval and upon publication in the State Register. Department personnel will then take appropriate steps to inform the regulated community of the amendments. Additionally, a copy of the regulation will be posted on the Department's website, accessible at www.scdhec.gov/regulations-table. Printed copies may also be requested, for a fee, from the Department's Freedom of Information Office.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The amendments are necessary to incorporate changes in state law as well as changes to current practices and standards. The amendments incorporated consistency with statutory requirements, to update and revise definitions, license requirements and fees, staff and training, reporting, disaster management, accommodations for patients, patient care and services, design and construction, fire protection, prevention and life safety, and policies and procedures. Many of the proposed amendments align the licensing standards with the Federal Regulation for coverage with Medicare (*see* 42 C.F.R. Part 482), which are applicable to a substantial amount of existing facilities. Finally, the proposed amendments relating to fees update the manner and method of fees such that there are more convenient and efficient transactions with the Department.

DETERMINATION OF COSTS AND BENEFITS:

Implementation of these proposed amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any inherent requirements of these proposed amendments. There are no anticipated additional costs to the regulated community.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The proposed amendments will have no effect on the environment of this State. These regulations contribute to the Department's function of protecting public welfare and promoting safety and wellbeing for patients receiving care and treatment from hospital facilities and institutional general infirmaries.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment. If the proposed revision is not implemented, the regulation will be maintained in its current form; the benefits of the proposed amendments herein will not be realized.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(A)(3)(h):

These revised regulations are updated to ensure alignment with current state laws and to update and revise definitions, license requirements and fees, staff and training, reporting, disaster management, accommodations for patients, patient care and services, design and construction, fire protection, prevention and life safety, and policies and procedures.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-16. Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.

Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394, 44-37-40, 44-37-50, and 63-7-40

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SECTION 100
DEFINITIONS

101. Definitions.

For the purpose of these Standards, the following definitions shall apply:

A. Administrator: The individual designated by the governing body or owner who is in charge of and responsible for the administration of the facility.

B. Annual (Annually): A time period that requires an activity to be performed at least every twelve to thirteen (12 to 13) months.

C. Contact Investigation: Procedures that occur when a case of infectious TB is identified, including finding persons (contacts) exposed to the case, testing and evaluation of contacts to identify Latent TB Infection (LTBI) or TB disease, and treatment of these persons, as indicated.

D. Department: The South Carolina Department of Health and Environmental Control.

E. Facility: Hospitals and institutional general infirmaries licensed by the Department, shall be defined and classified as follows:

1. General Hospital: A facility with an organized medical staff to maintain and operate organized facilities and services to accommodate two or more nonrelated persons for the diagnosis, treatment and care of such persons overnight and provides medical and surgical care of acute illness, injury or infirmity and must provide on-campus emergency services; that may provide obstetrical care~~,~~; and in which all diagnoses, treatment or care are administered by or performed under the direction of persons currently licensed to practice medicine, surgery, or osteopathy in the State of S.C.

2. Specialized Hospital: A facility which has an organized medical staff, maintains and operates organized facilities and services to accommodate two or more nonrelated persons for the diagnosis, treatment and/or care of such persons overnight and which provides a specialized service for one type of care~~, such as, maternity, orthopedics, pediatrics, E.E.N.T., psychiatry, etc.~~ and must provide on-campus emergency services; and in which all diagnoses, treatment or care are under the direction of persons currently licensed to practice medicine, surgery, osteopathy in the State of S.C.

3. Institutional General Infirmary: A facility which is established within the jurisdiction of a larger nonmedical institution and which maintains and operates organized facilities and services to accommodate two or more nonrelated students, residents or inmates with illness, injury or infirmity for a period exceeding 24 hours for the diagnosis, treatment and care of such persons and which provides medical, surgical and professional nursing care, and in which all diagnoses, treatment and care are performed under the direction of persons currently licensed to practice medicine and surgery in the State of S.C.

4. Long Term Acute Care Hospital (LTACH): A general hospital which has been classified and certified as a long term acute care hospital designed to provide extended medical and rehabilitative care for patients who are clinically complex and have acute or chronic conditions. In a LTACH patients have an average length of stay of 25 days or more.

5. Critical Access Hospital (CAH): A general hospital designated by the state as such through the Medicare Rural Hospital Flexibility Program, in accordance with 42CFR485 Subpart F.

~~6. Privately-Owned Educational Institutional Infirmary: These facilities may be established within the jurisdiction of a larger nonmedical institution which maintains and operates organized facilities and services to accommodate two or more nonrelated students, faculty, and staff with illness, injury, or infirmity for a period exceeding twenty-four hours for the diagnosis, treatment, and care of such persons and which provides medical, surgical, and professional nursing care, and in which all diagnoses, treatment, and care are performed under the direction of persons currently licensed to practice medicine and surgery in South Carolina. However, privately-owned education infirmaries also may care for patients who are not students, faculty, or staff when the privately-owned education infirmary has agreed to provide such care to this class or patients prior to January 1, 2007 pursuant to 44-7-261.~~

F. Designee: A physician, dentist, osteopath, podiatrist, physician's assistant, or advanced practice registered nurse who has staff privileges, selected by a prescriber to sign verbal orders for medication or treatment in the prescriber's absence.

G. Dietitian: An individual who is registered by the Commission on Dietetic Registration and currently licensed as a dietitian by the South Carolina Department of Labor, Licensing and Regulation.

H.Existing Facility: A facility which was in operation and/or one which began the construction or renovation of a building, for the purpose of operating the facility, prior to the adoption of these standards. The licensing standards governing new facilities apply if and when an existing facility is not continuously operated and licensed under these Standards.

I. Health Assessment: An evaluation of the health status of a staff member or volunteer by a physician, other legally authorized healthcare provider, or registered nurse, pursuant to written standing orders and/or protocol approved by a physician's signature.

J. Licensee: The individual, corporation, organization, or public entity that has been issued a license to provide care, treatment, and services at a facility and with whom rests the ultimate responsibility for compliance with this regulation.

K.Live Birth: The complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which after such expulsion or extraction, breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of the voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Heartbeats are to be distinguished from transient cardiac contractions and respirations are to be distinguished from fleeting respiratory efforts or gasps.

L. License: A certificate issued by the Department to the licensee that authorizes the operation of a hospital or institutional general infirmary.

M. Legally Authorized Healthcare Provider: An individual authorized by law and currently licensed in South Carolina to provide specific medical treatments, care, or services to staff members and/or patients, e.g., advanced practice registered nurses, physician assistants.

N.New Facility: A facility which began operation and/or one which began construction or renovation of a building for the purpose of operating the facility after the adoption of these standards.

O.Nurse: A registered nurse, licensed practical nurse, or vocational nurse as those terms are defined by each party state's practice laws.

P. Patient: Any individual who is receiving treatment or services at the facility.

Q.Quarterly: A time period that requires an activity to be performed at least four (4) times a year within intervals ranging from eighty-one to ninety-nine (81 to 99) days.

R.External Medical Surge: Providing medical care services in an area outside of the licensed inpatient hospital building(s). For purposes of External Medical Surge, these locations are called Alternate Care Sites.

S. Internal Medical Surge: An emergency situation when a facility needs to set up and utilize beds beyond its licensed bed capacity in an area within the licensed inpatient facility building(s).

T. Inpatient Dialysis: Dialysis which, because of medical necessity, is furnished to an End-Stage Renal Disease (ESRD) patient on a temporary inpatient basis in a hospital.

U.Emergency Care: The treatment which is usually and customarily available at the respective hospital and that must be provided immediately to sustain a person's life, to prevent serious permanent

disfigurement or loss or impairment of the function of a bodily member or organ, or to provide for the care of a woman in active labor and the infant.

SECTION 200
LICENSE REQUIREMENTS AND FEES

201. License Requirements.

A. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise or market) as a hospital or institutional general infirmary in South Carolina without first obtaining a license from the Department. Admission of patients or the provision of care, treatment, and/or services to patients prior to the effective date of licensure is a violation of S.C. Code Ann. Section 44 7 260(A) (1976, as amended). (I)

B. A license shall be effective for a period of time specified by the Department.

C. A new facility, or one that has not been continuously licensed under these or prior standards, shall not admit patients until permission is granted by the Department.

D. Hospitals that provide services to patients requiring skilled nursing care must maintain a separate license for the areas where the services are provided.

E. Upon receipt of a written request from the hospital authorities to the Department requesting such certification, any general hospital having a current license to operate may be certified as a suitable facility for the performance of abortions. A hospital shall comply with Chapter 41 of Title 44 of the S.C. Code of Laws. (I)

F. Applicants for a license shall file application under oath on a form and frequency specified by the Department. An application shall be signed/authenticated by the owner, if an individual or partnership; or in the case of a corporation, by two of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction over it. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in case his address is different from that of the facility; the names of persons in control thereof and such additional information as the Department may require, including affirmative evidence of ability to comply with reasonable standards, rules and regulations as may be lawfully prescribed. No proposed hospital shall be named nor may an existing hospital have its name changed to the same or similar name as a hospital licensed in the State. Applicants shall make payment of all outstanding fees (initial licensure fees, annual licensure fees, inspection fees, construction fees, etc.) prior to the Department's issuance of a license.

G. Licensing Fees. The initial and annual license fee shall be ten dollars ($10.00) per licensed bed. ~~Annual license fees must also include any outstanding inspection fees. Such fees shall be made payable by check or credit card to the Department~~All fees are non-refundable, and shall be made payable to the Department via a secured portal or specific website.

H. A facility shall request issue of an amended license, by application to the Department prior to any of the following circumstances:

1. Change of ownership by purchase or lease;

2. Change of facility's name;

3. Addition ~~or replacement~~ of beds (an inspection will be required prior to issuance of license);

4. Deletion of beds; ~~or~~

5. Reallocation of types of beds as shown on license~~.~~; or

6. Relocation of a facility.

202. ~~Exceptions~~Variance to Licensing Standards.

~~The Department reserves the right to make exceptions to these standards where it is determined that the health and welfare of the community requires the services of the facility. When an "exception" applies to an existing facility, it will continue to meet the standards in effect at the time it was licensed.~~A variance is an alternative method that ensures the equivalent level of compliance with the standards in this regulation. The Facility may request a variance to this regulation in a format as determined by the Department. Variances shall be considered on a case by case basis by the Department. The Department may revoke issued variances as determined to be appropriate by the Department.

SECTION 300
ENFORCING REGULATIONS AND ENFORCEMENT ACTIONS

301. General.

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

302. Inspections and Investigations.

A. An inspection shall be conducted prior to initial licensing. Inspections shall be conducted as deemed appropriate by the Department. (I)

B. All facilities, proposed facilities, or unlicensed facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by South Carolina Code of Laws. (II)

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records. If photocopies are made for the Department inspector, they shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify individuals in enforcement action proceedings. Physical area of inspections shall be determined by the extent to which there is potential impact or effect upon patients as determined by the inspector. (I)

D. A facility or proposed facility found noncompliant with the standards of this regulation shall submit an acceptable plan of correction to the Department that shall be signed by the administrator and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;

2. The actions taken to prevent recurrences (actual and similar); and

3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the response(s) by the facility or proposed facility, shall be provided to the public upon written request with the redaction of the names of those persons in the report as provided by S.C. Code Ann. Sections 44-7-310 and 44-7-315 (1976, as amended).

F. In accordance with S.C. Code Section 44 7 270, the Department may charge a fee for inspections. The fee for initial and biennial routine inspections shall be four hundred fifty dollars ($450.00) plus ten dollars ($10.00) per licensed bed. The fee for initial unit increase or service modification is two hundred fifty dollars ($250.00) plus ten dollars ($10.00) per licensed bed. The fee for follow up inspections shall be two hundred fifty dollars ($250.00) plus ten dollars ($10.00) per licensed bed.

303. Compliance.

A. A license shall not be issued until the licensee has demonstrated to the Department that the proposed facility is in compliance with the licensing standards. In the event a licensee who already has a facility or activity licensed by the Department makes application for another facility or activity or increase in licensed capacity, the currently licensed facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility or activity or an amended license to the existing facility. Facilities shall comply with applicable State, Federal, and local laws, codes, and regulations. (II)

B. The license is considered property of the Department and may not be duplicated in such a manner that it cannot be distinguished from the original. (II)

C. Any additions or renovations to an existing facility shall be approved by the Department prior to occupancy.

~~***SECTION 400***~~
~~***ENFORCEMENT ACTIONS***~~

~~**401. General.**~~**304. Enforcement Actions**

~~A.~~When the Department determines that a licensee, proposed licensee, or an unlicensed facility owner is in violation of statutory provisions, rules, or regulations relating to the operation of a facility, the Department, upon proper notice to the licensee, may impose a monetary penalty and/or deny, suspend, revoke, or refuse to issue or renew a license.

~~B. Food service permits may be revoked or suspended for violations in accordance with DHEC Regulation 61-25.~~

~~402~~**305. Violation Classifications.**

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health and safety of the persons in the facility or a substantial probability that death or serious physical harm could result there from. A physical condition or one (1) or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. When a specific time is designated for correction, each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health and safety of persons in the facility. The citation of a Class II violation may specify the time within which the violation is required to be corrected. When a specific time is designated for correction, each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation may specify the time within which the violation is required to be corrected. When a specific time is designated for correction, each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

D. Violations of §44-7-320(A)(1)(~~b~~c) ~~and (A)(1)(d)~~ of the South Carolina Code of Laws of 1976, as amended, are considered Class I violations.

E. The notations, "(I)" or "(II)" placed within sections of this regulation, indicate those standards are considered Class I or II violations, respectively, if they are not met. Standards not so annotated are considered Class III violations.

F. In arriving at a decision to take enforcement action, the Department will consider the following factors: the number and classification of violations, including repeat violations; specific conditions and their impact or potential impact on health and safety of the patients; efforts by the facility to correct cited violations; behavior of the licensee that would reflect negatively on the licensee's character, such as illegal or illicit activities; overall conditions of the facility; history of compliance; any other pertinent conditions that may be applicable to statutes and regulations.

G. When a decision is made to impose monetary penalties, the Department may invoke S.C. Code Ann. Section 44-7-320(C) (1976, as amended), to determine the dollar amount or may utilize the following schedule as a guide to determine the dollar amount:

Frequency of Violation of Standard within a 24-month period	**MONETARY PENALTY RANGES**		
	Class I	**Class II**	**Class III**
1st	$ 200-1000	$ 100-500	$ 100
2nd	500-2000	200-1000	100-500
3rd	1000-5000	500-2000	200-1000
4th	5000	1000-5000	500-2000
5th	5000	5000	1000-5000
6th and more	5000	5000	5000

H. In addition to or in lieu of any action taken by the Department affecting the license of any hospital, when it is established that any officer, employee, or member of the hospital medical staff has recklessly violated the provisions of Section ~~1210.A.5~~1201.D.1, the Department may require the hospital to pay a civil penalty of up to ten thousand dollars pursuant to 44-7-260(E).

I. Any Department decision involving the issuance, denial, renewal, suspension, or revocation of a license and/or the imposition of monetary penalties where an enforcement action order has been issued may

be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

SECTION 400
POLICIES AND PROCEDURES

401. General. (II)

A. The Facility shall maintain and adhere to written policies and procedures addressing the manner in which the requirements of this regulation shall be met. The Facility shall develop, implement, and enforce policies and procedures. The Facility shall be in full compliance with the policies and procedures. (II)

B. The Facility shall establish a time period for review of all policies and procedures, and such reviews shall be documented and signed by the Chief Executive Officer. All policies and procedures shall be accessible to Facility staff, printed or electronically, at all times.

402. Quality of Care. (II)

The Facility shall develop, implement, and maintain an effective, ongoing, facility-wide, data-driven quality assessment and performance improvement program. The Facility's governing body shall ensure that the program reflects the complexity of the Facility's organization and services; involves all Facility departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

403. Security. (II)

In order to ensure the safety and well-being of all patients, staff, and visitors, the Facility's governing body (or its designee) shall conduct an annual risk assessment to identify potential areas or situations that may cause harm or where an incident may occur. Based upon the findings of that assessment, the Facility's governing body (or its designee) shall develop and implement a plan to provide for the appropriate level of security necessary.

SECTION 500
STAFF AND TRAINING

501. General.

Every facility shall be organized, equipped, staffed and administered in order that adequate care may be provided for each person admitted.

502. Control. (II)

~~A.The governing body, or the owner, or the person or persons designated by the owner as the governing authority shall be the supreme authority in the hospital responsible for the management control of the hospital and appointment of the medical staff. The governing body will work with the senior managers and leaders of the organized medical staff to annually evaluate the hospital's performance in relation to its mission, vision, and goals.~~ The Facility shall have a governing body which is effective in carrying out its responsibilities for the conduct of the Facility. In the absence of an organized governing body, the Facility shall maintain written documentation that identifies the individual or individuals that are legally responsible for the conduct of the Facility's operations.

~~B.The governing body is ultimately accountable for the safety of patients and staff and the quality of care, treatment, and services provided.~~

~~C.A written set of bylaws for operation of the hospital shall be developed by the governing authority. Committees as determined by the needs and services of the hospital shall be provided. The medical staff shall be accountable to the governing authority for the clinical and scientific work of the hospital.~~

503. Chief Executive Officer.

The Facility shall appoint a Chief Executive Officer (CEO) ~~shall be the administrator of the facility and be selected by the governing body or owner and shall have charge of and be~~who is responsible for the administration of the facility ~~in~~and all its branches and departments ~~and shall see that the bylaws and amendments thereto are complied with~~. The Facility shall notify the Department of ~~A~~any change in the ~~position of the~~ Chief Executive Officer ~~shall be reported immediately by the governing body or owner to the Department~~ in writing within twenty-four (24) hours and shall provide the Department the name of the newly-appointed or interim CEO and effective date of the appointment.

504. Medical Staff Appointment. (II)

A.The ~~hospital~~Facility shall have a medical staff organized in accordance with the facility's by-laws and accountable to the governing body including, but not limited to the quality of professional services provided by individuals with clinical privileges. Prior to a physician's initial appointment and periodic reappointment, the governing body shall assure itself that the physician is qualified and competent to practice in ~~his~~their profession. This organized group shall, with the approval of the hospital governing body, adopt bylaws, rules and regulations to govern its operation as an organized medical staff. ~~Hospital~~Facility bylaws shall contain renewal procedures, authority to limit or terminate staff privileges, and appeal procedures. A hospital is prohibited from using economic criteria unrelated to quality of care or professional competency in determining an individual's qualifications for initial or continuing hospital medical staff membership or privileges. (II)

B.To be eligible for membership on a staff an applicant must be licensed to practice in his profession in the State of South Carolina competent in his respective field, worthy in character and in matters of professional ethics, and meet the requirements of the hospital's bylaws. Medical staff membership must be limited to doctors of medicine or osteopathy by the State Board of Medical Examiners, dentists licensed to practice dentistry by the State Board of Dentistry and podiatrists licensed to practice podiatry by the State Board of Podiatry Examiners. No individual is automatically entitled to membership on the medical staff or to the exercise of any clinical privilege merely because he is licensed to practice in any state, because he is a member of any professional organization, because he is certified by any clinical examining board, or because he has clinical privileges or staff membership at another ~~hospital~~Facility without meeting the criteria for membership established by the governing body of the respective ~~hospital~~Facility.

C.The medical staff, either as a whole or on a department or clinical service basis, shall meet at a frequency as determined by the ~~facilities~~Facility's policies and procedures to review and analyze their clinical experience. Written minutes of such meetings shall be recorded and filed. There shall be mechanisms in place for monitoring and evaluation of the quality of patient care services, for improving services, and for evaluation of the effectiveness of improvement efforts.

D.The governing body may establish categories for membership in the medical staff. These categories for membership shall be identified and defined in the medical staff by-laws, rules, or regulations.

E. In hospitals maintaining organized departments or services~~, such as medicine, surgery, obstetrics, pediatrics, orthopedics, etc.,~~ the medical staff shall elect periodically a chief of staff and staff members to be the responsible heads or chiefs for each department or service, subject to the approval of the governing body. Minutes of all department or service meetings shall be recorded and filed.

F. In compliance with such rules for professional services of resident physicians as the medical staff prescribes, the medical staff shall supervise resident physicians in the diagnosis and treatment of all patients and in the performance of any other professional duties and shall recommend them for approval or disapproval to the governing body and chief executive officer. (II)

G. All persons admitted to any facility covered by these Standards must be under the care of a person ~~duly~~ licensed to practice medicine, dentistry or osteopathy. Patients of podiatrists and dentists who are members of the medical staff of a ~~hospital~~Facility must be co-admitted by a doctor of medicine or osteopathy who is a member of the medical staff of the ~~hospital~~Facility who shall be responsible for the general medical care of the patient. Oral surgeons who have successfully completed a postgraduate program in oral surgery accredited by a nationally recognized accredited body approved by the U.S. Department of Education may admit patients without the requirement of co-admission if permitted by the bylaws of the ~~hospital~~Facility and medical staff. (I)

H. All ~~hospitals~~Facilities shall have a licensed physician available on call at all times. (I)

505. Nursing Services. (II)

A.Nursing Services shall be organized and staffed at all times to provide safe, appropriate, and individualized care to each patient. The authority, responsibility and function of all patient care providers shall be clearly defined by written ~~hospital~~Facility policy and position descriptions.

B.The ~~hospital~~Facility must have an organized nursing service that provides 24-hour nursing services. ~~The nursing services must be furnished or supervised by a registered nurse.~~ This service must be ~~a well organized service of the hospital and~~ under the direction of a Chief Nursing Officer (CNO), who is a ~~single~~ registered nurse. A registered ~~professional~~ nurse shall be designated in writing to act in the~~ir~~ absence of the CNO. ~~Nurses must be currently licensed in the state of South Carolina.~~

C.There shall be a sufficient number of duly licensed registered nurses on duty at all times provide nursing care to meet the needs of the patient population for all areas where nursing care is provided. A registered nurse must be on duty at all times.

D.~~Other~~Facility personnel ~~shall~~may be employed to assist the registered nurse in providing nursing care. Licensed practical nurses and all other workers who are employed by a facility in nursing services shall be assigned based on their education, training, and competency.

E. All personnel who render nursing care services in the ~~hospital~~Facility shall be under the supervision of nursing leadership and shall be subject to all policies and procedures of the facility.

F. All nurses employed in a nursing role in a facility shall be currently licensed to practice in South Carolina or pursuant to the Nurse Licensure Compact.

~~G.A procedure manual that is in accordance with current accepted practices must be readily available to the nursing personnel.~~

506. Employees. (II)

A. The Chief Executive Officer shall designate an individual to conduct Human Resources Management within the organization. That individual, and other individuals as needed, shall have responsibility for hiring, personnel management, compensation and benefits, and maintenance of accurate and complete personnel records.

B. The facility shall develop and make available to the employee a written job description for each type of job in the facility. Each job description shall include a written description of the education, experience, license, certification, or other qualifications required for the position.

C. ~~The licensee shall maintain either personnel records or a data base in accordance with all appropriate state and federal laws.~~ The Facility personnel records shall contain, at a minimum, the following:

1. For clinical personnel, information sufficient to verify the employee's qualifications for the job for which that individual is employed. That information includes, but is not limited to: employee's education, professional certification or licensure status, other training, experience and indication of clinical competence.

2. ~~For nursing personnel, the information shall also include either a copy of the employee's South Carolina nursing license or a multi-state compact license. Applicants shall be hired only after obtaining verification of their license from the South Carolina Board of Nursing or verification of their multi-state license from the appropriate state Board.~~

~~3.~~ For non-clinical personnel, information regarding the employee's education, training, experience and professional competence sufficient to verify the employee's qualifications for the job for which that individual is employed. Such information shall be kept current.

~~4. Current information relative to periodic work performance and/or competences evaluations.~~

~~5~~3. Records of pre-employment health assessment as described in Section 602. ~~screenings and of subsequent health services rendered to the employees as are necessary to determine that all facility employees are physically able to perform the essential duties of their positions.~~

D. ~~The facility shall develop, establish and maintain personnel policies and practices which support sound patient care. The policies shall be in writing and made available to all employees. The policies shall be reviewed periodically but no less than annually and the date of the most recent review shall be indicated on the written policies. A procedure shall be established for notifying employees of changes in the established personnel policies.~~ The Facility must have a written procedure to ensure that nursing personnel, for whom licensure is required, have valid and current licensure.

507. Job Orientation and In-Service Training.

A. Orientation of all new personnel shall be structured to educate them about the organization and environment of the facility, the employees' specific duties and responsibilities, and patients' needs. ~~Each employee shall be familiar with the facility's emergency disaster plans. The hospital must ensure annual training of employees regarding emergency management, including surge policies and procedures and events that would indicate a need to implement surge policies and procedures. This requirement for job orientation may be accomplished through any combination of in-person or online sessions, completion of modules, videos, or other types of training approaches.~~

B. In-service training programs shall be planned and provided for all personnel to ensure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individuals attending. ~~This requirement for in-service training may be accomplished through any combination of in-person or online sessions, completion of modules, videos, or other types of training approaches.~~

C. Either as a component of orientation or in a separate session, all new employees who will have contact with patients or who will handle or potentially handle blood, body fluids or tissue must receive general education regarding infection prevention and control within the hospital.

D. Each employee shall be familiar with the Facility's emergency disaster plan and fire response plans. The hospital must ensure at orientation and annually thereafter that employees receive training regarding emergency management, including surge policies and procedures and events that would indicate a need to implement surge policies and procedures, and fire response.

~~**508. Plans and Training for Fires and Other Internal Emergencies. (II)**~~

~~A. Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire and other emergencies. All employees shall be made familiar with these plans and instructed as to required actions.~~

~~B. Each employee shall receive instructions covering fire protection training.~~

~~C. A fire drill shall be conducted for each shift at least quarterly. Records of drills shall be maintained to report the date, time, shift and a description and evaluation of the drill.~~

~~D. Drills shall be designed and conducted to:~~

~~1. Assure that all personnel are capable of performing assigned tasks or duties;~~

~~2. Assure that all personnel know the location, use and how to operate firefighting equipment;~~

~~3. Assure that all personnel are thoroughly familiar with the fire plan; and~~

~~4. Evaluate the effectiveness of plans and personnel.~~

SECTION 600
EMPLOYEE HEALTH (II)

601. Employee Health Program.

A hospital shall provide an employee health program to support a safe, healthy workplace by providing timely and quality health assessments, prevention services and if needed, intervention strategies. In order to minimize the possibility of contamination and transfer of infection, the employee health program shall include the establishment of policies and monitoring procedures to ensure that all employees are free from communicable infections and open skin lesions.

602. New Employees.

A.To ensure that every person accepted for employment is medically capable of performing the required job duties, a new employee shall be required to satisfactorily pass a health assessment conducted prior to direct patient contact by one of the following:

1. Medical Doctor or Doctor of Osteopathy;

2. Physician Assistant;

3. Nurse Practitioner; or

4. Registered nurse, pursuant to standing orders approved by a physician as required by hospital policy by the physician. The standing orders must be reviewed annually, with a copy maintained at the facility.

B.The health assessment must ensure that all potential hospital employees are evaluated for conditions related to infectious diseases that may have an impact on patient care, the employee, or other healthcare workers. Based upon recommendations of the CDC's Advisory Committee on Immunization Practices (ACIP) for immunization of healthcare personnel, as listed in the CDC Guideline for infection control in healthcare personnel (1998) and as amended, this evaluation must include:

1. Medical history, including immunization status and assessment for conditions that may predispose the person to acquiring or transmitting communicable diseases;

2. Tuberculosis screening, which is performed in a manner prescribed in the CDC and the Department's most current tuberculosis guidelines; and

3. Serologic screening for vaccine-preventable diseases, as deemed appropriate by the hospital.

C.The hospital must provide evidence of education of employees about influenza vaccination and must offer the influenza vaccine to these persons.

D.Employee health programs must provide evidence of ongoing review and monitoring of both CDC and the Department recommendations and updates and methods for revising the programs as needed.

603. Employee Records.

A.All employee health records, including any medical history, shall be retained in a separate and confidential file in Employee Health. Access to these records will be permitted only to those authorized through hospital policy.

B.The hospital shall have policies and procedures for the maintenance and destruction of employee health records after employment has been terminated.

604. Volunteer Workers. (II)

A.All volunteer workers who handle food or provide patient care shall have a physical examination prior to their initial food handling or patient care activity.

B.For patient care volunteers, the tuberculin testing and treatment program described in Section 602.B also applies.

REPORTING (II)

701. ~~Fire Report.~~

~~The Department shall be notified immediately regarding any fire, regardless of size or damage that occurs in the facility, and followed by a complete written report to include fire department reports, if any, to be submitted within a time period determined by the facility, but not to exceed 7 business days.~~

~~702. Accident and/or~~ Incident Report<u>s</u>.

A. <u>The Facility shall document every incident, and include an incident review, investigation, and evaluation as well as corrective action taken, if any. The Facility shall retain all documented incidents reported pursuant to this section for six (6) years after the Patient involved is last discharged. For the first year following discharge, these records shall be kept on site and readily available at that Facility.</u>

B. ~~A record of each accident and/or~~<u>The Facility shall report the following types of incidents</u> ~~occurring in the facility, including serious medication errors and adverse drug reactions, shall be retained~~<u>to the Department and the patient's responsible party, sponsor, or emergency contact within twenty-four (24) hours of the incident. The Facility shall notify the Department via the Department's electronic reporting system or as otherwise determined by the Department</u>. ~~Incidents resulting in death or serious injury shall be reported, in writing, to the Department within 10 days of the occurrence. Information included in a facilities' report that is acquired from a peer review committee shall maintain its privilege pursuant to S.C. Code of Laws Sections 40-71-20, 44-30-60, and 44-7-315. However, the duty of hospitals to report serious accidents and incidents is not affected by any privilege or confidentiality.~~ The following incidents~~, including but not limited to those stated,~~ shall be reported:

1. ~~Suicides.~~

~~2. Wrong site surgery.~~

~~3. Medication errors resulting in death or serious injury.~~

~~4. Major fractures or head injuries resulting from falls or other events.~~

~~5. Patient death or serious injury resulting from being in a restraint.~~

~~6. Criminal events and assaults.~~

~~7. Transfusion errors.~~

~~8. Neonatal injuries.~~

~~9. Maternal deaths or injuries.~~

~~10. Elopement events.~~

~~11. Anesthesia-related events resulting in death or serious injury.~~

~~12. Ventilator errors resulting in death or serious injury.~~

~~13. Infant abductions.~~ <u>Surgical or Invasive Procedure Events.</u>

a. Surgery or other invasive procedure performed on the wrong site;

b. Surgery or other invasive procedure performed on the wrong patient;

c. Wrong surgical or other invasive procedure performed on a patient;

d. Unintended retention of a foreign object in a patient after surgery or other invasive procedure; and

e. Intraoperative or immediately postoperative/postprocedure death in an American Society of Anesthesiologists (ASA) Class 1 patient.

2. Product or Device Events.

a. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting.

b. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended; and

c. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting.

3. Patient Protection Events.

a. Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person;

b. Patient death or serious injury associated with patient elopement (disappearance); and

c. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting.

4. Care Management Events.

a. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration);

b. Patient death or serious injury associated with unsafe administration of blood products;

c. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting;

d. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy;

e. Patient death or serious injury associated with a fall while being cared for in a healthcare setting;

f. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting;

g. Artificial insemination with the wrong donor sperm or wrong egg;

h. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen; and

i. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.

5. Environmental Events.

a. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting;

b. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances;

c. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting; and

d. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting.

6. Radiologic Events.

a. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area.

7. Potential Criminal Events.

a. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider;

b. Abduction of a patient of any age;

c. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting; and

d. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting.

~~B~~C. The Facility shall submit a separate written investigation report within five (5) calendar days of every incident required to be reported to the Department pursuant to Section 701.B via the Department's electronic reporting system or as otherwise determined by the Department. Reports submitted to the Department shall contain at a minimum: facility name, patient age and sex, date of incident, location, witness names, extent and type of injury and how treated, *e.g.*, hospitalization, identified cause of incident, internal investigation results if cause unknown, identity of other agencies notified of incident and the date of the report.

702. Loss of Essential Services.

Should a facility experience a loss of an essential service such as cooling, potable water, or electrical power, the facility shall notify the Department by email to HQEP@dhec.sc.gov or other email address prescribed by the Department after ensuring the safety of the patients, but not to exceed twenty-four (24) hours from the loss of service.

703. Facility Closure.

A. Prior to the permanent closure of a facility, the Department shall be notified in writing of the intent to close and the effective closure date. Within 10 days of the closure, the facility shall notify the Department of the provisions for the maintenance of the records, the identification of displaced patients, the relocated site, and the dates and amounts of patient refunds. On the date of closure, the license shall be returned to Department.

B. In instances where a facility temporarily closes, the Department shall be given written notice within a reasonable time in advance of closure. At a minimum this notification shall include, but not be limited to: the reason for the temporary closure, the location where the patients have been/will be transferred, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards of the facility prior to its reopening. If the facility is closed for a period longer than one year, and there is a desire to re-open, the facility shall ~~re-apply to the Department for licensure and shall~~ be subject to all licensing requirements ~~at the time of that application,~~prior to reopening, including construction-related requirements for a new facility.

704. Zero Census.

In instances when there have been no patients in a facility for any reason for a period of ninety (90) calendar days or more, the ~~f~~Facility shall notify the Department in writing that there have been no admissions, no later than the hundredth (100th) day following the date of departure of the last active patient. At the time of that notification, the Department shall consider, upon appropriate review of the situation, the necessity of inspecting the ~~f~~Facility prior to any new and/or re-admissions to the ~~f~~Facility. If the ~~f~~Facility has no patients for a period longer than one year, and there is a desire to admit a patient, the ~~f~~Facility ~~shall re-apply to the Department for licensure and~~ shall be subject to all licensing requirements ~~at the time of that application~~prior to admission of a patient, including construction-related requirements for a new facility.

705. Joint Annual Report.

~~The Department requires each health care facility to annually complete a questionnaire named~~The Facility shall submit a "Joint Annual Report" ~~and return this report within the time period~~ as specified ~~in the report's accompanying cover letter~~ by the Department.

706. Hospital Infections Disclosure Act (HIDA) & Reporting Requirements. (I)

~~A hospital~~The Facility ~~is required to~~shall collect data and submit reports to the Department on hospital acquired infection rates and methods and adequacy of selected infection control process ~~to be in compliance with~~pursuant to S.C. Code of Laws Sections 44-7-2410 through 44-7-2460. ~~Hospitals are also required to report methods and adequacy of selected infection control processes. The Department will notify hospitals annually about the current HIDA reporting requirements and the methods for submitting those reports to the Department.~~

SECTION 800
REQUIREMENTS OF THE LEWIS BLACKMAN ACT (I)

801. Compliance.

In order to be in compliance with The Lewis Blackman Hospital Patient Safety Act, hospitals are required to:

A. Identify all clinical staff, clinical trainees, medical students, interns, and resident physicians as such with identification badges that include their names, their departments, and their job or trainee titles.

B. Institute a procedure whereby a patient may request that a nurse call his or her attending physician regarding the patient's personal medical care.

C. If the patient is able to communicate with and desires to call his or her attending physician or designee, upon the patient's request, the nurse must provide the patient with the telephone number and assist the patient in placing the call.

D. Provide a mechanism, available at all times, and the method for accessing it, through which a patient may access prompt assistance for the resolution of the patient's personal medical care concerns.

E. Establish procedures for the implementation of the mechanism providing for initiation of contact with administrative or supervisory clinical staff who shall promptly assess the urgent patient care concern and cause the patient care concern to be addressed.

F. Provide to each patient prior to, or at the time of the patient's admission to the hospital for inpatient care or outpatient surgery, written information describing the general role of clinical trainees, medical students, interns, and resident physicians in patient care.

SECTION 900
~~*DISASTER MANAGEMENT(II)*~~ *EMERGENCY PREPAREDNESS*

901. ~~Emergency Evacuation~~ All-Hazards Emergency Operations Plan. (II)

A. All facilities shall develop, implement, and maintain~~by contact and consultation with their county emergency preparedness agency,~~ a ~~suitable~~ written all-hazards emergency operations plan for actions to be taken in the event of a disaster and/or emergency evacuation. ~~In the event of mass casualties, the facility shall provide resources as available.~~ Additionally, in instances where there are applications for increases in licensed bed capacity~~,~~ or a change in ownership, the emergency ~~evacuation~~ plan shall be updated to reflect the proposed new total licensed bed capacity and/or change in ownership. The Facility shall review the plan ~~shall be updated, as appropriate,~~at least annually~~, or as needed~~.

B. ~~Each facility shall maintain a means of communication with their local emergency management agency that is capable of transmitting information and/or data during periods when normal communication systems are inoperable. The facility shall also maintain a back-up system. Both systems shall be exercised periodically.~~The all-hazards emergency operations plan shall include, but not be limited to:

1. A sheltering plan to include:

a. Name, address, and phone number of the sheltering facility(ies) to which patients will be relocated during a disaster; and

b. A letter of agreement signed by an authorized representative of each sheltering facility, which shall include: the number of relocated patients that can be accommodated; sleeping, feeding, and medication plans for the relocated patients; and provisions for accommodating relocated staff members. The letter shall be updated with the sheltering facility at least every three (3) years and whenever significant changes occur. For those facilities located in Beaufort, Berkeley, Charleston, Colleton, Dorchester, Georgetown, Horry, and Jasper counties, at least one (1) sheltering facility shall be located in a county other than these counties.

2. A transportation plan, to include letter of agreement signed by an authorized representative with each entity for relocating patients, which addresses:

a. The relocation needs of the patients and staff contingent upon the type of disaster/emergency confronted;

b. Procedures for providing appropriate medical support, food, water and medications during relocation based on the needs and number of the patients; and

c. Estimated time to accomplish the relocation during normal conditions.

3. A staffing plan for the relocated patients, to include:

a. How care will be provided to the relocated patients, including facility staff members that will accompany patients who are relocated;

b. Prearranged transportation arrangements to ensure staff members are relocated to the sheltering facility; and

c. Co-signed statement by an authorized representative of the sheltering facility if staffing, bedding, or medical supplies that are to be provided by the sheltering facility.

C. ~~Each facility shall operate under an incident command system that is in compliance with FEMA's National Incident Management System (NIMS), and the Hospital Incident Command System (HICS).~~ The Facility shall maintain written acknowledgement from the local county emergency management agency of such agency's receipt of the Facility's all-hazards emergency operations plan.

D. ~~Annually, prior to June 1st of each year, each facility shall validate/provide the Department the information required by the Department's Critical Data Sheet (CDS) Information system. Hospital data provided to the CDS system will assist the Department, during times of disaster and emergencies, determine the appropriateness of evacuation or shelter-in-place. The disaster/emergency evacuation plan shall include, but not be limited to:~~

~~1. A sheltering plan to include:~~

~~a. Name, address and phone number of the sheltering facility(ies) to which the patients will be relocated during a disaster; and~~

~~b. A letter of agreement signed by an authorized representative of each sheltering facility which shall include: the number of relocated patients that can be accommodated; sleeping, feeding, and medication plans for the relocated patients; and provisions for accommodating relocated staff members. The letter shall~~

~~be updated with the sheltering facility at least every three (3) years and whenever significant changes occur. For those facilities located in Beaufort, Charleston, Colleton, Horry, Jasper, and Georgetown counties, at least one (1) sheltering facility shall be located in a county other than these counties.~~

~~2. A transportation plan, to include agreements with entities for relocating patients, which addresses:~~

~~a. The relocation needs of the patients and staff contingent upon the type of disaster/emergency confronted;~~

~~b. Procedures for providing appropriate medical support, food, water and medications during relocation based on the needs and number of the patients;~~

~~c. Estimated time to accomplish the relocation during normal conditions; and~~

~~d. Primary and secondary routes to be taken to the sheltering facility.~~

~~3. A staffing plan for the relocated patients, to include:~~

~~a. How care will be provided to the relocated patients, including facility staff members that will accompany patients who are relocated;~~

~~b. Prearranged transportation arrangements to ensure staff members are relocated to the sheltering facility; and~~

~~c. Co-signed statement by an authorized representative of the sheltering facility if staffing, bedding, or medical supplies are to be provided by the sheltering facility.~~ Facilities annually, prior to June 1st of each year, shall:

1. Validate/provide the information required by the Department's Critical Data Sheet (CDS); and

2. Submit a shelter-in-place plan in a format determined by the Department, if the Facility may seek to shelter-in-place during an emergency evacuation.

E. Within 30 days prior to the renewal of its license, ~~Each~~the facility shall ~~validate/~~provide ~~the Department~~ the information required for the Department's Emergency Evacuation Plan Summary ~~in Section 901.D. no less than annually~~. Submission of this information will be in a format determined by the Department.

F. Each Facility shall maintain a means of primary and secondary communication with their local county emergency management agency that is capable of transmitting information and/or data during periods when normal communication systems are inoperable. The Facility shall also maintain a back-up system. Both systems shall be tested periodically.

902. Internal Medical Surge.

A. ~~It is the responsibility of the facility to know what areas are within the licensed inpatient building(s). If a hospital needs to set up and utilize beds in an area outside of the licensed inpatient hospital building(s), it must follow Section 903 of this regulation.~~

~~B.~~ A facility desiring to activate internal medical surge and temporarily admit patients in excess of licensed bed capacity due to an emergency shall provide written notification to the Department upon prescribed forms that include the following information ~~should do the following~~:

1. ~~Request that the Department concur that an~~A description of the emergency situation ~~exists.~~;

2. ~~During the call to the Department, facility should be prepared to:~~

~~a. Describe the emergency situation;~~

~~b.~~ An ~~O~~outline of the maximum number of patients to be ~~temporarily~~ admitted;

~~c. Provide an anticipated date for discharge of the temporary patients; and~~

~~d. Describe how and where the temporary patients will be housed.~~

3. ~~Patients temporarily admitted during the emergency situation will not be required to undergo tuberculin screening or submit to an admission history and physical examination.~~An anticipated date of discharge of the patients; and

4. ~~The facility must notify the Department when the patient census has returned to, or moves below, normal bed capacity by discharge or transfer to licensed beds~~A description of how and where the patients will be housed.

B. The Facility must notify the Department in writing when the Facility has deactivated its internal medical surge and its patient census has returned to within the Facility's licensed bed capacity.

C. If the event occurs after normal business hours, the Department must be contacted promptly during the next business day.

D. Other issues, such as staffing for the care of the temporary patients, physicians' orders, additional food for the temporary patients and handling of medications, ~~should~~shall be resolved ahead of time by memorandum of agreements, internal policies and procedures, and emergency planning documents.

903. External Medical Surge.

A. Some emergency situations might overwhelm a ~~hospital's~~Facility's plans for Internal Medical Surge or render the licensed inpatient hospital building(s) unusable. In such situations, a ~~hospital~~Facility may activate External Medical Surge and operate an Alternate Care Site (ACS) under the authority of its license during an emergency situation such as a mass casualty event or ~~f~~Facility evacuation. To activate an ACS, the Facility's census must be projected to surge beyond its planned Internal Medical Surge capacity or the Facility's main building, or a portion of the building, must be rendered unusable.

B. If a ~~hospital~~Facility desires to be approved to operate an ACS, the ~~hospital~~Facility ~~must contact the Department for current requirements and guidance in planning~~ shall~~.~~:

1. ~~In order to facilitate activation of an ACS, hospitals are advised to~~ ~~c~~Conduct an assessment of the proposed ACS location utilizing the Department's Alternate Care Site Preliminary Assessment Form. ~~The Department will not authorize activation of an ACS until the hospital has provided assessment information.~~ Every ACS shall be planned, designed, and equipped to provide adequate accommodations for the care, safety, and treatment of each patient. Buildings selected for ACS should comply with the local building

codes and ordinances applicable to the buildings' original intended use. It is the ~~hospital's~~Facility's responsibility to use the assessment process to assure that an ACS building is in compliance with local codes and has the structural soundness and capacity to provide patient treatment contemplated by the ~~hospital~~Facility.

~~2. The Social Security Act contains a provision that allows an emergency waiver of the Emergency Medical Treatment and Active Labor Act (EMTALA) requirements that hospitals accept certain patients until stabilized. See 42 U.S.C. Section 1320b-5. In order for South Carolina hospitals with an ACS to qualify for these waiver provisions, hospitals should provide documentation from the DHEC Regional Public Health Preparedness Director that the ACS location can be identified as an alternative location for the direction or relocation of individuals to receive medical screenings under a State emergency and pandemic preparedness plans.~~

~~3.~~ Once a location has been identified, the Department will meet with ~~hospital~~Facility staff to discuss the details of the ACS. When appropriate, the Department will send ~~the requesting hospital a letter confirming~~written confirmation that the location has been ~~identified~~approved for future use as an ACS. The location will retain its status as an ACS unless modifications are made to the site. Modifications that might affect the use of an ACS include, but are not limited to, renovations, construction, demolition, or change of ownership. Any modifications to the site should be reported in writing to the Department. ~~Because changes to a site could affect its use as an ACS, hospitals are encouraged to construe the term "modifications" broadly.~~

C. ~~Alternate Care Sites can only be operated during emergency situations and activation must be coordinated with the Department. To activate an ACS, the hospital's census must be projected to surge beyond its Internal Medical Surge capacity or the hospital's main building, or a portion of the building, must be rendered unusable.~~

~~D. A facility desiring to activate External Medical Surge and activate an~~Prior to activating an Alternate Care Site~~, due to an emergency situation~~the Facility shall do the following:

1. ~~Request that the Department concur that an emergency situation does exist.~~Have prior approval of the ACS from the Department as described in Section 903.B; and

2. ~~As part of the activation process, the hospital shall be prepared to~~Provide the following information to the Department:

a. Describe the emergency situation;

b. Explain why activating Internal Medical Surge will not address the situation;

c. Identify the ACS;

d. Outline the maximum number of patients to be treated at the ACS; and

e. Provide an anticipated date for discontinuance of the ACS.

~~E. Immediately following activation with the Department, the hospital~~Facility ~~shall notify the DHEC Regional Emergency Point of Contact for possible coordination of activities under State emergency, pandemic preparedness, or mass casualty response plans.~~

~~F~~D. After the emergency situation is over, the ~~hospital~~Facility must notify the Department in writing when the ACS is ~~closed~~being deactivated.

~~G~~E. Other issues such as staffing, food service, equipment requirements, medication management, medical records, and physicians' orders ~~should~~shall be resolved ~~ahead of time~~prior to activation by memorandum of agreements, internal policies and procedures, and emergency planning documents.

904. Emergency Call Data. (I)

Emergency call information shall be immediately available to personnel ~~in charge~~ on each unit when needed. Emergency call data shall include at least the following information:

A. Non emergency telephone numbers of fire and police departments;

B. Name, address, and telephone number of all personnel to be called in case of fire or emergency;

C. Name, address, and telephone number of physician on call;

D. Name, address, and telephone number of supervisory personnel when on call; and

E. Address and telephone number of a poison control center.

~~**905. Security.**~~

~~In order to assure the safety and well-being of all patients, staff, and visitors, the administration shall conduct an annual risk assessment to identify potential areas or situations that may cause harm or where an incident may occur. Based upon the findings of that assessment, the administration shall develop and implement a plan to provide for the appropriate level of security necessary.~~

SECTION 1000
ACCOMMODATIONS FOR PATIENTS (II)

1001. Maximum Number of Beds

A. No facility shall have set up or in use at any time more beds than the number stated on the face of the license except in cases of justified emergencies. The following categories of beds are not chargeable to the licensed number:

1. Labor room;

2. Newborn nursery;

3. Recovery room;

4. Emergency room treatment;

5. Classroom use only.

B. Neonatal special care beds will be shown on the face of the license in addition to the licensed bed capacity.

C. The Facility shall have the capability to set up the number of beds stated on the face of its license.

1002. Location of Beds.

A.In semi-private and multi-bed rooms there shall be curtains or other means of providing privacy that completely shield the patient.

B.Beds, gurneys, recliners, chairs or other similar furniture shall not be placed in corridors, solaria or other locations not designed as patient room areas except in cases of justified emergencies.

SECTION 1100
MEDICAL RECORDS (II)

1101. Physician's Responsibility.

It shall be the responsibility of each physician to complete and authenticate the medical record within a stipulated time after discharge, not to exceed 30 days after discharge.

1102. Organization.

The responsibility for supervision, filing, indexing, maintenance and storage of medical records shall be assigned to a responsible employee of the hospital who has had training in this field.

1103. Indexing.

Medical records shall be properly indexed, organized, filed and ready for access by members of the staff.

1104. Ownership.

Medical records of patients are the property of the organization and must not be released from the hospital's authority or control except by court order.

1105. Contents.

A.Each entry in the medical records must be legible, dated, timed and signed/authenticated by the clinician or designee that created the entry. A medical record must be created for all patients admitted to the hospital and newborns delivered in the hospital. Initials will be accepted provided such initials can be readily identified within the medical record. A minimum medical record shall include the following information:

1. An admission record must be prepared for each patient and must contain the following information, when obtainable: Name; address, including county; ~~occupation;~~ age; date of birth; sex; marital status; religion; ~~county of birth; father's name; mother's maiden name; husband's or wife's name; dates of military service;~~ health insurance number; provisional diagnosis; case number; days of care; social security number; ~~the name of the person providing information;~~ name~~, address~~ and telephone number of person or persons to be notified in the event of emergency; name ~~and address~~ of referring physician; name ~~and address and telephone number~~ of attending physician; date and hour of admission;

2. History and physical within 48 hours after admission;

3. Provisional or working diagnosis;

4. Pre-operative diagnosis;

5. Plan of care;

6. Complete surgical record, if any, including technique of operation and findings, statement of tissue and organs removed and post-operative diagnosis;

7. Report of anesthesia;

8. Nurses' notes;

9. Progress notes;

10. Gross pathological findings and microscopic, if applicable;

11. Vital signs and other measurements appropriate to patient;

12. Medication Administration Record or similar document for recording of medications, treatments and other pertinent data. This record shall be signed/authenticated after each medication administered or treatment is rendered;

13. Final diagnosis and discharge summary, including date and time of discharge;

14. ~~Date and time of discharge summary;~~

~~15.~~ In case of death, cause and autopsy findings, if autopsy is performed, unless the death becomes subject to review by the coroner's office, and;

1~~6~~5. Special examinations, if any, e.g., consultations, clinical laboratory, x-ray and other examinations.

B. Contingent upon the availability of pertinent information in the perinatal records of the mother, newborn records should include the following:

1. History of hereditary conditions in mother's and/or father's family;

2. First day of the last menstrual period (L.M.P.) and estimated day of confinement (E.D.C.);

3. Mother's blood group and RH type - evidence of sensitization and/or immunization (such as, administration of anti-D hyperimmune globulin);

4. Serological test including dates performed for syphilis, HIV, Rubella, and Hepatitis B, results of any other tests performed during pregnancy (e.g., Group B Strep, Chlamydia, Gonorrhea, Herpes);

5. ~~Number, duration and outcome of previous pregnancies, with dates;~~

~~6.~~ Maternal disease (e.g., diabetes, hypertension, pre-eclampsia, infections);

~~7~~6. Drugs taken during pregnancy, labor and delivery;

~~8~~7. Results of measurements of fetal maturity and well-being (e.g., lung maturity and ultrasonography);

~~9~~8. Duration of ruptured membranes and labor, including length of second stage;

~~10~~9. Method of delivery, including indications for operative or instrumental interference;

~~11~~10. Complications of labor and delivery (e.g., hemorrhage or evidence of fetal distress), including a representative strip of the fetal ECG if recorded;

~~12~~11. Description of placenta at delivery, including number of umbilical vessels;

~~13~~12. Estimated amount and description of amniotic fluid;

~~14~~13. Apgar scores at one and five minutes of age. Description of resuscitations, if required, detailed description of abnormalities and problems occurring from birth until transfer to the special nursery or the referral facility;

~~15~~14. Results and date specimen was collected for neonatal testing to detect inborn metabolic errors and hemoglobinopathies, including PKU, hypothyroidism and various other metabolic disorders. Exception: Parents may object because of religious grounds only, and in writing using a form promulgated by the Department; and

~~16~~15. Results and dates of pulse oximetry screening and/or follow up of evaluation for critical congenital heart defects.

Exception: Parents may object only in writing to the screening for reason pertaining to religious beliefs.

C. When restraints are utilized, there must be an order to include length of time to be used and signed/ authenticated by the legally authorized healthcare provider approving use of restraint or seclusion either at the time they are applied to a patient, or in case of emergency, within 24 hours after they have been applied. Each procedure manual shall contain information and instructions on the specific types of safety precautions that may or may not be used.

1106. Orders for Medication and Treatment.

All medical records shall contain the necessary consent forms for the treatment provided, along with orders for medication and treatment, signed/authenticated and dated by the prescriber or his designee. All orders, including verbal orders, shall be properly recorded in the medical record, dated and signed/authenticated by the prescriber within 30 days.

1107. Storage.

A. Provisions shall be made by the hospital for the storage of medical records in an environment which will prevent unauthorized access and deterioration. The records shall be treated as confidential and shall not be disposed of before 10 years. Records may be destroyed after 10 years provided that:

1. Records of minors must be retained until after the expiration of the period of election following achievement of majority as prescribed by statute; and

2. The hospital retains a register, either electronic or paper based.

B. Facilities that store records in a format other than paper, such as, but not limited to, microfilm, before 10 years have expired must include the entire record.

C. In the event of change of ownership, all medical records shall be transferred to the new owners.

D. Prior to the closing of a hospital for any reason, the facility shall arrange for preservation of records to ensure compliance with these regulations. The facility shall notify the Department, in writing, describing these arrangements.

1108. Information to be Provided to Other Health Care Providers.

In order to contribute to the continuity of quality of care, procedures must be established and implemented to provide discharge summaries and/or other appropriate information to health care providers to whom patients are discharged, transferred or referred.

1109. Maintenance and Disposal.

Records shall be maintained and disposed of as specified in Section 1107.

1110. Access to Medical Records.

Only authorized personnel should have access to medical records and a hospital shall have policies and procedures to assure that a patient's protected health information is private. The patient shall have access to his/her clinical records within a reasonable timeframe and a hospital shall have a process in place to facilitate that access if requested.

SECTION 1200
PATIENT CARE AND SERVICES

1201. ~~Medications.~~ Basic Facility Functions. (I)

~~A.~~**A. Pharmaceutical Services.**

~~Drugs and biologicals must be prepared and administered in accordance with the orders of the legally authorized healthcare provider(s) responsible for the patient's care as specified under the hospital's governing body as it pertains to the care of the patient. All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with approved medical staff policies and procedures.~~The Facility must have pharmaceutical services that meet the needs of the patients. The Facility must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the Facility's organized pharmaceutical service.

1. Pharmacy management and administration. The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

a. A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

b. The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

c. Current and accurate records must be kept of the receipt and disposition of all drugs.

2. Delivery of services. In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

a. All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

b. All drugs and biologicals must be kept in a secure area and locked when appropriate.

c. Drugs listed in Schedules II, III, IV, and V of the State and Federal controlled substances laws must be kept locked within a secure area.

d. Only authorized personnel may have access to locked areas.

e. Outdated, discontinued, mislabeled, or otherwise unusable drugs and biologicals shall not be available for patient use and shall be returned to the pharmacy for proper disposition in accordance with good pharmaceutical practice and facility policy.

f. Multi-dose vials shall be labeled with the date and time when opened or the date and time the vial should expire, as defined by facility policy and/or manufacture guidelines, whichever timeframe is shorter.

g. When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

h. Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

i. Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program.

j. Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

k. Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

~~B~~ 3. Student nurses may only administer medications under the direct supervision of a registered nurse who is the student's instructor and/or preceptor. The medical record must be signed/authenticated by both parties.

~~C~~ 4. Self-administration of medications by patients may be permitted only when specifically ordered by the legally authorized healthcare provider in writing and the medications have been reviewed by a Registered Pharmacist prior to administration.

~~D~~ 5. Medication variances and adverse drug reactions shall be reported immediately to the prescriber, supervising nurse and pharmacist, and recorded in the patient's medical record.

B. Radiological Services.

The Facility must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, the therapeutic services and diagnostic services must meet professionally approved standards for safety and personnel qualifications.

1. The Facility must maintain, or have available, radiologic services according to needs of the patients.

2. The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

a. Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

b. Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

c. Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

d. Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

3. Personnel must adhere to the following:

a. A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

b. Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

4. Records of radiologic services must be maintained.

a. The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

b. The Facility must maintain the following for at least 5 years:

i. Copies of reports and printouts.

ii. Films, scans, and other image records, as appropriate.

~~1202~~C. Laboratory Services. ~~(H)~~

A.Organization:

1. The hospital must have laboratory services available, either on site or through a contractual agreement with a certified laboratory, whose services are provided in accordance with Clinical Laboratory Improvement Amendments (CLIA) requirements and possess a current CLIA certificate.

2. The laboratory shall be under the supervision of a laboratory director with training in clinical laboratory procedures.

3. Laboratory personnel shall be qualified by education, training and experience for the type of services rendered.

B.The laboratory shall:

1. Have appropriate and sufficient equipment, instruments, reagents, materials and supplies for the type and volume of testing performed.

2. Ensure the quality of testing through monitoring of analytical performance, quality control, proficiency testing and quality improvement activities and as defined by CLIA regulations.

3. Include safety procedures, engineering controls and personal protective equipment readily available, maintained, inspected and utilized to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

4. Include records and materials maintained and stored under conditions that ensure proper preservation.

5. Include a procedure manual for the complete collections and handling instructions for all laboratory specimens, and there must be documentation of an annual review.

6. Perform proficiency testing and have written procedures sufficient for the extent and complexity of testing performed in the laboratory.

7. Have a clearly defined policy and procedure outlining ongoing monitoring of analytical performance, including:

a. Number and frequency of controls,

b. Tolerance limits and,

c. Corrective actions based on quality control data.

8. The following clinical laboratory services must be available twenty-four (24) hours a day:

a. Chromosome analysis;

b. Viral Culture; and

c. Emergency laboratory services must be available either on-site or via contractual agreement twenty-four (24) hours per day, seven (7) days a week.

~~C.The laboratory must be constructed, arranged and maintained to ensure adequate and safe space, ventilation and utilities necessary for all phases of the testing and to minimize contamination.~~

~~D.The governing body shall approve the pathologist or physician as physician in charge or Medical Director of blood bank and transfusion services.~~

~~E.Hospitals which provide procurement, storage and transfusion of blood shall have acceptable facilities, including a refrigerator, for whole blood. The temperature shall be maintained at 2 to 6 degrees C. or 36 to 43 degrees F., and no foods may be kept in this refrigerator. Standards of the American Association of Blood Banks, as outlined in the most current edition of Standards for a Blood Transfusion Service, will be used as a guide for licensing purposes.~~

~~F. Records shall be kept on file indicating the receipt and disposition of all blood handled. Care shall be taken to ascertain that blood administered has not exceeded its expiration date, and meets all criteria for safe administration.~~

~~G.The facility shall make arrangements to secure on short notice all necessary supplies of blood, typed, and crossmatched as required, for emergencies.~~

The Facility must maintain, or have available, adequate laboratory services to meet the needs of its patients. The Facility must ensure that all laboratory services are provided in accordance with Clinical Laboratory Improvement Act (CLIA) requirements.

1. The Facility must have laboratory services available, either directly or through a contractual agreement with a CLIA-certified laboratory.

2. Emergency laboratory services must be available 24 hours a day.

3. A written description of services provided must be available to the medical staff.

4. The laboratory must make provision for proper receipt and reporting of tissue specimens.

5. The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

6. The Facility must maintain:

a. Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and

b. A fully funded plan to transfer these records to another Facility or other entity if such Facility ceases operation for any reason.

D. Emergency Services.

1. No person, regardless of his ability to pay or county of residence, may be denied emergency care if a member of the admitting hospital's medical staff or, in the case of a transfer, a member of the accepting hospital's medical staff determines that the person is in need of emergency care.

2. Hospitals that do not offer Obstetrical services shall have readily available in the emergency department a precipitous delivery kit, to include at a minimum: bulb suction syringe, cord clamp, scissors, sterile towels, and emergency telephone numbers for the appropriate Regional Perinatal Center.

3. If the care required for any patient is not available at the hospital, arrangements must be made for transfer to a more appropriate hospital. Prior to the transfer of a patient to another hospital, the receiving hospital shall be notified of the impending transfer.

4. On its initial and renewal licensure applications, each hospital shall classify itself to indicate its capability in providing emergency care. Such classification will be for the hospital's on-campus emergency service and, if applicable, its off-campus emergency service. General Hospitals shall be classified as a Type I, II, or III. Specialized Hospitals shall be classified as a Type I, II, III, or IV.

a. Type I means a hospital that offers comprehensive emergency care 24 hours per day, with at least one physician experienced in emergency care on duty in the emergency care area. There is in-hospital physician coverage by members of the medical staff or by senior-level residents for at least medical, surgical, orthopedic, obstetric/gynecologic, pediatric, and anesthesia services. Other specialty consultation is available within approximately 30 minutes.

b. Type II means a hospital that offers emergency care 24 hours per day, with at least one physician experienced in emergency care on duty in the emergency care area. Specialty consultation is available within 30 minutes by members of the medical staff or senior-level residents. The hospital's scope of services includes in-house capabilities for managing physical and related emotion problems, with provision for patient transfer to another organization when needed.

c. Type III means a hospital that offers emergency care 24 hours per day, with at least one physician available to the emergency care area within 30 minutes through a medical staff call roster. Specialty consultation is available by request of the attending medical staff member or by transfer to a designated hospital where definitive care can be provided.

d. Type IV means a hospital that offers reasonable care in determining whether an emergency exists, renders lifesaving first aid, and makes appropriate referral to the nearest organization that is capable of providing needed services. Type IV Hospitals do not represent or hold themselves out to the public as offering emergency care 24 hours per day. The mechanism for providing physician coverage at all times is defined by the medical staff.

5. A hospital licensed in South Carolina may open and operate freestanding emergency services within a 35-mile radius of its hospital campus. This freestanding emergency service shall be an extension of the existing hospital's on-campus emergency service.

6. For Types I, II, and III, the emergency service entrance shall be separated from the main entrance, well-marked and illuminated, easily accessible from the street and sufficiently covered or enclosed to protect ambulance patients from the elements during the unloading process.

7. For Types I, II, and III, the hospital shall post rosters designating medical staff members on duty or on call for primary coverage and specialty consultation in the emergency care area.

8. For Type IV, hospitals shall provide physician and registered nurse coverage 24 hours per day. Nursing and other allied health professionals shall be readily available in the hospital. Staff may have collateral duties elsewhere in the hospital, but must be able to respond when needed without adversely affecting patient care or treatment elsewhere in the hospital. Type IV hospitals shall have trained staff to

triage emergency care for each patient, staff, and visitor, to stabilize the presenting condition, and transfer to an appropriately licensed facility. Type IV hospitals must have an emergency area which includes a treatment room, storage for supplies and equipment, provisions for reception and control of patients, convenient patient toilet room, and communication hookup and access to a poison control center.

9. Diversion Status – Inability to Deliver Emergency Services.

a. Types I, II, and III hospitals shall develop and implement a diversion policy which describes the process of handling those times when the hospital must temporarily divert ambulances from transporting patients requiring emergency services to the hospital. The policy must include the following: when diversion is authorized to be called; who is authorized to call and discontinue diversion; efforts the hospital will make to minimize the usage of diversion; and how diversion will be monitored and evaluated.

b. Types I, II, and III hospitals shall notify local ambulance providers and/or other appropriate parties when the hospital is temporarily unable to deliver emergency services and is declaring itself on diversion.

~~**1203. Radiology. (II)**~~

~~A.Imaging services shall be under the supervision of a full-time radiologist, consulting radiologist, or a physician experienced in the particular imaging modality and the physician in charge must have the credentials required by facility policies.~~

~~B.Activities of the imaging service may include radio-therapy.~~

~~C.All imaging equipment shall be operated by personnel trained in the use of imaging equipment and knowledgeable of all applicable safety precautions required by the Department. Copies of additional regulations are available from the Department.~~

~~D.A written, signed/authenticated report on each x-ray or diagnostic image and therapy treatment shall be made a part of the patient's record; copies of the report shall be readily accessible in the imaging department. Each request for x-ray or diagnostic image examination shall include a concise statement of the reason for the examination.~~

~~E.The length of time that an x-ray image shall be kept on file shall be determined by the individual hospital. For its own protection, every hospital should consult with its legal counsel before selling or disposing of film.~~

~~F.Patients and employees shall be provided protection from radiation in accordance with current practices outlined by the Department.~~

~~G.Ultrasound and echocardiogram services shall be available within one hour on a twenty-four (24) hour basis.~~

~~**1204. Pharmacy Services. (I)**~~

~~A.The pharmaceutical service shall be directed by a registered pharmacist either on a full or part-time basis. The pharmacist directing the pharmaceutical services is responsible to the administration of the hospital for developing, supervising and coordinating all of the activities of the pharmacy department, which should include, but are not limited to, the following:~~

1. Dispensing medications in such form that will minimize additional preparation before administering to the patient.

2. Monitoring all medication orders to ensure that clinically significant chemical and therapeutic incompatibilities within the patient's drug regimens are reported to the prescribing physician.

3. Providing education programs for the facility's personnel and counseling patients regarding their medications, including their safe use.

4. Providing a method by which medications can be obtained during the absence of a pharmacist in the facility in such a manner that will minimize the potential for medication error and assure control and accountability of any drugs. A pharmacist shall be available on an on-call basis at all times.

5. Assisting in the formulation of professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, and safety procedures relating to drugs in the facility.

6. Monthly review of drugs and drug records in all locations in which drugs are stored, including, but not limited to, nursing stations, emergency rooms, outpatient departments, operating suites, emergency kits, etc.

B.Each institutional pharmacy shall be directed by a pharmacist, herein after referred to as the pharmacist-in-charge, who is licensed to engage in the practice of pharmacy in this state.

C.The pharmacist-in-charge must be assisted by a sufficient number of licensed pharmacists and registered pharmacy technicians as may be required to competently and safely provide pharmacy services.

D.The pharmacist-in-charge shall maintain and file with the Board of Pharmacy on a form provided by the board, a current list of all pharmacy technicians assisting in the provision of pharmacy services.

1205. Drug Distribution and Control.

The pharmaceutical service shall have written policies and procedures for control and accountability, drug distribution, and assurance of quality of all drugs and biological products throughout the hospital. The pharmacist-in-charge shall provide the current license for the institutional pharmacy from the SC Board of Pharmacy, the individual's professional license, and the professional licenses of all personnel working within the pharmacy upon request of the Departments inspectors. The pharmacist-in-charge of an institutional pharmacy shall establish written policies and procedures to provide for access to drugs by the medical staff whenever a licensed pharmacist is not physically present in an institutional facility by use of night cabinets and/or by access to the pharmacy. A licensed pharmacist must be on call at all times.

A.A record of the stock and distribution of all controlled substances in Schedule II shall be maintained in such a manner that the disposition of any particular item may be readily traced. All such records shall be maintained in compliance with the requirements of the Federal and State Controlled Substances Acts.

B.Records for investigational drugs shall be maintained in the pharmacy in compliance with the Federal Food and Cosmetic Act Regulations.

1206. Physical Facilities and Storage.

A.Drug storage on the nursing units shall be reviewed monthly by the pharmacist or a properly trained individual designated by the pharmacist; a record of each review shall be maintained. All floor stocks shall

~~be properly controlled. Medications requiring refrigeration shall be kept in a secured refrigerator used exclusively for medications, or in a secured manner in which medications are separated from other items kept in a refrigerator (e.g. Lock Box). Refrigerators shall be provided with a thermometer accurate to plus or minus 2 degrees F. Documentation of appropriate temperature control is required by manual or electronic means.~~

~~B. Pharmacy practice shall be governed by the SC Board of Pharmacy Practice Act as detailed in the S.C. Code of Laws. If services are provided at more than one location, each location must be permitted by the SC Board of Pharmacy.~~

~~C. Only personnel approved by the hospital administrator or his/her designees shall have access to the pharmacy.~~

~~D. Emergency boxes, kits or (crash) carts shall be sealed and, when not in actual use, stored either in a secured area or under visual control from the nurses' station. The contents of these containers shall be approved by the appropriate committee of the facility. An inventory list of the contents shall be maintained in or on the container.~~

~~1207. Labeling of Medications. (I)~~

~~A. Any medication administered to inpatients shall be identified with its name and strength labeled on the container in which it is provided or on each single unit package. The labeling of medications administered to inpatients shall be in compliance with applicable Federal, State, and local laws and regulations. The labeling information may also be available through electronic means.~~

~~B. Labeling of drugs dispensed to outpatients shall be in compliance with applicable federal, state, and local laws and regulations .~~

~~C. Outdated or discontinued medications shall be returned to the pharmacy for proper disposition in accordance with good pharmaceutical practice and facility policy. Medications that have been subjected to contamination shall not be redispensed.~~

~~D. Unused medications may be turned over to the patient for whom prescribed on discharge only on the written order of the attending physician. Such medications must be returned to the pharmacy to be labeled in accordance with Section 1207.A before release.~~

~~E. Medical staff in conjunction with the pharmacist in charge shall establish policy and procedure when certain medications not specifically prescribed as to time or number of doses will be automatically stopped after a time limit set by the medical staff.~~

~~F. Multi-dose vials shall be labeled with the date and time when opened.~~

~~G. Up-to-date reference materials shall be readily available.~~

__~~1208~~E. Central Supply.~~ (I)~~

__~~A~~1.~~ ~~The department head shall be qualified for the position by education, training and experience as determined by the ~~hospital~~Facility policies and procedures. (II)

__~~B~~2.~~ ~~The number of supervisory and other personnel shall be related to the scope of the services provided. (II)

C3.– There shall be written policies and procedures for the decontamination and sterilization activities performed in central supply and elsewhere in the ~~hospital~~Facility. These policies and procedures shall ~~relate, but are not limited to~~address the following:

~~1~~a.— The use of sterilization process monitors, including temperature and pressure recordings, and the use and frequency of appropriate chemical indicator and bacteriological spore tests for all sterilizers.

~~2~~b.— Designation of the shelf life for each hospital-wrapped and hospital-sterilized medical item and, to the maximum degree possible, for each commercially prepared item, by a specific expiration date that sets a limit on the number of days an item will be considered safe for use. When possible, load control numbers shall be used to designate the sterilization equipment used for each item, including the sterilization date and cycle.

~~D~~4.– A recognized method of checking sterilizer performance shall be used. A chemical indicator of some type should be included in the largest package of each load. Biological indicators (live bacterial spores) should be included in all steam and hot air sterilizers at least once per week or more often depending upon the degree of sterilizer usage. Gas sterilizers should employ such indicators on at least a weekly basis and preferably on a daily basis. Further, the gas sterilization of implants, prosthetic devices, etc., should be accompanied by a biological monitor in each load. Monthly checks shall be made to ensure the above, and a written report retained.

~~E~~5.– Adequate precautions shall be taken to ensure that sterile supplies and equipment are not mixed with unsterile material. Suitable space shall be provided for keeping equipment and supplies in a clean, convenient and orderly manner.

~~F~~6.— All packaged supplies and containers for solutions, drugs, medicated supplies, etc., shall be labeled so as to remain plainly legible before and after sterilization. Labels shall include at least the expiration date of the contents.

~~G~~7.– Outdated medical supplies, solutions, etc., shall be returned to central supply for resterilization or disposal.

~~1209~~1202. ~~Surgery~~ Optional Hospital Services. (~~I~~I)

A. Surgical Services.

~~A.The surgical service shall be under the supervision of a member of the active staff of physicians.~~

~~B.The operating rooms must be supervised by a registered nurse or a doctor of medicine or osteopathy.~~

~~C.Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.~~

~~D.Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse.~~

~~E.Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.~~

~~F. Hospitals providing surgery should have available consulting physicians to address additional patient needs.~~

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

1. The organization of the surgical services must be appropriate to the scope of the services offered.

a. The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

b. Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.

c. Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

d. Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

2. Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

a. Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

i. A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration, and except as provided under Section 1202.A.2.a.iii.

ii. An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under Section 1202.A.2.a.iii.

iii. An assessment of the patient must be completed and documented after registration (in lieu of the requirements of Section 1202.A.2.a.i and -ii) when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

b. A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

c. The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

d. There must be adequate provisions for immediate post-operative care.

e. The operating room register must be complete and up-to-date.

f. An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

g. Hospitals shall provide surgical equipment and instruments in good repair and free of potentially harmful microorganisms to assure safe and aseptic treatment. Any indication of contamination shall be immediately called to the attention of the nursing supervisor or the physician in charge of the service.

~~**1210. Facilities.**~~

~~The operating rooms shall be separated from non-sterile areas and shall be located so as not to be used as a passageway between, or subject to contamination from, other parts of the hospital.~~

~~**1211. Equipment. (I)**~~

~~A.Hospitals shall provide surgical equipment and instruments in good repair and free of potentially harmful microorganisms to assure safe and aseptic treatment. Any indication of contamination shall be immediately called to the attention of the nursing supervisor and the physician in charge of the service.~~

~~B.Life support and medical gas equipment shall be readily available and functional.~~

~~1212~~B. Anesthesia Services.~~ (I)

~~A.Anesthesia shall be administered according to the South Carolina Code of Laws and the South Carolina Code of State Regulations by:~~

~~1. A qualified anesthesiologist;~~

~~2. A doctor of medicine or osteopathy other than an anesthesiologist;~~

~~3. A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;~~

~~4. A certified registered nurse anesthetist (CRNA), as defined in S.C. Code Ann. Section 40-33-20(20), is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or~~

~~5. An anesthesiologist's assistant, as defined in S.C. Code Ann. Section 40-47-1210(2), who is under the supervision of an anesthesiologist who is immediately available if needed.~~

~~B.The organization of anesthesia services must be appropriate to the scope of the services offered.~~

~~C.Operations under a general anesthetic shall not be performed nor a general anesthetic given until the patient has had a physical examination except in emergency situations. The results of these examinations shall be entered in the patient's record. The history and physical must be readily available in the patient medical record.~~

~~D.Anesthesia apparatus shall be equipped with a device to measure the oxygen concentration of the gas being inhaled by the patient. The device shall emit an audible and/or visual alarm should the proportion of oxygen fall below a safe level.~~

If the hospital furnishes anesthesia services, those services must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

1. The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by:

a. A qualified anesthesiologist;

b. A doctor of medicine or osteopathy (other than an anesthesiologist);

c. A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

d. A certified registered nurse anesthetist (CRNA) is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

e. An anesthesiologist's assistant, who is under the supervision of an anesthesiologist who is immediately available if needed.

2. Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

a. A preanesthesia evaluation completed and documented by an individual qualified to administer anesthesia performed within 48 hours prior to surgery or a procedure requiring anesthesia services.

b. An intraoperative anesthesia record.

c. A postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.

C. Nuclear Medicine Services.

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

1. The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

a. There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

b. The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

2. Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

a. In-house preparation of radiopharmaceuticals is by, or under the supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

b. There is proper storage and disposal of radioactive material.

c. If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services.

3. Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be:

a. Maintained in safe operating condition; and

b. Inspected, tested, and calibrated at least annually by qualified personnel.

4.The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

a. The hospital must maintain copies of nuclear medicine reports for at least 5 years.

b. The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

c. The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

d. Nuclear medicine services must be ordered only by a practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

~~1213.~~ D. Outpatient Services.~~ (II)~~

~~A.If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice. Outpatient services must be appropriately organized and integrated with inpatient services. The hospital must assign one or more individuals to be responsible for outpatient services and have appropriate professional and nonprofessional personnel available.~~

~~B.If the hospital provides outpatient services, complete records shall be kept on all outpatients and shall be completed immediately after treatment is rendered. These records shall contain sufficient identification data, a description of what was done and/or prescribed for the patient and must be signed or authenticated by the attending physician. When a patient is admitted as an inpatient, all of his outpatient records shall be made a part of his permanent medical record. Records of patients are the property of the facility and must not be taken from the hospital property except by court order. These records shall be maintained and disposed of as specified in Section 1107.~~

~~C. Outpatient Services shall be in a location that is easily accessible for all patients and shall have easy access to all necessary hospital services.~~

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

1. Outpatient services must be appropriately organized and integrated with inpatient services.

2. The hospital must:

a. Assign one or more individuals to be responsible for outpatient services.

b. Have appropriate professional and nonprofessional personnel available where outpatient services are offered, based on the scope and complexity of outpatient services.

3. Outpatient services must be ordered by a practitioner who meets the following conditions:

a. Is responsible for the care of the patient.

b. Is licensed in the State where he or she provides care to the patient.

c. Is acting within his or her scope of practice under State law.

d. Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:

i. All practitioners who are appointed to the hospital's medical staff and who have been granted privileges to order the applicable outpatient services.

ii. All practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the medical staff and the hospital for ordering the applicable outpatient services for their patients.

~~**1214. Emergency Services. (I)**~~

~~A.No person, regardless of his ability to pay or county of residence, may be denied emergency care if a member of the admitting hospital's medical staff or, in the case of a transfer, a member of the accepting hospital's medical staff determines that the person is in need of emergency care.~~

~~1. If a patient presents in labor, she should be delivered in the hospital to which she has come if appropriate delivery facilities exist, If she is a "high risk" patient or an adverse outcome is expected for the baby if delivered there, e.g., less than 34 weeks gestation, she should be transported to a hospital with appropriate capabilities unless delivery is imminent or unless the hospital has such capabilities.~~

~~2. Hospitals that do not offer Obstetrical services shall have readily available in the emergency department a precipitous delivery kit, to include at a minimum: bulb suction syringe, cord clamp, scissors, sterile towels, and emergency telephone numbers for the appropriate Regional Perinatal Center.~~

~~3. If the care required for any patient is not available at the facility, arrangements must be made for transfer to a more appropriate facility. Prior to the transfer of a patient to another hospital, the receiving hospital shall be notified of the impending transfer.~~

~~4. In addition to or in lieu of any action taken by the Department affecting the license of any hospital, when it is established that any officer, employee, or member of the hospital medical staff has negligently violated the provisions of this section, the Department may require the hospital to pay a civil penalty of up to ten thousand dollars pursuant to S.C. Code Ann. Section 44-7-260(E) (1976, as amended).~~

~~B. Each hospital shall provide emergency services which include life-saving procedures when life is in jeopardy. Policies and procedures governing the acceptance and care of emergency patients shall be established. An appropriate record shall be maintained on each person who presents for emergency services.~~

~~1. Equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer of the critically ill or injured to other hospitals. A minimum capacity shall be established and equipment provided to perform stabilization procedures.~~

~~2. Basic services, such as radiology or routine laboratory services shall be maintained and personnel available for call.~~

~~3. A licensed physician shall be available and on call at all times. A registered nurse and ancillary personnel trained in emergency procedures shall be on duty within the hospital who are available 24 hours a day subject to call to assist in providing emergency services.~~

~~C.A poison control chart shall be readily available in the emergency room with communications access to a Poison Control Center for consultation.~~

~~D. The emergency service entrance shall be separated from the main entrance, well marked and illuminated, easily accessible from the street and sufficiently covered or enclosed to protect ambulance patients from the elements during the unloading process.~~

~~E.Space for stretchers and wheelchairs should be accessible to the facility and the facility should have the appropriate equipment to transport patients. Stretchers should be sufficiently sturdy to serve as examining tables.~~

~~F. In those instances wherein a specific hospital has been designated to provide emergency services for a political or other subdivision through mutual planning efforts of all the hospitals located in this subdivision, or otherwise determined, such designation obviates the necessity for the remaining hospitals to provide general emergency services.~~

E. Rehabilitation Services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

1. The organization of the service must be appropriate to the scope of the services offered.

a. The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

b. Physical therapy, occupational therapy, speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists.

2. Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.

a. All rehabilitation services orders must be documented in the patient's medical record.

b. The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice.

F. Psychiatric Services.

If the hospital provides psychiatric services, the services must be organized and staffed to ensure the health and safety of patients.

1. A physician, preferably a board-certified psychiatrist, shall be designated as physician-in-charge (or chief) of the psychiatric service. A designated physician who is experienced in the practice of psychiatry should be on call at all times.

2. A registered nurse who has had at least two years of training and/or experience in psychiatric nursing shall be responsible for the nursing care of psychiatric patients. At least one registered nurse shall be on duty in each nursing unit at all times.

3. Each patient must receive a psychiatric evaluation that must:

a. Be completed within 60 hours of admission;

b. Include a medical history;

c. Contain a record of mental status;

d. Note the onset of illness and the circumstances leading to admission;

e. Describe attitudes and behavior;

f. Estimate intellectual functioning, memory functioning, and orientation; and

g. Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

4. Treatment plan:

a. Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities. The written plan must include:

i. A substantiated diagnosis;

ii. Short-term and long-range goals;

iii. The specific treatment modalities utilized;

iv. The responsibilities of each member of the treatment team; and

v. Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

b. The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

5. Progress notes for the patient must be documented, in accordance with applicable State scope-of-practice laws and hospital policies, by the following qualified practitioners: Doctor(s) of medicine or osteopathy, or other licensed practitioner(s), who is responsible for the care of the patient; nurse(s) and social worker(s) (or social service staff) involved in the care of the patient; and, when appropriate, others significantly involved in the patient's active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated, as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

6. The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

G. Respiratory Care Services.

If the hospital provides respiratory care services, the services must be organized and staffed to ensure the health and safety of patients.

1. The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

a. There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

b. There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

2. Services must be delivered in accordance with medical staff directives.

a. Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

b. If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services.

c. Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.

d. All respiratory care services orders must be documented in the patient's medical record.

~~1215~~H. Inpatient Dialysis Services. ~~(I)~~

If the hospital provides inpatient dialysis services, the services must be organized and staffed to ensure the health and safety of patients.

~~A~~ 1. Written policies and procedures shall be developed and maintained by the service provider responsible for the service in consultation with other appropriate health professionals and the administration. Procedures shall be approved by the administration and medical staff where such is appropriate.

~~B~~ 2. Renal Dialysis Service Equipment and Supplies

~~1~~a. Equipment and supplies shall include at least:

~~a~~i. A dialysis machine or equivalent (with appropriate monitoring equipment) for each bed or station.

~~b~~ii. Dialysis equipment appropriate for pediatric patients, if treated.

~~2~~b. Water used for dialysis purposes shall be analyzed for bacteriological quality at least monthly and chemical quality at least quarterly and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques. Water used to prepare a dialysate shall not contain concentrations of elements or organisms in excess of those specified below:

ELEMENTS	**LIMIT IN MILLIGRAMS PER LITER**
Aluminum	.01
Arsenic	.005
Barium	.100
Cadmium	.001
Calcium	2.0
Chloramines (Tested Daily)	.001
Chlorine (Tested Daily)	.500
Chromium	.014
Copper	.100
Fluorides	.200
Lead	.005
Magnesium	4.0
Mercury	.0002
Nitrates (Nitrogen)	2.0
Potassium	8.0
Selenium	.090
Silver	.005
Sodium	70.0
Sulfates	100.0
Zinc	.100
Bacteria	200 colonies per milliliter

~~3~~c. A written preventive maintenance program for all equipment used in dialysis and related procedures including, but not limited to, all patient monitoring equipment, isolated electrical systems, conductive flooring, patient ground systems, and medical gas systems shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

~~**1216. Dental Surgery. (II)**~~

~~In a hospital providing dental services, the services shall be performed by a qualified practitioner of dentistry who shall be a member of the medical staff.~~

~~**1217. Physical Therapy. (II)**~~

~~If offered as a service of the hospital, physical therapy shall be on orders of a physician and administered by or under supervision of a registered physical therapist. Adequate space and equipment shall be provided.~~

~~**1218. Occupational Therapy. (II)**~~

~~If offered as a service of the hospital, occupational therapy shall be on orders of a physician and administered by or under supervision of an occupational therapist. Adequate space and equipment shall be provided.~~

~~**1219. Psychiatric Services. (II)**~~

~~A. A physician, preferably a board-certified psychiatrist, should be designated as physician-in-charge (or chief) of the psychiatric service. A designated physician who is experienced in the practice of psychiatry should be on call at all times.~~

~~B. A registered nurse who has had at least two years training and/or experience in psychiatric nursing shall be responsible for the nursing care of psychiatric patients. At least one registered nurse shall be on duty in each nursing unit at all times.~~

__~~1220~~I. Chemical and Substance Abuse Treatment Services. ~~(II)~~

If the hospital provides chemical and substance abuse treatment services, the services must be organized and staffed to ensure the health and safety of patients.

__ ~~A~~1.~~–~~ A physician, who is experienced in the treatment of chemical and substance abuse, shall be designated as physician-in-charge of this service. Such a physician shall also be on call at all times.

__ ~~B~~2.~~–~~ A registered nurse who has had at least two years training and/or experience in chemical and substance abuse care shall be responsible for the nursing care of this service. At least one registered nurse shall be on duty in each nursing unit at all times who has demonstrable training in chemical and substance abuse treatment. Relevant content of this training shall include physical and psychological assessment, psychopharmacology, basic counseling and intervention techniques, and the role of self-help groups in the recovery process. The training may be received through on-the-job training, specialized workshops, or classroom experience.

__~~1221~~J. Pediatrics Services.~~ (II)~~

If the hospital provides pediatric services, the services must be organized and staffed to ensure the health and safety of patients.

__ ~~A~~1.~~–~~ Organization: Pediatric services, if provided, shall be under the supervision of a registered nurse.

~~B~~2.– Facilities: Pediatric services shall have separate facilities for the care of children. Facilities and procedures shall be provided for isolation of children having contagious infections or communicable diseases.

~~C~~3. Pediatric Nursery: Pediatric nurseries shall provide at least 40 square feet per bassinet or 80 square feet per crib.

SECTION 1300
PERINATAL SERVICES

1301. Newborn Hearing Screening.

A. A facility that averages greater than 100 deliveries a year shall conduct a hearing screening on each newborn prior to discharge. In addition, the facility shall provide educational information about the screening procedure, the importance of the screening and the importance of having a complete audiobiological evaluation after discharge if the need is indicated.

B. If a facility averages fewer than 100 deliveries a year, a hearing screening is not required for each newborn, but the facility shall give the parents of each newborn educational information concerning the hearing screening procedure and the importance of having the screening procedure after discharge.

C. Each facility required to conduct newborn hearing screening shall regularly report the results of the screening to the Department in the required format.

1302. Shaking infant video & infant CPR information for parents and caregivers of newborn infants and adoptive parents.

A. A facility shall provide to the parents of each newborn baby delivered in the facility a video presentation on the dangers associated with shaking infants and young children. The facility shall also make available information on the importance of parents and caregivers learning infant CPR.

B. The facility shall request that the maternity patient, the father, or the primary caregiver view the video. Those persons whom the facility requests to view the video shall sign a document prescribed by the Department of Health and Environmental Control stating that they have been offered an opportunity to view the video.

C. The facility shall only use a video approved by the Director, or his/her designee, of the Department of Health and Environmental Control.

1303. Providing a Safe Haven for Abandoned Babies.

Facilities and outpatient facilities shall:

A. Accept temporary physical custody of an infant not more than sixty (60) days old who is voluntarily left by a person who does not express an intent to return for the infant and the circumstances create a reasonable belief that a person does not intend to return for the infant.

B. Be in full compliance with EMTALA rules and regulations and perform any act necessary to protect the physical health or safety of the infant.

C. Offer the person information concerning the legal effect of leaving the infant by delivering to the person the information brochure supplied by the state DSS. Ask the person to identify any parent other than the person leaving the infant. Attempt to obtain from the person information concerning the infant's background and medical history as specified in the forms provided by DSS and appropriate forms available from facility files.

D. Using the DSS form, an attempt must be made to get information concerning use of controlled substances by the infant's mother and other pertinent health information which might determine medical care required by the infant.

E. If the person does not wish to provide or is unable to provide the information to the facility, the person must be offered the DSS form with a prepaid envelope supplied to the facility by DSS.

F. No later than the close of the first business day, after the date on which the facility takes possession of the infant, the facility must notify DSS that it has taken temporary physical custody of the infant. DSS will have legal custody of the infant upon receipt of this notice and DSS will assume physical custody no later than 24 hours after receiving notice that the infant is ready for discharge.

1304. Paternity – In-Hospital Voluntary Paternity Acknowledgement Program.

A. In accordance with 45 CFR 303, a hospital that provides obstetrical services at a minimum must provide to both the mother and alleged father:

1. Written materials about paternity establishment.

2. Forms as provided by the Department necessary to voluntarily acknowledge.

3. Notice, both orally and in writing of the alternatives to the legal consequences of, and the rights and responsibilities of acknowledging paternity, and

4. The opportunity to speak with staff, either by telephone or in person, who are trained to clarify information and answer questions about paternity establishment.

B. Hospital must forward completed voluntary acknowledgement forms, or copies to the Department Division of Vital Records.

1305. Perinatal Organization.

A. Each hospital providing perinatal services shall request designation as a Level I, II, III, or IV perinatal hospital, or regional perinatal center (RPC) by letter to the Department. Initially, a hospital shall demonstrate capability to comply with requirements of a particular designation by submitting to the Department documentation pertaining to the request for desired designation. For licensure renewals, along with maintaining compliance with the requirements of Section 1306, the hospital shall have birth weight-specific neonatal mortality data readily available for Department review relative to hospitals in the state of the same designation.

B. Each Level I, II, III, and IV hospital shall maintain and document a relationship with its designated RPC for consultation, transport and continuing education. All patients shall be transferred to the appropriate RPC when medically appropriate, if beds are available. This agreement/relationship shall include the ability to share data, as appropriate, related to these functions.

C. Labor and delivery shall occur in a hospital capable of meeting the expected needs of both the mother and the neonate. Ongoing risk assessment shall occur to determine the appropriate level of care.

1306. Designation of Inpatient Perinatal Care Services.

A. Basic Perinatal Center with Well Newborn Nursery (Level I). Level I hospitals shall provide services for normal uncomplicated pregnancies. Level I hospitals shall identify maternity patients requiring transfer to a facility providing the appropriate level of care for the fetus, consult with the RPC on such matters, and offer a basic level of newborn care to infants at low risk. Level I hospitals shall have personnel who provide care for physiologically stable infants born at or beyond 35 weeks of gestation and stabilize ill newborn infants born at less than 35 weeks of gestation until they can be transferred to a facility where the appropriate level of neonatal care is provided. Level I hospitals shall have personnel and equipment available to provide neonatal resuscitation at every delivery and to evaluate and provide routine postnatal care for healthy term newborn infants. Level I hospitals shall have the capability to begin an emergency cesarean delivery within an interval based on timing that best incorporates maternal and fetal risks and benefits. When it is anticipated or determined that these criteria will not be or have not been met, consultation and a plan of care shall be initiated and mutually agreed upon with the RPC and documented in the medical record, immediately after the patient is stabilized. Level I hospitals shall provide care of postpartum conditions and make provisions of accommodations and policies that allow families, including their other children, to be together in the hospital following birth. Appropriate anesthesia, radiology, and laboratory and blood bank services shall be available on a twenty-four (24) hour basis. Management shall include emergency resuscitation and/or stabilization for both maternal and neonatal patients in preparation for transfer/transport for more specialized services. Hospitals at this level shall not provide care or services which are designated only for higher level hospitals, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

B. Specialty Perinatal Center with Special Care Nursery (Level II). In addition to complying with all requirements of Section 1306.A, Level II hospitals shall provide services for both normal and selected high-risk obstetrical and neonatal patients. Level II hospital care shall include management of neonates who are at least 32 weeks of gestation with an anticipated birth weight of at least 1500 grams and problems expected to resolve rapidly (neonates not in need of sub-specialty services on an urgent basis). Level II hospitals shall provide care for infants convalescing after intensive care. Level II hospital shall stabilize infants born before 32 weeks of gestation and weigh less than 1500 grams until transfer to a neonatal intensive care facility. Level II hospitals shall have experienced personnel capable of providing continuous positive pressure airway pressure or mechanical ventilation for a brief period (less than 24 hours) or both until the infant's condition improves or the infant can be transferred to a higher-level facility. Level II hospitals shall have equipment (e.g. portable x-ray equipment, blood gas laboratory) and personnel (e.g. physicians, specialized nurses, respiratory therapists, radiology technicians, and laboratory technicians) available at all times to provide ongoing care and address emergencies. Referral to a higher level of care should occur for all infants when needed, for medical or subspecialty intervention. Support personnel shall include respiratory therapists, radiology technicians, laboratory technicians, and a lactation consultant. A board-certified or board-eligible pediatrician shall be in the hospital or on site within 30 minutes, 24 hours a day. There shall be no limit on the duration of Nasopharyngeal Continuous Positive Airway Pressure (NCPAP) or Nasal Prong Continuous Positive Airway Pressure (NPCPAP) when cared for by a neonatologist. The provision of CPAP or mechanical ventilation beyond the immediate stabilization period requires the immediate availability of respiratory therapists with neonatal training (including intubation of premature infants), nursing support with training to identify and respond to complications of ventilation, and the immediate availability of personnel and equipment to evacuate a pneumothorax. Level II hospitals with a board certified or board eligible neonatologist having responsibilities limited to a single center and in house or within 30 minutes of the unit at all times may provide care for patients requiring mechanical ventilation for up to 24 hours. For shared neonatology coverage, a certified Neonatal Nurse Practitioner having

responsibilities limited to a single center and in house may provide coverage for that center. Neonates requiring the initiation of mechanical ventilator support beyond 24 hours of age shall be referred to the RPC. Neonates shall not require high-frequency ventilation support. These hospitals shall manage no less than an average of 500 deliveries annually, calculated over the previous three years based on the individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. A Level II hospital shall not admit outborn neonates into its nursery without prior concurrence with the RPC. Level II units shall not transport neonates between hospitals. Hospitals at this level shall not provide care or services which are designated only for higher level hospitals, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

C. Subspecialty Perinatal Center with Neonatal Intensive Care Unit (Level III). In addition to complying with all requirements of Sections 1306.A through 1306.B, Level III hospitals shall provide all aspects of perinatal care, including intensive care and a range of continuously available subspecialty consultation as recommended in the most recent edition of the *Guidelines for Perinatal Care* (GPC) by the American Academy of Pediatrics (AAP) and The American College of Obstetricians and Gynecologists. Level III hospitals shall provide care for mothers and infants at less than 32 weeks gestation, estimated fetal weight less than 1500 grams, and anticipated complex medical or surgical conditions for mother or infant that may require sub-specialty services. Level III hospitals shall also provide care for infants born at less than 32 weeks of gestation and weigh less than 1500 grams at birth or have actual or anticipated complex medical or surgical conditions regardless of gestational age. Level III hospital care shall include expertise in neonatology and maternal-fetal medicine. Level III neonatal intensive care units (NICUs) shall include continuously available personnel (neonatologists, neonatal nurses, and respiratory therapists) and equipment available to provide life support as long as needed. Level III facilities shall provide ongoing assisted ventilation for periods longer than 24 hours, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide. Level III hospitals shall provide services and care for women and fetuses at high risk, both admitted and transferred to the facility. Level III hospitals shall have advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise, social services, and pastoral care. Pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity shall also be readily available in Level III hospitals. Level III hospitals shall have the capability to perform advanced imaging with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography. Level III hospitals shall also have the capability to perform major surgery on site or at a closely related institution. A board-certified or board-eligible neonatologist shall be in the hospital or on site within 30 minutes, 24 hours a day. A board-certified maternal-fetal medicine specialist (perinatologist) shall be available for supervision and consultation, 24 hours a day. Perinatal consultation requirements may be met via telemedicine arrangements with a RPC. In addition to the Level II capabilities, Level III hospitals shall have the staffing and technical capability to manage high-risk obstetric and complex neonatal patients, including neonates requiring prolonged ventilatory support, surgical intervention, or 24-hour availability of multispecialty management. Hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually, calculated over the previous three years, and at least an average of 100 neonate admissions who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery based on individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. The NICU budget shall include support for outcomes measurement, including data collection and membership in a multi-institutional collaborative quality improvement data base. Level III hospitals shall collect data to assess outcomes within their facility and to compare with other hospitals within their level. Hospitals at this level shall not provide additional care or services designated only for RPC's, or perform neonatal transport, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

D.Regional Perinatal Center with Neonatal Intensive Care Units (Level III) (RPC). In addition to complying with all requirements of Sections 1306.A through 1306.C, the RPC shall provide consultative, outreach, and support services to Level I, II, and III hospitals in the region. The RPC shall manage no less than an average of 2000 deliveries annually, calculated over the previous three years. Personnel qualified to manage obstetric or neonatal emergencies shall be in-house. A board- certified maternal-fetal medicine specialist (perinatologist) shall be in the hospital or on site within 30 minutes for supervision and consultation, 24 hours a day. The RPC shall participate in residency programs for obstetrics, pediatrics, and/or family practice. Physician-to-physician consultation shall be available 24 hours a day for Level I, II, and III hospitals. Regional Perinatal Centers shall coordinate the development and implementation of professional continuing education to maintain competency and provide education to other facilities within the region, facilitate transport from the perinatal centers to the regional perinatal center and back transport when possible, and collect data on long-term outcomes to evaluate the effectiveness of delivery of perinatal care services and the efficacy of new therapies. The RPC shall provide a perinatal transport system that operates 24 hours a day, seven days a week, and return transports neonates to lower level perinatal hospitals when the neonates' condition and care requirements are within the capability of those hospitals.

E. Complex Neonatal Intensive Care Unit (Level IV). In addition to complying with all requirements of Sections 1306.A through 1306.C, Level IV hospitals shall include additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants and have pediatric medical and surgical specialty consultants available 24 hours a day. Level IV hospitals shall have capability to perform surgical repair of complex congenital or acquired conditions (e.g. Congenital malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation). Level IV hospitals shall maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the facility. Not all Level IV hospitals need to act as regional centers. Regional organization of perinatal health care services requires that there be coordination in the development of specialized services, professional continuing education to maintain competency, facilitation of opportunities for transport and return transport, and collection of data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health care services and the safety and efficacy of new therapies. Level IV hospitals shall collect data to assess outcomes within their facility, and to compare with other hospitals within their level, if applicable.

1307. Personnel.

A.Detailed components of support services and medical, nursing and ancillary staffing for each level shall meet the recommendations outlined in the most recent edition of the *Guidelines for Perinatal Care*.

B.The following medical specialists and subspecialists shall have medical staff credentials and/or written consultative agreements as follows:

1. Level I shall include:

a. Membership: Physician designated as physician-in-charge of obstetric services, physician designated for supervision of newborn care, anesthesia personnel with credentials to administer obstetric anesthesia available within 30 minutes, 24-hours a day, one person capable of initiating neonatal resuscitation available at every delivery.

b. Consultation: Obstetrician, pediatrician, general surgeon.

2. Level II, in addition to Level I requirements, shall include:

a. Membership: General surgeon, pathologist, radiologist, obstetrician, pediatrician, and anesthesiologist;

b. Consultation: Maternal-fetal medicine specialist, neonatologist, and pediatric surgeon.

3. Level III and RPC, in addition to Level II requirements, shall include:

a. Membership: Maternal-fetal medicine specialist or effective consultation with Maternal- Fetal medicine specialist, (available 24 hours a day, 7 days a week) via telemedicine, obstetrician or radiologist with special interest and competence in maternal disease and its complications, pediatric radiologist, anesthesiologist with perinatal training and/or experience; pathologists with special competence in placental, fetal, and neonatal disease, and pediatric surgeon.

b. Urgent Consultation: Pediatric subspecialists including cardiology, neurology, hematology, genetics, endocrinology, nephrology, gastroenterology-nutrition, infectious diseases, pulmonology, immunology, pathology, metabolism and pharmacology. Pediatric surgical subspecialists, to include cardiovascular, neurosurgery, orthopedics, ophthalmology, urology and otolaryngology.

c. For Level III hospitals: Pediatric medical subspecialists, pediatric anesthesiologists, pediatric surgeons, and pediatric ophthalmologists may be at the site or at a closely related institution by prearranged consultative agreement. Prearranged consultative agreements can be performed using, for example, telemedicine technology, or telephone consultation, or both from a distant location.

4. Level IV, in addition to Level III requirements, shall include: Membership and on-site: Maternal-fetal medicine specialist, obstetrician or radiologist with special interest and competence in maternal disease and its complications, pediatric radiologist, anesthesiologist with perinatal training and/or experience; pathologists with special competence in placental, fetal, and neonatal disease, and pediatric surgeon.

1308. Neonatal Intensive Care Nurse Staffing.

Neonatal intensive care nurse staffing is required if any of the following conditions exist:

A. Any advanced support therapy, e.g., extracorporeal membrane oxygenation, nitric oxide, high frequency ventilation, peritoneal dialysis;

B. Acute pre- or post-operative surgical conditions, except for minor surgical procedures such as inguinal hernia repair;

C. Ventilator support (with the exception of do-not-resuscitate situations and chronic ventilator-dependent conditions);

D. Less than 32 weeks of gestation and less than 1500 grams on the first day of life;

E. Chest tubes required;

F. Cardio-pulmonary resuscitation required in the previous 24 hours;

G. Vital signs required every hour or more frequently;

H. Umbilical artery or vein catheterization or three or more intravenous sites required;

I. Pressor agent (excluding initial stabilization) or inotropic support required, e.g., dopamine (doses for renal perfusion maintenance excluded);

J. Complex diagnostic/assessment support required; or

K.Evidence of seizure activity/unstable neurologic status.

1309. General Facility and Care Requirements.

A.Environment, equipment, supplies, and procedures utilized in the care of perinatal patients shall meet the recommendations outlined in the most recent edition of the *Guidelines for Perinatal Care*. The environmental temperature in newborn care areas should be independently adjustable, as to maintain per the GPC.

B.Obstetrical Care: In each hospital providing obstetrical services, written policies and procedures shall be established and implemented through cooperative efforts of the medical and nursing staffs. These policies and procedures shall outline the process, providers, and methods of providing risk-appropriate care to the obstetrical patient, and shall include, but not be limited to:

1. Admission criteria and documentation;

2. Preterm labor;

3. Maternal transfer to another hospital;

4. Induction and augmentation;

5. Analgesia and anesthesia;

6. Labor process;

7. Capability to perform cesarean delivery within 30 minutes of the decision to do so;

8. Immediate neonatal care/resuscitation;

9. Recovery room care; and

10. Postpartum care.

1310. Neonatal Care.

Specific policies and procedures for the care of the neonate shall follow the recommendations outlined in the most recent edition of the GPC.

1311. Neonatal Resuscitation.

A.Personnel, equipment, supplies, and medications as recommended by the most recent edition of the American Heart Association and AAP *Textbook of Neonatal Resuscitation* shall be readily available in every hospital providing perinatal services.

B. In order to meet the potential need for resuscitation of every neonate, at least one person who has a current provider-designation, as defined by completion of the AAP Neonatal Resuscitation Program, shall be on site.

C. Personnel trained and qualified to perform neonatal resuscitation must be immediately available and not responding from an area removed from the delivery or nursery area.

D. Equipment, supplies, and medications for neonatal resuscitation must be immediately available to the delivery and nursery areas at all times.

1312. Inter-hospital Care of the Perinatal Patient (Transport).

A. Each hospital providing perinatal services shall establish and implement a written plan which outlines the process, providers, and methods of providing risk-appropriate stabilization and transport of any high-risk perinatal patient requiring specialized services. This plan shall be updated in conjunction with the designated RPC on an annual basis, and shall include, but not be limited to, procedures outlining:

1. Communication between referring hospitals and the RPC, transport teams and medical control, and perinatal providers and families;

2. Indications for both acute phase and return transport between perinatal hospitals, to include essential contact persons and telephone numbers for referral and transport; and

3. A list of all medical record copies and additional materials to accompany each patient in transport.

B. Equipment, supplies, and procedures used in preparation and support of transport of maternal patients shall be based upon the most recent edition of the GPC. Equipment, supplies, and procedures used in the transport of a neonate shall be based upon the most recent edition of the AAP *Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients*.

1313. Evaluation of Perinatal Care.

A. Review of maternal and neonate mortality and morbidity shall be conducted at least every three months by the medical staff or designated committee, regardless of the size or designation of the perinatal service. A perinatal mortality and morbidity review committee composed of representatives from the pediatric, obstetrical, and nursing staffs, with additional participation from other professionals, depending upon the cases to be reviewed, shall be established at all perinatal centers.

B. In all perinatal centers, selected case reviews shall include, but not be limited to:

1. Analysis of total perinatal mortality with identification of deaths attributable to various categories of complication;

2. Analysis of perinatal morbidity and related factors.

C. Level I and II hospitals shall review all live births or fetal/neonatal deaths in which the neonate weighed at least 350 grams and less than 1500 grams, utilizing the Department's *Very Low Birthweight Self-monitoring Tool*. Each completed self-monitoring DHEC form shall be retained by the facility and a copy made available to the Department as specified in the self-monitoring tool.

D.Each event shall be evaluated for potential opportunities for intervention with the intervention and follow-up described, if applicable. Written minutes of committee meetings shall be maintained and made available to the Department for review

E. Each Level I, II, and III perinatal center shall annually review and document the findings from these case reviews with its designated RPC. Minutes of these meetings shall be maintained and made available to the Department for review.

SECTION 1400
VITAL STATISTICS

1401. General.

Hospitals must comply fully with the Regulations of the Department relating to vital statistics.

1402. Birth Certificates.

A.For inpatient newborns a licensee shall be responsible for filing a birth certificate for all live births occurring in the licensed facility (see ~~DHEC~~ Regulation 61-19 for definition of live birth). The record should be filed as prescribed within five (5) days of delivery per ~~DHEC~~ Regulation 61-19.

B.A licensee shall be responsible for filing a birth certificate for outpatient newborns brought to the emergency room when a live birth was delivered either at home or en route to the hospital. If the live birth is delivered by a licensed midwife or other practitioner, the licensee shall not be responsible for filing a birth certificate.

1403. Death Certificates.

Filing of a death certificate shall be in accordance with ~~DHEC~~ Regulation 61-19 and the S.C. Code of Laws.

SECTION 1500
FOOD AND NUTRITION SERVICE (II)

1501. Approval.

All facilities that prepare food on-site shall be approved by the Department, and shall be regulated, inspected, and graded pursuant to ~~DHEC~~ Regulation 61-25.

1502. Services.

All facilities shall provide food and nutrition services to meet the daily nutritional and dietary needs of patients in accordance with written policies and procedures.

1503. Management.

The nutrition services shall be under the direction of a dietitian or qualified food and nutrition manager/director who has a written agreement for consultation services by a dietitian. These services shall be organized with established lines of accountability and clearly defined job assignments. A qualified food and nutrition manager/director shall be a person who:

A. Is a graduate of a dietetic technician training program approved by the American Dietetic Association; or

B. Is a graduate of a course of study meeting the requirements of the American Dietetic Association and approved by the Department; or

C. Is certified by the Certifying Board for Dietary Managers of the Dietary Managers Association and maintains that credential; or

D. Has at least three (3) years of training and experience in meal service supervision and management in military service equivalent in content to the programs described in paragraph A, B, or C above.

1504. Personnel.

A. Dietary services shall be organized with established lines of accountability and clearly defined job assignments for those engaged in food preparation and serving. There shall be trained staff members/volunteers to supervise the preparation and serving of the proper diet to the patients including having sufficient knowledge of food values in order to make appropriate substitutions when necessary.

B. The qualified food and nutrition manager/director shall be responsible for supervising food and nutrition service personnel, the preparation and serving of the food, and the maintenance of proper records. When the qualified food and nutrition service manager/director is not on duty, a responsible person shall be assigned to assume their job responsibilities.

C. Work assignments and duty schedules shall be posted and kept current.

D. No person, infected with or a carrier of a communicable disease, or while having boils, open or infected skin lesions, or an acute respiratory infection, shall work in any area of food preparation and service.

E. Employees shall wear clean garments, maintain a high degree of cleanliness, and conform to hygienic practices while on duty. Individuals engaged in the preparation and service of food shall wear clean hair restraints, e.g., hair nets, hair wraps, hats, that will properly restrain all hair of the face and head and prevent contamination of food and food contact surfaces. They shall wash their hands thoroughly in an approved hand washing lavatory before starting work, after visiting the bathroom and as often as may be necessary to remove soil and contamination.

1505. Diets.

Diets shall be prepared in conformance with orders of a physician or, if permitted by the facility's policies, a dietitian. A current diet manual shall be readily available to attending physicians, food and nutrition service personnel, nursing personnel, and dietitians.

A. Diets shall be prescribed, dated and signed or authenticated by the physician or dietitian.

B. Facilities with patients in need of special or therapeutic diets shall provide for such diets.

C. Notations shall be made in the medical record of diet served, counseling or instructions given, as identified by patient and/or nutritional assessment and patient's tolerance of the diet.

D. Diets shall be planned, written, prepared and served with consultation from a dietitian.

E. Persons responsible for diets shall have sufficient knowledge of food values in order to make substitutions when necessary. All substitutions made on the master menu shall be documented.

F. Nothing in this regulation shall be read or interpreted to prohibit a facility's policies from allowing a dietitian to:

1. Order or prescribe patient diets, including therapeutic diets;

2. Order laboratory tests to monitor the effectiveness of dietary plans and orders; and/or

3. Make subsequent modifications to patient diets based on the results of laboratory tests.

1506. Planning of Menus and Food Supplies.

A.Menus shall be planned and written at least two weeks in advance and dated as served. The current week's menus, including routine and special diets and any substitutions or changes made, shall be posted in one or more conspicuous places in the Food and Nutrition Services area.

B.Records of menus as served shall be filed and maintained for at least 30 days.

C.Food supplies shall be adequate to meet menu and emergency plan requirements.

D.Records of food and supplies purchased shall be kept on file.

1507. Preparation and Serving of Food.

A.Food shall be prepared by methods that conserve the nutritive value, flavor and appearance. The food shall be palatable, properly prepared, and sufficient in quantity and quality to meet the nutritional needs of the patients.

B.A file of tested recipes, adjusted to appropriate yield, shall correspond to items on the posted menus.

C.Food shall be served with special attention given to preparation and prompt serving in order to maintain correct food temperatures in accordance with ~~DHEC~~ Regulation 61-25 and to meet individual needs.

D.Food and Nutrition service personnel will have the responsibility of accompanying the food cart to the patient care area when necessary to complete tray assembly. Facilities with automated food distribution systems in operation are not required to have dietary personnel accompanying the cart. Each facility shall designate who will be responsible for distribution of trays, feeding of patients, and collection of soiled trays.

1508. Dietary and Food Sanitation.

A.Sanitary conditions shall be maintained in all aspects of the storage, preparation and distribution of food.

B.The facility shall be in compliance with local health codes and ~~DHEC~~ Regulation 61-25.

C.Written procedures for cleaning, disinfecting and sanitizing all equipment and work areas shall be developed and followed.

D. Written reports of inspections by state and local health authorities shall be kept on file in the facility with notations made of actions taken by the facility to comply with recommendations.

E. Drugs shall not be stored in the food and nutrition services area or any refrigerator or storage area utilized by the food and nutrition services area.

F. All walk-in refrigerators and freezers must be equipped with opening devices which will permit opening of the door from the inside at all times.

1509. Meal Service.

A minimum of three nutritionally balanced meals in each 24-hour period shall be offered for each patient unless otherwise directed by the patient's physician. Not more than 14 hours shall elapse between the serving of the evening meal and breakfast. As an exception, there may be up to 16 hours between the scheduled serving of the evening meal and breakfast the following day if approved by the patient's attending physician and the patient, and if a nourishing snack is provided after the evening meal.

1510. Ice and Drinking Water.

Ice and water that meets the approval of the Department shall be available and precautions shall be taken to prevent contamination. Ice delivered to patient areas in bulk shall be in nonporous, easily cleanable covered containers. The ice scoop shall be stored in a sanitary manner with the handle at no time coming in contact with the ice. Clean, sanitary drinking water shall be available and accessible in adequate amounts at all times.

SECTION 1600
MAINTENANCE (II)

An institutional structure, its component parts, facilities, and all equipment shall be kept in good repair and operating condition.

SECTION 1700
HOUSEKEEPING AND REFUSE DISPOSAL (II)

1701. Housekeeping.

A. A facility shall be kept neat and clean. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, windows and premises. There must be an effective rodent and insect control program for the facility to prevent infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times. Dry dusting and dry sweeping are prohibited.

B. Upon discharge or transfer of a patient, all bedside equipment shall be cleansed and disinfected. Bed linen shall be removed and mattresses turned; if damaged, replaced. Beds shall be made with fresh linens to maintain them in a clean and sanitary condition for each patient.

C. Employee locker rooms shall be maintained in a clean and sanitary condition.

D. Janitor closets, floors, walls, sinks, mops, mop buckets, and all equipment shall be cleaned daily or more often as needed. A supervisory hospital employee shall make frequent inspections to assure compliance.

E. All storage spaces shall be kept clean, orderly and free of trash, papers, old cloths and empty boxes. In areas provided with a sprinkler system, a minimum vertical distance of 18 inches shall be maintained between the top of stored items and the sprinkler heads.

1702. Refuse Disposal.

A. All garbage and refuse storage shall be in accordance with ~~DHEC~~ Regulation 61-25.

B. All contaminated dressings, pathological, and/or similar waste shall be properly disposed of in accordance with ~~DHEC~~ Regulation 61-105.

C. All radioactive waste shall be disposed of by a method in accordance with ~~DHEC~~ Regulation 61-63.

D. All outside areas, grounds and/or adjacent buildings on the premises shall be maintained neat and clean.

SECTION 1800
INFECTION CONTROL (I)

1801. General.

A. The hospital shall provide a safe and healthy environment that minimizes infection exposure and risk to patients, employees, health care workers, volunteers and visitors. The hospital shall implement and maintain a written, effective, organized, active, hospital-wide program for the surveillance, prevention, control, and investigation of infections, infectious agents and communicable diseases, with the goal of implementing best practices and continuously reducing infections. The infection prevention and control program must be implemented in a manner that minimizes the risk of health care associated infections. The hospital must designate a qualified employee as the hospital's Infection Practitioner, whose function is to administer the infection prevention and control program. The Infection Practitioner must be provided with the resources and assistance necessary to carry out the activities of the infection prevention and control program. Each hospital must assess the time requirement needed for surveillance and infection prevention activities at each of its locations and provide sufficient staffing to meet the organization's assessed needs.

B. Hospital policies and procedures for infection prevention and control shall comply with Federal and State laws and regulations and shall reference guidelines, including but not limited to, the following:

1. Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; 29 CFR 1910 Occupational Safety and Health Standards with emphasis on compliance with 29 CFR 1910-1030 (Bloodborne Pathogens);

2. The Center for Disease Control and Prevention's (CDC) Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPIC);

3. CDC's Guideline for Hand Hygiene in Health-Care Settings;

4. CDC's Guidelines for Environmental Infection Control in Health-Care Facilities;

5. CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities;

6. CDC's Guidelines for the Management of Multidrug-Resistant Organisms In Healthcare Settings;

7. ~~DHEC~~ Regulation 61-105;

8. CDC's Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings; and

9. CDC's Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005.

C. The hospital must comply with and demonstrate compliance with this regulation as well as their own policies and procedures.

1802. Infection Control Training.

A. The hospital shall require annual education regarding infection prevention and control for all employees, students, and volunteers who have contact with patients or who handle or potentially handle blood, body fluids, or tissue. If any of these persons work or perform tasks at more than one hospital, the hospital may accept infection prevention and control education received at another hospital or at an in-person or online seminar to meet this requirement, but only if the education is reported to and documented by the hospital.

B. Infection prevention and control education requirements may be met through in-person or online training, or completion of modules, videos or other training materials designed to convey such education.

C. In addition to general infection prevention education provided during initial orientation, each employee, student, and volunteer who has contact with patients or who handles or potentially handles blood, body fluids or tissue, shall receive infection prevention and control education specific to his/her job classification and work activities to inform him/her about the infection prevention and control policies and procedures of his/her position. Infection prevention and control training should be targeted to the functions of different categories of employees.

1803. Patient/Public Education and Disclosure.

Prior to or upon admission to the hospital as an inpatient or for outpatient surgery, the hospital must provide to patients materials designed to educate the patient and his/her responsible party about the prevention of healthcare associated infections and the public availability of healthcare associated infection reports through the Hospital Infections Disclosure Act, S.C. Code Ann. Section 44-7-2410, et. seq. The hospital must document provision of this information to the patient or responsible party. The hospital is not required to provide the information to the patient or responsible party if he or she is unable or unwilling to receive the information or if there is no responsible party.

1804. Live Animals.

Service animals, therapy animals, and personal pets may be permitted for strictly limited visitation pursuant to strict hospital policies; however, no non-human primates may be allowed in the hospital. Each hospital must have appropriate policies which require at a minimum that the animal is free of fleas, ticks, and intestinal parasites, has been screened by a veterinarian within the past twelve (12) months prior to entering the facility, has received all required inoculations, is clean and well-groomed, and presents no apparent threat to the health and safety of patients, visitors, employees or others. All animals must be supervised by persons who know the animal and its behavior and can control the animal.

1805. Laundry and Linens.

A. Linen includes surgical clothing. An adequate supply of clean, sanitary linen shall be available at all times.

B. The hospital shall have a clean linen storage area and a separate soiled linen storage area. These storage areas shall be used solely for their intended purposes. The soiled linen storage area shall have mechanical ventilation to the outside.

C. In order to prevent contamination of clean linen by dust or other airborne particles or organisms, linen shall be stored and transported in a sanitary manner, i.e., enclosed and covered. Clean linen shall be stored in a dedicated cart, closet, or cabinet which is covered and dedicated only for the use of clean linen. Non-linen items shall not be stored in the same cart as clean linen. Clean non-linen items may be stored in the same closet or cabinet as clean linen, but shall not be stored on the same shelf.

D. The hospital shall have policies addressing the storage, handling, distribution, collection, and reprocessing of linen for the hospital. If the hospital uses an off-site laundry, the hospital must ensure through contract that the linen is handled and cleaned properly to institutional standards. The hospital will assure that laundry services whether operated by the hospital or contracted will exercise necessary precautions to render all linen to be safe for reuse.

E. The hospital shall have policies for collecting, transporting, and storing all soiled linen. Soiled linen shall be kept in closed or covered containers while being collected, transported or stored and shall be stored separately from clean linen and patient areas. These containers shall be cleaned and disinfected weekly at a minimum and immediately if visibly soiled. Hospitals operating laundries within the buildings accommodating patients shall provide proper insulation to prevent transmission of noises to patient areas. The laundry shall be well ventilated and the general air movement shall be from the cleanest areas to the most contaminated areas.

F. All used linen must be handled as if it is infectious. Used linen shall be placed in durable bags which, by color or terminology, identify the contents as contaminated and must be transported in these closed bags to the soiled linen holding area or laundry. All linen from patients with infectious or communicable diseases shall be placed in durable bags identified “contaminated” and transported in these closed bags to the soiled linen holding area or laundry.

G. Soiled linen shall be neither sorted nor rinsed in patient rooms.

H. Laundry operations shall not be carried out in patient rooms or where food is prepared, served, or stored.

I. Soiled linen area floors shall be cleaned daily. The area shall be cleaned and disinfected weekly at a minimum and more frequently if necessary to control odors and bacteria.

J. If linen chutes are used, the linen shall be enclosed in durable bags, identified, by color or terminology, as contaminated, before placing in the chute. Chutes shall be cleaned monthly.

K. Personnel must wear appropriate protective attire in accordance with the hospitals policies and procedures. Personnel must wash their hands thoroughly after handling soiled linen.

1806. Waste Management.

A. The hospital shall be able to demonstrate that it has a comprehensive waste management program for identification, collection, handling, and management, of all medical waste, including nonhazardous and hazardous pharmaceutical waste.

B. The hospital shall provide for a regular review of its policies and procedures to assure compliance of its waste management practices in comparison with federal EPA and state regulatory requirements.

C. Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be disposed of in compliance with the following standards: Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; related regulations at 29 CFR 1910; the Department's *Guidelines for Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*; ~~DHEC~~ Regulation 61-105, and other applicable federal, state and local laws and regulations.

D. The hospital shall inform personnel involved in the handling and disposal of potentially infectious waste of health and safety hazards, and ensure that they are trained in appropriate handling and disposal methods.

E. The hospital shall have policies for the use and disposal of sharps. The hospital shall use sharps containers capable of maintaining their impermeability after waste treatment to avoid subsequent physical injuries during final disposal. Disposable syringes with needles, including sterile sharps that are being discarded, scalpel blades, and other sharp items must be placed into puncture-resistant containers located as close as practical to the point of use.

F. Regulated medical wastes awaiting treatment shall be stored in a properly ventilated area inaccessible to vermin. Waste containers that prevent development of noxious odors must be used. If treatment options are not available at the site where the medical waste is generated, the hospital must ensure transport of the regulated medical wastes in closed, impervious containers to the on- site treatment location or to another facility for treatment as appropriate. Regulated medical wastes must be treated by using a method (e.g., steam sterilization, incineration, interment, or an alternative treatment technology) in accordance with local, state and federal laws and regulations.

1807. Water Requirements.

A. The hospital shall establish written policies and procedures to prevent waterborne microbial contamination within the water distribution system.

B. The hospital shall ensure the practice of hand hygiene to prevent the hand transfer of pathogens, and the use of barrier precautions (e.g. gloves) in accordance with established guidelines.

C. The hospital shall eliminate contaminated water or fluid from environmental reservoirs (e.g. in equipment or solutions) wherever possible.

D. The hospital shall not place decorative fountains and fish tanks in patient-care areas. If decorative fountains are used in separate public areas, the hospital shall ensure that they are disinfected in accordance with manufacturer's instructions and safely maintained.

E. The hospital plumbing fixtures which require hot water and which are accessible to patients shall be supplied with water which thermostatically controlled to a temperature of at least 100 degrees F. (37.8 degrees C) and not exceeding 125 degrees F. (51.7 degrees C.) at the fixture.

F. The hospital shall have a written plan to respond to disruptions in water supply. The plan must include a contingency plan to estimate water demands for the entire facility in advance of significant water disruptions (i.e., those expected to result in extensive and heavy microbial or chemical contamination of the potable water), sewage intrusion, or flooding.

G.When a significant water disruption or an emergency occurs, the hospital shall:

1. Adhere to any advisory to boil water issued by the municipal water utility;

2. Alert patients, families, employees, volunteers, students and visitors not to consume water from drinking fountains, ice, or drinks made from municipal tap water, while the advisory is in effect, unless the water has been disinfected;

3. After the advisory is lifted, run faucets and drinking fountains at full flow for greater than 5 minutes, or use high-temperature water flushing or chlorination;

4. All ice and drinks that may have been contaminated must be disposed and storage containers cleaned; and

5. Decontaminate the hot water system as necessary after a disruption in service or a cross-connection with sewer lines has occurred.

H.The hospital shall adhere to Association for the Advancement of Medical Instrumentation (AAMI) standards for quality assurance performance of devices and equipment used to treat, store and distribute water in hemodialysis units and for the preparation of concentrates and dialysate.

I. The hospital shall follow appropriate recommendations to prevent cross connection and other sources of contamination of ice for human consumption, and to prevent contamination of hydrotherapy equipment and medical equipment connected to water systems (e.g. automated endoscope reprocessors).

J. The hospital shall maintain and implement policies and procedures addressing the management of failure of waste water systems.

SECTION 1900
DESIGN, CONSTRUCTION, REPAIRS, ALTERATIONS, AND ~~CONSTRUCTION~~ADDITIONS

1901. General. (II)

~~Every facility~~ The Facility shall be planned, designed, and equipped to provide ~~adequate facilities~~ for and promote the care, safety, and ~~treatment~~well-being of each patient. The Facility design shall be such that all patients shall have access to required services.

1902. Codes and Standards. (II)

~~The design and construction specifications for hospitals shall conform to the most current nationally accepted standards for hospital design set forth in the International Building Code (IBC); International Fire Codes (IFC); International Plumbing Codes (IPC); International Mechanical Codes (IMC); National Fire Protection Association (NFPA) codes – NFPA 10 – Standard for Portable Fire Extinguishers, NFPA 11 – Standard for Low-, Medium-, and High-Expansion Foam, NFPA 12 – Standard on Carbon Dioxide Extinguishing Systems, NFPA 12A – Standard on Halon 1301 Fire Extinguishing Systems, NFPA 13 –~~

~~Standard for the Installation of Sprinkler Systems, NFPA 13R - Standard for the Installation of Sprinkler Systems in Low-Rise Residential Occupancies, NFPA 14 - Standard for the Installation of Standpipe and Hose Systems, NFPA 15 - Standard for Water Spray Fixed Systems for Fire Protection, NFPA 16 - Standard for the Installation of Foam-Water Sprinkler and Foam-Water Spray Systems, NFPA 17 - Standard for Dry Chemical Extinguishing Systems, NFPA 17A - Standard for Wet Chemical Extinguishing Systems, NFPA 18 - Standard on Wetting Agents, NFPA 20 - Standard for the Installation of Stationary Pumps for Fire Protection, NFPA 22 - Standard for Water Tanks for Private Fire Protection, NFPA 24 - Standard for the Installation of Private Fire Service Mains and Their Appurtenances, NFPA 25 - Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems, NFPA 30 - Flammable and Combustible Liquids Code, NFPA 30A - Code for Motor Fuel Dispensing Facilities and Repair Garages, NFPA 52 - Vehicular Gaseous Fuel Systems Code, NFPA 54 - National Fuel Gas Code, NFPA 58 - Liquefied Petroleum Gas Code, NFPA 59 - Utility LP-Gas Plant Code, NFPA 70 - National Electrical Code®, NFPA 72 - National Fire Alarm and Signaling Code, NFPA 96 - Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations, NFPA 99 - Health Care Facilities Code, NFPA 101 - Life Safety Code®, and NFPA 110 - Standard for Emergency and Standby Power Systems; International Code Council (ICC) American National Standards I (ANSI) A117.1 - Accessibility Codes; the *Guidelines for Design and Construction of Health Care Facilities* as published by the Facility Guidelines Institute (FGI); and International Existing Building Code (IEBC).~~

A. Facility design and construction shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal. Further, the design and construction shall comply with the provisions of the Facility Guidelines Institute's (FGI) *Guidelines for Design and Construction of Hospitals* and *Guidelines for Design and Construction of Outpatient Facilities*. When conflict exists for compliance with the FGI *Guidelines* and officially adopted codes or this regulation, the Facility shall comply with the strictest provision.

B. Unless specifically required otherwise by the Department, all facilities shall comply with the codes and regulations applicable at the time of final plan approval by the Department.

1903. Submission of Plans. (II)

A. ~~When construction is contemplated either for new buildings, additions or major alterations or replacement to existing buildings, buildings being licensed for the first time, buildings changing license type, or facilities increasing occupant load/licensed capacity, plans and specifications shall be submitted to the Department for review. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. These submissions shall be made in at least three stages: schematic, design development, and final. All plans shall be drawn to scale with the title, stage of submission and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction the owner shall employ a registered architect and/or engineer for supervision and inspections. The Department shall conduct periodic inspections throughout each project.~~Plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina. Unless directed otherwise by the Department, the architect and/or engineer shall submit plans at the schematic, design development, and final stages. All plans shall be drawn to scale. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction, the Facility shall employ a registered architect and/or engineer for construction administration. Upon approval of the Department, construction administration may be performed by an entity other than the architect. The Department shall conduct periodic inspections throughout each project.

B. ~~When alterations are contemplated that are new construction, or projects with changes to the physical plant of a licensed facility which has an effect on: the function, use or accessibility of an area; structural integrity; active and passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under the said hood); door, wall and ceiling system assemblies; exit corridors; Increase the occupant load/licensed capacity; and projects pertaining to any life safety systems, require preliminary drawings and specifications, accompanied by a narrative completely describing the proposed work, shall be submitted to the Department Cosmetic changes utilizing paint, wall covering, floor covering, etc., that are required to have a flame spread rating or other safety criteria shall be documented with copies of the documentation and certifications, kept on file at the facility and made available to the Department.~~ Plans and specifications shall be submitted to the Department for a project that has an effect on:

1. The function of a space;

2. The accessibility to or of an area;

3. The structural integrity of the facility;

4. The active and/or passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under an exhaust hood);

5. Doors;

6. Walls;

7. Ceiling system assemblies;

8. Exit corridors;

9. Life safety systems; or

10. Increases the occupant load or licensed capacity of the facility.

C. The Facility shall submit ~~A~~all subsequent addenda, change orders, field orders, and documents altering the Department's review ~~must be submitted~~. Any substantial deviation from the accepted documents shall require written notification, review, and approval from the Department.

- D. The licensee shall pay the following inspection fees during the construction phase of the project. The plan inspection fee is based on the total estimated cost of the project whether new construction, an addition, or a renovation. The fees are detailed in the table below.

Construction Inspection Fees	
Plan Inspection	
Total Project Cost	**Fee**
< $10,001.00	$750
$10,001 $100,000-	$1,500
$100,001 - $500,000	$2,000
> $500,000	$2,500 plus $100 for each additional $100,000 in project cost
Site Inspection	

50% Inspection	$500
80% Inspection	$500
100% Inspection	$500

E. Cosmetic changes utilizing paint, wall covering, floor covering, etc., that are required to have a flame-spread rating, smoke development, or other safety criteria shall be documented with copies of the documentation and certifications kept on file at the facility and made available to the Department.

F. Any construction work which violates codes or standards will be required to be brought into compliance.

1904. Construction ~~Inspections~~Permits. (II)

~~Construction work which violates codes or standards will be required to be brought into compliance. All projects~~The Facility shall obtain all required permits (i.e., zoning and building) from the locality having jurisdiction for all projects. Construction without proper permitting shall not be inspected by Department.

1905. Patient Rooms.

A.~~Cubicle curtains with built-in curtain tracks shall be provided in all multiple bed rooms which will shield each patient completely. Curtains will be flameproof.~~ The Facility shall ensure that all curtains are flame proof (including cubicle curtains).

B. The Facility shall ensure patient ~~B~~beds ~~must be~~are placed with at least three feet ~~apart~~of clearance on three sides of the bed.

C. The Facility shall ensure ~~A~~at least one private room ~~shall be~~is provided in each nursing unit for purposes of medical isolation, incompatibility, personality conflicts, etc.

1906. Signal System. (II)

A signal system shall be provided for each patient. The system shall consist of a call button for each bed, bath, toilet and treatment/examination room; a light at or over each patient room door visible from the corridor; a control panel in utility rooms, treatment/examination rooms, medication rooms, nurses' lounges and floor kitchens. Indicators and control panels shall employ both an audible and visual signal.

1907. Nurses Station.

The ~~Hospital~~ Facility shall ensure ~~A~~each nurses' station ~~shall~~ serves no~~t~~ more than forty-four (44) beds, unless additional services and facilities are provided. In order for a nurses' station to be permitted to serve more than forty-four (44) beds, the Facility shall provide the Department, in writing, justification ~~must be furnished~~ showing how the additional beds served will not adversely affect the ~~health~~ care provided to each patient.

1908. Utility Rooms.

A.Soiled Utility Room~~:~~. The Facility shall ensure ~~A~~at least one soiled utility room per nurses' station ~~shall be~~is provided, which contains a clinical sink, work counter, hand wash sink, waste receptacle, and soiled linen receptacle.

B. Clean Utility Room. The Facility shall ensure ~~A~~at least one clean utility room per nurses' station ~~shall be~~is provided, which contains a counter with hand wash~~ing~~ sink, ~~and~~ space for the storage, and space assembly of supplies for nursing procedures. If the Facility provides individually sealed, one-time-use packaged items for patient care, a hand wash sink is not required.

~~Exception: Item B above does not apply to facilities licensed prior to May 1968.~~

C. Nourishment Room. The Facility shall ensure there is at least one nourishment room per nurses' station which contains a counter with hand wash sink, refrigerator, ice machine, space for storage, and space for the assembly of packaged food and drink for patient use.

~~1909. Temperature and Humidity. (II)~~

~~A. Minimum design temperature of 75 degrees F. (23.9 degrees C.) at winter design conditions and 81 degrees F. maximum summer design conditions shall be provided for all occupied areas not listed below. The systems shall be designed to provide the following temperatures and humidities in the areas noted:~~

~~Area~~	~~Temperature~~		~~Relative Humidity~~	
~~Designation~~	~~F~~	~~C~~	~~Minimum~~	~~Maximum~~
~~Operating Room~~	~~68-75~~	~~20.0-24.0~~	~~20~~	~~60~~
~~Recovery Rooms~~	~~75~~	~~23.9~~	~~30~~	~~60~~
~~Intensive Care Units~~	~~75-80~~	~~23.9-26.7~~	~~30~~	~~60~~

~~B. Perinatal design temperature and humidity shall follow the current edition of *Guidelines for Perinatal Care*.~~

SECTION 2000
FIRE PROTECTION, PREVENTION AND LIFE SAFETY (I)

2001. Alarms.

A. A partial, manual, automatic, supervised fire alarm system shall be provided. The system shall be arranged to transmit an alarm automatically to a third party by an approved method. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. There must be a fire alarm pull station in or near each nurses station.

C. All fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems must be connected to the main fire alarm system and trigger the system when they are activated.

2002. Emergency Generator Service.

A. Facilities shall provide certification that construction and installation of emergency generator service complies with requirements of all adopted State, Federal, or local codes, ordinances, and regulations.

B. An emergency generator shall be provided to deliver emergency electrical service during interruption of the normal electrical service and shall be provided to the distribution system as follows:

1. Exit lights and exit directional signs;

2.- Exit access corridor lighting;

3.- Lighting of means of egress and staff work areas;

4.- Fire detection and alarm systems;

5.- In patient care areas;

6.- Signal system;

7.- Equipment necessary for maintaining telephone service;

8.- Elevator service that will reach every patient floor when rooms are located on other than the ground floor;

9.- Fire pump;

10.— Equipment for heating patient rooms;

11.— Public restrooms;

12.— Essential mechanical equipment rooms;

13.— Battery-operated lighting and a receptacle in the vicinity of the emergency generator;

14.— Alarm systems, water flow alarm devices, and alarms required for medical gas systems;

15.— Patient records when solely electronically based.

2003. Fire Reports. (II)

The Facility shall immediately notify the Department by email to firewatch@dhec.sc.gov or other email address prescribed by the Department regarding any fire, regardless of size or damage that occurs in the facility, and followed by a complete written report to include fire department reports, if any, to be submitted within a time period determined by the facility, but not to exceed 7 business days.

2004. Fire Safety. (II)

The facility shall comply with the provisions of the codes officially adopted by the South Carolina Building Codes Council, and the South Carolina State Fire Marshal.

2005. Plans and Training for Fires. (II)

A. Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fires. All employees shall be made familiar with these plans and instructed as to required actions.

B. Each employee shall receive fire protection training.

C. A fire drill shall be conducted for each shift at least quarterly. Records of drills shall be maintained to report the date, time, shift and a description and evaluation of the drill.

D. Drills shall be designed and conducted to:

1. Assure that all personnel are capable of performing assigned tasks or duties;

2. Assure that all personnel know the location, use and how to operate firefighting equipment;

3. Assure that all personnel are thoroughly familiar with the fire plan; and

4. Evaluate the effectiveness of plans and personnel.

2006. Tests and Inspections. (II)

The Facility shall maintain and test all fire protection and suppression systems in accordance with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility.

2007. Gases.

The Facility shall take safety precautions against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously, and cylinders shall be properly secured in place.

2008. Furnishings and Equipment. (II)

A. The Facility shall maintain the physical plant free of fire hazards or impediments to fire prevention.

B. The Facility shall not permit portable electric or unvented fuel heaters.

C. The Facility shall require all wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows to be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant.

SECTION 2100
PREVENTIVE MAINTENANCE OF LIFE SUPPORT EQUIPMENT

A written preventive maintenance program for all life support equipment including, but not limited to, all patient monitoring equipment, isolated electrical systems, conductive flooring, patient grounding systems, and medical gas systems shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to ~~insure~~ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of life support equipment to indicate its history of testing and maintenance.

~~*SECTION 2200*~~
~~*GENERAL*~~

~~Conditions which have not been covered in these regulations shall be handled in accordance with the best practices as interpreted by the Department.~~

ATTACHMENT B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394, 44-37-40, 44-37-50, and 44-41-70(a)

Notice of Drafting:

The Department of Health and Environmental Control ("Department") proposes amending R.61-16, Minimum Standards for Licensing Hospitals and Institutional General Infirmaries. Interested persons may submit written comments to the Healthcare Quality Office of Policy and Communications, S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; HQRegs@dhec.sc.gov; or the Healthcare Quality Public Comment Form (forms.office.com/g/9VMEXLWtq0). To be considered, the Department must receive comments no later than 5:00 p.m. on August 28, 2023, the close of the Notice of Drafting comment period.

This notice supersedes the Notice of Drafting that was published in South Carolina State Register Volume 47, Issue 3 on March 24, 2023.

Synopsis:

Pursuant to S.C. Code Sections 44-7-250 and -260(A)(1), the Department establishes and enforces minimum standards for the licensure, maintenance, and operation of hospitals to ensure the safe and appropriate treatment of persons served in this state. The Department proposes amending R.61-16, Minimum Standards for Licensing Hospitals and Institutional General Infirmaries, to ensure alignment with current state laws and to update and revise definitions, license requirements and fees, staff and training, reporting, disaster management, accommodations for patients, patient care and services, perinatal services, design and construction, fire protection, prevention and life safety, and policies and procedures.

The proposed amendments may also include stylistic changes, which may include corrections for clarity and readability, grammar, punctuation, definitions, references, codification, and overall improvement of the text of the regulation.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

ATTACHMENT C

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

R.61-16, Minimum Standards for Licensing Hospitals and Institutional General Infirmaries

As of August 28, 2023, close of the Notice of Drafting comment period:

Name	Section
Tidelands Health	**General**
Comment: **Cardiac Catheterization** **Changes to the state's Certificate of Need program via 2023 Act 20 greatly impact licensing for hospitals. Specifically, Tidelands Health would like to comment regarding licensure requirements for cardiac catheterization laboratories. We would encourage DHEC to adopt the cardiac catheterization safety, quality and reporting requirements currently contained in the State Health Plan as licensure requirements in 61-16, with updates as needed to align with current Society for Cardiovascular Angiography & Interventions, American College of Cardiology (ACC) and the American Heart Association (AHA) guidelines.** **We would also strongly encourage DHEC to consider additional or standalone regulations/licensure requirements for the provision of cardiac catheterization and other cardiac services in ASFs and freestanding, non-hospital cardiac catheterization laboratories that, with the passage of 2023 Act 20, do not currently require a CON or licensure by DHEC. Of particular importance is the development of regulations specifying the types of procedures these facilities can/cannot perform and the process of referring/transferring patients to qualified hospitals in case of adverse outcomes.** **Department Response:** **Not Adopted. The proposed amendments to the regulation address quality and safety of care of all areas in the hospital. At this time, Department staff have not determined it necessary to include provisions specifically addressing cardiovascular services/procedures.**	
Name	**Section**
Trident Health	**General**
Comment: **Cardiovascular Services** **Trident Medical Center agrees with SCHA on the following recommendation pertaining to cardiovascular services.** **Since May 25, 2023, South carolina has been without a regulatory scheme to ensure the quality and safety of cardiovascular care. Prior to that date, South Carolina's certificate of need ("CON") laws, provided such protection by requiring applicants wishing to provide cardiac catheterizations and open-heart surgery in South Carolina to ensure they would meet certain standards. This regulatory revision is DHEC's first, and hopefully not its last, opportunity to remedy this patient safety issue.** **Implementing rigorous standards for cardiovascular services in hospital licensure is critical**	

to maintaining safe cardiac care in South Carolina. The 2020 South Carolina Health Plan ("State Health Plan") provides the appropriate standards for the regulation of cardiac care in South Carolina hospitals. See Chapter 8, pp. 65-81. These standards have been thoroughly vetted by various health care policy making authorities and are familiar to South Carolina's regulated community. Trident Medical Center is in agreement with SCHA in suggesting DHEC incorporate the following language into Regulation 61-16 for hospital-based cardiac catheterization and open-heart surgery.

SCHA recommends adopting the definitions for cardiac catheterizations contained on pages 65 - 66 of the State Health Plan. Additionally, SCHA would recommend DHEC incorporate the cardiac catheterization "Scope of Services" section from the State Health Plan into Regulation 61-16. State Health Plan pp. 66-67.

The State Health Plan also contains a set of standards for cardiac catheterization volumes. The higher the volume the better the care. These standards are set by the American Heart Association, American College of Cardiology, and Society for Cardiovascular Angiography and Interventions ("SCAI").

In the absence of CON, projecting volume standards is no longer necessary. The standards, however, are still an excellent method for evaluating cardiac catheterization programs. SCHA would urge DHEC to incorporate those same volume standards into Regulation 61-16 for the evaluation of catheterization procedures and catheterization labs.

The State Health Plan includes specific numbers for various catheterization procedures (e.g. 200 minimum diagnostic catheterizations procedures annually). SCHA suggests DHEC omit the specific numbers and instead refer only to the applicable standards published by the American Heart Association, American College of Cardiology, and SCAI. Doing so prevents a scenario where volumes change, but the regulatory process is too slow to adapt.

Florida has language (See Fla. Admin. Code Ann. R. 59A-3.246.) that could serve as model:

All licensed hospitals that establish adult diagnostic cardiac catheterization laboratory services under section 408.0361, F.S., shall operate in compliance with the most recent guidelines of the American College of Cardiology/American Heart Association regarding the operation of diagnostic cardiac catheterization laboratories. Hospitals are considered to be in compliance with American College of Cardiology/American Heart Association guidelines when they adhere to standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.

In addition, SCHA requests certain cardiac catheterization procedures and catheterization labs remain hospital based. Specifically, percutaneous coronary interventions ("PCIs") and comprehensive catheterization laboratories. According to the American College of Cardiology/American Heart Association/SCA! standards these services and facilities are best provided and located in hospitals for patient safety reasons. SCHA proposes the same standards apply in Regulation 61-16.

Department Response:
Not Adopted. The proposed amendments to the regulation address quality and safety of care of all areas in the hospital. At this time, Department staff have not determined it necessary to include provisions specifically addressing cardiac catheterization procedures. Moreover, Department staff have concerns that adding volume thresholds in the State Health Plan would be

inconsistent with the General Assembly's intent in repealing Certificate of Need ("CON") requirements for offering/establishing health services in hospitals.

Name	Section
Trident Medical Center	General

Comment:
<u>Open Heart Surgery</u>
Trident Medical Center agrees with SCHA on the following recommendation pertaining to open heart.

Trident Medical Center recommends DHEC the State Health Plan definitions and scope of services for open heart surgery. State Health Plan pp 75-77. DHEC should also incorporate the applicable standards published by American Heart Association/American College of Cardiology/SCA! for open heart surgery and include all of the standards contained in the State Health Plan on pages 77-80. Just as with cardiac catheterization however, DHEC should convert the standards from projections to retrospective volume reviews for the service year.

Department Response:
Not Adopted. The proposed amendments to the regulation address quality and safety of care of all areas in the hospital. At this time, Department staff have not determined it necessary to include provisions specifically addressing open heart surgery. Moreover, Department staff have concerns that adding volume thresholds in the State Health Plan would be inconsistent with the General Assembly's intent in repealing CON requirements for offering/establishing health services in hospitals.

Name	Section
Trident Medical Center	General

Comment:
Additional Cardiovascular care Regulation Needed
Trident Medical Center agrees with SCHA on the following recommendation pertaining to the need of regulation for cardiovascular care.

The absence of regulation of cardiovascular services poses significant risk for South Carolina patients. Unfortunately, placing standards in Regulation 61-16 alone will not eliminate this risk. Without CON, physicians can perform cardiovascular services in ambulatory surgery centers and possibly other locations. Trident Medical Center strongly encourages the Department to open the ambulatory surgery center regulation 61-91 for comment as soon as possible. In addition, DHEC should examine whether Regulation 61-108, Standards for Licensing Freestanding or Mobile Technology is another possible mechanism for regulating cardiovascular care in South Carolina. If so, it should open those regulations for comment.

Finally, Trident Medical Center would encourage DHEC to work with the South Carolina Board of Medical Examiners to modify the office-based surgery rules to include regulation of cardiovascular procedures as well.

Department Response:
Acknowledged.

Name	Section
Trident Medical Center	General

Comment:
Development of New Hospital:
Trident Medical Center request DHEC clarify rules on the development of a new hospital.
Trident Medical Center recommends the following language:

"In order to license a new hospital, the new hospital:
1. must contain both surgical and non-surgical beds;
2. must provide medical and surgical services with at least twelve (12) of the major diagnostic categories as recognized by the Centers for Medicare and Medicaid Services (CMS);
3. must accept all governmental payers;
4. must have a 24-hour emergency services department."

Trident Medical Center would not support any language that would mandate a minimum number of beds to be licensed in a new hospital.

Department Response:
Not Adopted. At this time, Department staff determined the proposed additions are unnecessary for ensuring safe and adequate treatment for persons served in SC hospitals. Further, Department staff have concerns that the adoption of the proposed additions would be inconsistent with the intent of the General Assembly in sunsetting CON requirements for construction or establishment of hospitals.

Name	Section
Caroline Miler Titze	**1306.C**

Comment:
This letter requests that DHEC amend Section 1306 (CJ related to Level III neonatal intensive care unit to remove the arbitrary 100 very low birth weight volume requirement of 100 which serves to basically restricts competition and access to care by virtually preventing any additional, otherwise qualified hospitals, from achieving a Level III designation.

If Summerville Medical Center opened a Level III Neonatal Intensive Care Unit, they would be able to provide quality care close to home for all mothers and families here in Summerville. Additional beds would improve access to a higher level of NICU services closer to home and would prevent new parents from being separated from their newborns, and overall improve newborn health.

Thank you for your consideration. I hope that you will take the steps as you propose changes to R.61-16 that will improve access to a Level III NICU in Summerville and Dorchester counties.

Department Response:
Not Adopted. Department staff have determined to revise this section at a later date. Additional input from the community and stakeholders will be needed. Department staff's plan with respect to revising the perinatal sections will be forthcoming.

Name	Section
Coastal Carolina Hospital	**1201**
Comment:	

I have reviewed the comments being submitted by the South Carolina Hospital Association regarding additions to Regulation 61-16 regarding FEDS, and I concur with SCHA's proposed changes.

I recommend that Regulation 61-16 be amended to incorporate specific standards for FEDs in South Carolina that require the facility to:

1. Operate under the license of an existing South Carolina hospitals emergency service.

2. Be required to meet the same licensures standards as hospital emergency services with respect to staffing, construction, and availability of services.

3. Be located within 35 miles of the existing hospital under whose license it operates or in a county without a hospital.

Department Response:
Adopted. See Section 1201.D.5.

Name	Section
Lexington Medical Center, Shelley Pifer	**General**

Comment:
Freestanding Emergency Department
Lexington Medical Center supports SCHA's recommendation to apply a 35-mile radius requirement to the construction of a Freestanding Emergency Department, which means a FSED must be within a 35-mile radius of the hospital opening and operating the FSED. As noted by SCHA, this is a change from the county-based requirement in the State Health Plan.
LMC would also like to recommend that the FSED, must accept all governmental payers and if a for-profit facility then >3% indigent/charity cases.

Department Response:
Partially adopted. Regarding the recommended FSED requirements, please see Section 1201.D.5. At this time, Department staff determined the proposed addition of acceptance of all government payers was unnecessary for ensuring safe and adequate treatment for persons served in SC hospitals.

Name	Section
Trident Medical Center	**General**

Comment:
Free Standing Emergency Departments
Trident Medical Center agrees with SCHA on the following recommendation pertaining to FSEDs.

CON repeal also leaves questions about Free-Standing Emergency Departments ("FSEDs") in South Carolina. Trident Medical Center requests DHEC make clear only South Carolina licensed hospitals can open and operate FSEDs in South Carolina. Additionally, Trident Medical Center recommends DHEC adopt the 35-mile radius requirement to the FSED that CMS uses.

Trident Medical Center recommends the following language:

"A hospital licensed in South Carolina may open and operate a free-standing emergency department within a 35-mife radius of its hospital campus. This free-standing emergency department shall be an extension of the existing hospital's emergency service."

Department Response:
Adopted. See Section 1201.D.5.

Name	Section
Shelley Pifer	**General**

Comment:
Development of a New Hospital
Lexington Medical Center recommends the following criteria for the development of a new hospital to be added to Regulation 61-16:
1) The new hospital must contain both surgical and non-surgical beds.
2) The new hospital must provide medical and surgical services with at least twelve (12) of the major diagnostic categories as recognized by the Centers for Medicare and Medicaid Services (CMS).
3) The new hospital must accept all governmental payers and provide charity care.
4) The new hospital must be licensed for a minimum of 75 beds unless the hospital will be built in a critical access area.
5) The new hospital must have a 24-hour emergency services department.

Department Response:
Not Adopted. At this time, Department staff determined the proposed additions are unnecessary for ensuring safe and adequate treatment for persons served in SC hospitals. Further, Department staff have concerns that the adoption of the proposed additions would be inconsistent with the intent of the General Assembly in sunsetting CON requirements for establishment/construction of hospitals.

Name	Section
Hilton Head Medical Center	**General**

Comment:
I have reviewed the comments being submitted by the South Carolina Hospital Association regarding additions to Regulation 61-16 regarding FEDS, and I concur with SCHA's proposed changes.

I recommend that Regulation 61-16 be amended to incorporate specific standards for FEDs in South Carolina that require the facility to:

I. Operate under the license of an existing South Carolina hospital's emergency service.

2. Be required to meet the same licensures standards as hospital emergency services with respect to staffing, construction, and availability of services.

3. Be located within 35 miles of the existing hospital under whose license it operates or in a county without a hospital.

Department Response:
Adopted. See Section 1201.D.5.

Name	Section
Hilton Head Medical Center	General

Comment:

Cardiovascular Services

Regulation 61-16 does not specifically regulate the provision of specialized interventional cardiovascular services such as therapeutic catheterization and open heart surgery. Previously these services were regulated by CON based on standards set forth in the SCHP.

There is a substantial body of clinical evidence that the quality of patient outcomes from these specialized procedures is related to the volume of procedures performed. This quality/volume relationship holds for both the facility where these procedures are performed and the operators (physicians) performing the procedures.

Moreover, development of these facilities requires a substantial investment in facilities, equipment, and the recruitment and training of specialized clinical staff. Growth in the volume of these specialized cardiovascular procedures has slowed in recent years as newer, alternative technologies have been developed. The proliferation of programs performing therapeutic catheterizations, such as percutaneous coronary intervention ("PCI"), and open heart surgeries will necessarily result in the reduction in volumes at existing providers, which could negatively affect quality. In addition, there is a shortage of trained clinical staff to perform these procedures, and a significant expansion in the number of these programs will challenge both existing and new providers to attract needed clinical staff at a reasonable cost. Hospitals must maintain these services 24 hours per day/7 days per week, which is in the best interest of the community. Maintaining continuous coverage may be impacted or the availability of services in some instances may become compromised if specialized staff is spread over multiple, non-emergent sites.

Another concern is that the lack of licensure standards for these specialized cardiovascular services will lead to these procedures being performed in settings outside of a hospital. For example, there is a trend in states without CON or licensure regulation of specialized cardiovascular services for ambulatory surgery center ("ASCs") to perform PCI procedures. Performing PCis in an ASC setting presents a significant risk for patients who experience serious complications from the procedure such as the perforation of an artery. ASCs do not offer even basic emergency services, and a patient experiencing a life-threatening event would need to be stabilized and transported to a hospital offering comprehensive cardiac care, which could be a significant distance away.

The absence of licensure regulations for specialized cardiovascular programs is particularly concerning with respect to pediatric services. Currently, only the Medical University of South Carolina performs specialized cardiovascular procedures on pediatric patients in South Carolina. The number of such procedures is relatively small, and there are a limited number of pediatric cardiologists, pediatric cardiovascular surgeons, and other highly trained support staff to operate a high quality pediatric program. Concentrating these services in the state's most comprehensive pediatric hospitals is appropriate to ensure the best outcomes for patients. The creation of new pediatric specialized cardiovascular programs at other hospitals will challenge both the quality and economic feasibility of these services for South Carolina's pediatric population.

I have reviewed the recommendations submitted by SCHA regarding the addition of cardiovascular services to Regulation 61-16 and agree that the standards set forth in the 2020 South Carolina Health Plan provide a reasonable framework for licensure standards. Specifically, SCHA requests certain cardiac catheterization procedures and catheterization labs remain hospital based. Specifically, I recommend that:

1. The performance percutaneous adults coronary interventions ("PCis") and the operation of comprehensive catheterization laboratories' shall be limited to hospitals. In addition, new providers seeking licensure to perform PC/ and other therapeutic cardiac catheterizations shall meet all other standards listed on pp. 69-74 of the 2020 South Carolina Health Plan.

2. New providers seeking to licensure to perform pediatric or adult open heart surgery must be a licensed South Carolina hospital and comply with the standards listed on pp. 77-81 of the 2020 South Carolina Health Plan.

3. New providers seeking licensure to perform pediatric cardiac catheterization shall be required to comply with the standards set forth on pp. 72-73 of the 2020 South Carolina Health Plan.

Regulation 61-16 should make clear that the above new standards apply only to new providers and not to providers already authorized to perform these services as of the date of adoption of the amended regulation

Department Response:
Not Adopted. The proposed amendments to the regulation address quality and safety of care of all areas in the hospital. At this time, Department staff determined the addition of standards specific to cardiovascular care services is unnecessary to ensure the safe and adequate treatment for persons served in South Carolina hospitals. Moreover, Department staff have concerns that incorporation of volume standards prescribed by the State Health Plan would be inconsistent with the General Assembly's intent in eliminating CON requirements for establishing or offering health services in hospitals.

Name	Section
Shelley Pifer	**General**

Comment:
Radiation Oncology
LMC recommends the following language be added to Regulation 61-16 regarding Radiation Oncology and freestanding cancer centers:
1) A freestanding cancer center must have a hospital transfer agreement with a hospital that is located in the county that is the closest to the facility.
2) A freestanding cancer center must accept all governmental payers and provide charity care.

Department Response:
Not Adopted. The present regulation amendment concerns the licensure requirements for hospitals, not freestanding cancer centers.

Name	Section
Shelley Pifer	**101**

Comment:

Lexington Medical Center supports SCHA's public comment about adding a definition to this section for "acute hospital care at home."

Department Response:
Not adopted. The Department lacks statutory authority to license and regulate acute hospital care at home. If a hospital intends to provide acute hospital care at home services, such services would not be provided under its hospital license.

Name	Section
Shelley Pifer	**505**

Comment:
Lexington Medical Center supports SCHA's public comment regarding "nursing ratios" in this section. LMC agrees with SCHA in that specific nurse-to-patient ratios should not be mandated and supports SCHA's request to avoid mandating nurse ratios in Regulation 61-16.

Department Response:
Acknowledged. Department staff have not proposed revising the regulation to establish nursing ratio requirements.

Name	Section
Spartanburg Regional Healthcare System	**505**

Comment:
505.G Procedure Manual
SRHS recommends that the section be updated to note that the procedure manual may either be written or electronic.

Department Response:
Partially Adopted. Department staff propose deleting 505.G regarding procedure manuals for nursing personnel. However, Department staff have proposed adding Section 401 regarding policies and procedures, including Section 401.B's requirement that such policies and procedures be accessible either electronically or in print.

Name	Section
Spartanburg Regional Healthcare System	**506.C**

Comment:
506.C.2 Nursing
SRHS recommends that licensees have the option to maintain a printed nursing license or have the ability to access national database who provide notification of license issues.
506.C.2 Personnel Policies:
Given the extensive nature of the personnel policies, SRHS requests the Department clarify the regulations to define annual review or recommends that licensees are required to review them no less than every two years.

Department Response:
Partially adopted. Regarding the comment that Facilities have the option to maintain printed nursing licenses, Department staff propose amending Section 506.D to allow facilities to have a procedure for ensuring nursing personnel have valid and current licensure.

Partially adopted. Regarding review of personnel policies and given the extensive nature of policies and procedures, Department staff propose deleting the noted language concerning

personnel policies in the current Section 506.D and amending Section 401.B to allow Facilities to establish a time period for review of all their policies and procedures.

Name	Section
Tidelands Health	**506.D**

Comment:
Tidelands Health would recommend clarifying the definition of "personnel policies" in this section to refer to policies associated with hospital employees (excluding patient care and other policies). Tidelands Health would also recommend changing the review requirement for personnel policies from one year to at least two years.

Department Response:
Partially adopted. Department staff propose deleting the noted language concerning personnel policies in the current Section 506.D and amending Section 401.B to allow Facilities to establish a time period for review of all their policies and procedures.

Name	Section
McLeod Health	**506.D**

Comment:
McLeod Health recommends providing clarity on this section of the regulation. Although Section 506D is designated as an Employee section, it addresses policies and practices, which support sound patient care. At times, the Department has applied this regulation to all policies, thus requiring an annual review of all policies. McLeod Health recommends a risk-based methodology to determine the cadence of policy review.

Department Response:
Partially adopted. Department staff propose deleting the noted language concerning personnel policies in the current Section 506.D and amending Section 401.B to allow Facilities to establish a time period for review of all their policies and procedures.

Name	Section
Lexington Medical Center, Shelley Pifer	**702**

Comment:
Lexington Medical Center supports SCHA's public comment regarding providing more clarity on the reporting requirement in this section. Lexington Medical Center supports aligning this section with the National Quality Forum accident/incident reporting requirements.

Department Response:
Adopted. See Section 701.B.

Name	Section
Tidelands Health	**702**

Comment:
Currently, there is significant uncertainty within the hospital community about this section of the regulation and what needs to be reported.
One solution would be for DHEC to join other states in adopting National Quality Forum or Joint Commission accident/incident reporting requirements, which would help clear up ambiguity.
Otherwise, we would suggest amending the language as follows:

702(A)(A): Clarify the first sentence to indicate that records shall be retained by the facility.
702(A)(1): Clarify that suicides of patients and staff occurring in the facility shall be reported.
702(A)(4): Clarify this section applies to major factures or head injuries involving patients, staff or visitors.
702(A)(6): Clarify this section applies to criminal events and assaults involving patients, staff or visitors. To avoid confusion, we believe it is important to define assault and clarify the severity of what should be reported.
In addition, we would suggest DHEC clarify the definitions of "serious injury" and "injury" in this section, as follows:
"Serious injury" describes an event that can result in death, loss of a body part, disability, loss of bodily function, or require major intervention for correction (e.g., higher level of care, surgery).
"Injury" means physical or mental damage that substantially limits one or more of the major life activities of an individual in the short term, which may become a disability if extended long term. Further, injury includes a substantial change in the patient's long-term risk status such that care or monitoring, based on accepted national standards, is required that was not required before the event.

Department Response:
Adopted. See Section 701.B.

Name	Section
Shelley Pifer	**705**

Comment:
Lexington Medical Center suggests that the Joint Annual Reports as required by hospitals should be submitted by March 31st of the calendar year. This is six months into the fiscal year since many of the hospitals in the state are on a fiscal year of October 1 to September 30. Providing a definite timeline would avoid spotty submissions and would make the data timelier and more meaningful.

Department Response:
Not Adopted. Individual hospitals have different fiscal years.

Name	Section
Tidelands Health	**900**

Comment:
Every hospital in South Carolina is a signatory to the statewide Mutual Aid Agreement ("MAA"). It reflects the basic tenets of a cooperative and coordinated response plan and sharing of resources in the event of an emergency. The MAA is a primary component of most hospitals' disaster preparedness plan. Given the uniform use of the MAA statewide, Tidelands Health believes reference to the MAA should be incorporated into § 900 and a hospital's participation in the MAA should be considered satisfaction of the requirements contained in § 901.

Department Response:
Not Adopted. The MAA does not meet all of the regulatory requirements for Emergency Disaster Preparedness.

Name	Section
Trident Medical Center	**901**

Comment:
Regulation 61-16 Section 901 Emergency Evacuation (A)

Trident Medical Center would request the following changes to the language in Section A:
"All facilities shall develop, by contact and consultation with their ~~county~~ city and/or county emergency preparedness agency, a suitable written plan for actions to be taken in the event of a ~~disaster~~ emergency situation and/or ~~emergency~~ evacuation. In the event of mass casualties, the facility shall provide resources as available. Additionally, in instances where there are applications for increases in licensed bed capacity, the emergency evacuation plan shall be updated to reflect the proposed new total licensed bed capacity. The plan shall be updated, as appropriate, annually, or as needed."

Department Response:
Not Adopted. During an emergency, the Department communicates with the County Emergency Management.

Name	Section
Trident Medical Center	**901**

Comment:
Regulation 61-16 Section 901Emergency Evacuation - Request to Add New Section (F)
Regulation 901 for Emergency Evacuation requires significant pre-planning and submission of plans to the Department. Given that hospital operators are best able to gauge the ability to safely care for patients through an Emergency situation like a hurricane, we would recommend that if hospitals comply in submitting by June 1 annually their Critical Data Sheet, Sheltering Plan, Transportation Plan and Staffing Plan, that these hospitals would be automatically granted the ability to Shelter in Place during an Emergency Event or Hurricane.

Trident Medical Center recommends the following language be added:

"If, in compliance with Regulation 61-16, Section 901, a hospital complies in submitting their Emergency Evacuation Critical Data Sheet, Sheltering Plan, Transportation Plan and Staffing Plan by June 1 annually, the hospital would automatically be granted the ability to shelter in place during an emergency event, storm or hurricane up to the level proscribed in their plans and documents."

This would formalize the actions that the Department has in fact take over the past 12 months into the Regulations.

Department Response:
Not Adopted. Mandatory Medical Evacuation (MME) Orders and facilities' ability to shelter in place may vary based upon input from other agencies and offices. The submission of mentioned sheets and plans does not automatically grant the hospital the ability to shelter in place.

Name	Section
Trident Medical Center	**901.D.2.d**

Comment:
Trident Medical Center agrees with SCHA on the following recommendation pertaining to emergency evacuations.

This regulation requires an emergency transportation plan to include primary and secondary routes to a sheltering facility. Trident Medical Center recommends deleting this provision because the advent of GPS and mapping technology will allow for the most appropriate route at the time of transport based on conditions at the time.

Department Response:
Adopted. See Section 901.B.2.

Name	Section
Tidelands Health	**901.D.2.d**

Comment:
This provision of the regulation requires an emergency transportation plan to include primary and secondary routes to a sheltering facility. Tidelands Health recommends deleting this provision because the advent of GPS and mapping technology allow for the most appropriate route during transport based on conditions at the time.

Department Response:
Adopted. See Section 901.B.2.

Name	Section
Trident Medical Center	**902**

Comment:
Trident Medical Center agrees with SCHA on the following recommendation pertaining to internal medical surge.

Trident Medical Center would propose the language change to allow a hospital to notify DHEC of the emergent situation rather having to wait for DHEC to concur an emergency exists. Hospitals are best suited to determine whether an internal emergency exists within their facility. Notification will still allow DHEC to understand the nature of the emergency and will not enable the hospital to implement its internal surge plan avoiding possible delays that could impact patient care.

Department Response:
Adopted. See Section 902.A.

Name	Section
Tidelands Health	**902.B.1**

Comment:
This provision of the regulation requires a hospital facing an emergency request concurrence from DHEC prior to activating internal medical surge protocols. This approach can unnecessarily delay implementation of the surge plan.
Instead, Tidelands Health would propose amending this section to require hospitals to notify DHEC of the emergency rather than waiting for DHEC to agree an emergency exists. This would provide DHEC needed information about the emergency while allowing hospitals to rapidly implement surge plans and respond most efficiently and effectively to support patient care in an emergency.

Department Response:
Adopted. See Section 902.A.

Name	Section
McLeod Health	**1002.B**

Comment:
Department of Health and Environmental Control (Department) Regulation 61-16 Section 1002(B) limits bed placement to areas designed as patient room areas "except in cases of justified

emergencies." McLeod Health understands there are also fire code limitations related to hallway beds that are beyond the scope of this regulation but ultimately, hospitals would like more flexibility to determine when it is appropriate to place patients in hallway beds. To that end, McLeod Health is offering two suggestions to address the hallway bed issue. We are hopeful the Department will consider them and other possible strategies during this regulatory review process.

One method for addressing hallway beds would be to allow hospitals to classify some areas, like emergency departments, as "suites" instead of individual rooms off a corridor. This concept is more fully described in sections 18/19.2.5.7 of the Joint Commission's Life Safety Code. The suite concept promotes free movement of caregivers with easy access to patients, equipment, and supplies. Providing for suite classification in Regulation 61-16 might be one method for alleviating the hallway bed issue.

Another concept to explore would be expanding the definition of "justified emergency." As all South Carolina hospitals have seen throughout the last three years, emergency departments and hospital beds can fill up quickly. Even in non-pandemic times, emergency departments (ED) can quickly become overcrowded or have several high acuity cases that demand the attention of many caregivers working in the ED. Perhaps the Department, in partnership with hospitals, could develop a formula that accounts for the acuity of patients being seen in the ED, the number of patients waiting to be seen, and the average wait times for those patients in the waiting area. Once the formula exceeds a certain threshold, then the hospital can begin to treat some patients in hallway beds. As long as a hospital was operating at or above that threshold, then treatment of hallway beds would qualify as a justified emergency. McLeod Health recommends DHEC review the NEDOCS score, as a potential formula for determining a "justified emergency."

Department Response:
Not Adopted. Department staff have fire life and safety and patient privacy concerns with the proposed amendments. Department staff are open for discussion to address this issue.

Name	Section
Tidelands Health	**1002.B**

Comment:
Section 1002(B) limits bed placement to areas designed as patient room areas "except in cases of justified emergencies."
To support the health and safety of patients, it's important hospitals have flexibility in their use of hallway beds to support patient care. On any given day or time, hospitals can experience surges of patients or unusually high numbers of high-acuity, resource-intensive patients.
The South Carolina Hospital Association has proposed classifying some areas of the hospital, such as emergency departments, as suites rather than individual rooms off a corridor as described in sections 18/19.2.5.7 of the National Fire Protection Association's Life Safety Code. The suite concept could be one approach for alleviating the hallway bed issue.
The Association has also proposed consideration of a formula for determining when the use of hallway beds is appropriate that could consider, for example, the acuity of patients being seen in the ER, the number of patients waiting to be seen and the average wait times for those patients in the waiting area.
Tidelands Health supports further exploration of these ideas as part of the review of 61.16 and would welcome an opportunity to participate in discussions with DHEC about this issue.

Department Response:

Not Adopted. Department staff have fire life and safety and patient privacy concerns with the proposed amendments. Department staff are open for discussion to address this issue.

Name	Section
Trident Medical Center	**1002.B**

Comment:

Regulation 61-16 Section 1002 Locations of Beds (B)

Trident Medical Center agrees with SCHA on the following recommendations pertaining to the location of beds.

Section 1002(8) limits bed placement to areas designed as patient room areas "except in cases of justified emergencies." Trident Medical Center understands there are also fire code limitations related to hallway beds that are beyond the scope of this regulation but ultimately, hospitals would like more flexibility to determine when it is appropriate to place patients in hallway beds. To that end, SCHA is offering two suggestions to address the hallway bed issue. Trident Medical Center is hopeful the Department will consider them and other possible strategies during this regulatory review process.

One method for addressing hallway beds would be to allow hospitals to classify some areas, like emergency departments, as "suites" instead of individual rooms off a corridor. This concept is more fully described in NFPA 101 Life Safety Code used by the Joint Commission. The suite concept promotes free movement of caregivers with easy access to patients, equipment, and supplies. Providing for suite classification in Regulation 61-16 might be one method for alleviating the hallway bed issue.

Another concept to explore would be expanding the definition of "justified emergency." As all South Carolina hospitals have seen throughout the last two years, emergency departments and hospital beds can fill up quickly. Even in non-pandemic times, emergency departments can quickly become overcrowded or have several high acuity cases that demand the attention of many caregivers working in the ED. Perhaps DHEC in partnership with hospitals could develop a formula that accounts for the acuity of patients being seen in the ED, the number of patients being waiting to be seen, and the average wait times for those patients in the waiting area. Once the formula exceeds a certain threshold, then the hospital can begin to treat some patients in hallway beds. As long as a hospital was operating at or above that threshold, then treatment of hallway beds would qualify as a justified emergency.

Ultimately, South Carolina's hospitals and health systems, SCHA, and DHEC all want to best possible health outcome for our citizens. Hallway beds are a complex problem that deserves continued discussion and analysis.

Department Response:

Not Adopted. Department staff have fire life and safety and patient privacy concerns with the proposed amendments. Department staff are open for discussion to address this issue.

Name	Section
Shelley Pifer	**1105**

Comment:

With the rise of identity theft cases, only the most essential demographic information should be required from a patient to decrease the patient's risk of ID theft. Therefore, Lexington Medical Center suggests the following changes to this section:

A.1: An admission record must be prepared for each patient and must contain the following information, when obtainable: Name; address, including county; ~~occupation~~; age; date of birth; sex; marital status; religion; ~~county of birth; father's name; mother's maiden name; husband's or wife's names; dates of military service~~; health insurance number; provisional diagnosis; case number; days of care; social security number; ~~the name of the person providing information~~; name, ~~address~~, and telephone number of person or persons to be notified in the event of emergency; name ~~and address~~ of referring physician; name ~~and address and telephone number~~ of attending physician; date and hour of admission;

Department Response:
Adopted. See Section 1105.A and -B.

Name	Section
Tidelands Health	**1201.D**

Comment:
This regulation requires that all medication variances and adverse drug be reported immediately to the prescriber, supervising nurse and pharmacist and included in the patient's record. Tidelands Health would suggest amending this section of the regulation to clarify that medication variances and adverse drug reactions shall be reported as soon as possible to the prescriber, supervising nurse and pharmacist if it could affect the patient's safety or quality of care. Variances and
adverse drug reactions should also be reported to the FDA Adverse Event Reporting System as required by law and to the hospital's internal reporting system pursuant to applicable hospital policy. The patient's medical record should contain all treatments, care and services. Specifics of the medication variance and associated investigations may be tracked according to the organization's risk management plan.

Department Response:
Not Adopted. At this time, Department staff determined the current language of the regulation adequately addresses medication variances and reporting of such events.

Name	Section
Spartanburg Regional Healthcare System	**1203.B**

Comment:
1203. Radiology
Section 1203.B Activities of the imaging service may include radio-therapy.
SRHS recommends the following sections in italics be added related to radio-therapy:
Section 1203.B.1: Quality and Patient Safety
With the rapidly evolving changes in technology and the need for licensees to adapt to those changes in technology and service locations, in order to ensure patient safety and quality of care, all licensees providing radio-therapy treatments must be in compliance the most current Safety is No Accident publication from the American Society for Radiation Oncology.
https://www.astro.org/ASTRO/media/ASTRO/Patient%20Care%20and%20Research/PDFs/Safety_is_No_Accident.pdf
Section 1203.B.1: All radio-therapy treatments provided will be under the control of a board certified or board eligible radiation oncologist.
Section 1203.B.2: The licensee provider must have access to a radiation physicist certified or eligible for certification by the American Board of Radiology or its equivalent.

Section 1203.B.3: The licensee must have access to simulation equipment capable of precisely producing the geometric relationships of the equipment to be used for treatment of the patient.
Section 1203.B.4: The licensee shall operate its own tumor registry or actively participate in a central tumor registry.
Section 1203.B.5: Any licensee providing megavoltage radiation therapy services outside of a hospital shall adopt protocols for the transportation of patients for the provision of necessary support and emergency services, which shall include a written agreement for the acceptance and transfer of patients needing such emergency care, with the nearest acute care hospital or any acute care hospital within 30 minutes travel time.
Section 1203.B.6: Any licensee providing megavoltage radiation therapy services must be accredited by a nationally recognized radiation therapy accrediting agency at each location within 3 years of initial licensure.

Department Response:
Not Adopted. Instead, Department staff have proposed amending Radiological Services section to be consistent with the Federal Medicare Conditions of Participation. See Section 1201.B.

Name	Section
Tidelands Health	**1207.F**

Comment:
Tidelands Health would recommend amending this provision to indicate that multi-dose vials shall be labeled with the date and time when opened or the date and time the vial should expire, as defined by facility policy and/or manufacture guidelines, whichever timeframe is shorter.

Department Response:
Adopted. See Section 1201.A.2.f.

Name	Section
Shelley Pifer	**1209**

Comment:
Lexington Medical Center suggests the following changes to this section:
Change section C. to add IR Techs can scrub within their scope of practice for endovascular cases. Therefore, C. should read "Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse. For endovascular cases, interventional radiology techs may perform "scrub" duties within their scope of practice."

Department Response:
Partially Adopted. Department staff have proposed amendments to the Surgical Services section that are consistent with the Federal Medicare conditions of participation. See Section 1202.A.

Name	Section
Shelley Pifer	**1211**

Comment:
Change "and" to "or" in Section A. Therefore, A. should read "Hospitals shall provide surgical equipment and instruments in good repair and free of potentially harmful microorganisms to assure safe and aseptic treatment. Any indication of contamination shall be immediately called to the attention of the nursing supervisor OR the physician in charge of the service.

Department Response:

Adopted. See Section 1202.A.2.g.

Name	Section
Spartanburg Regional Healthcare Systems	**1214**

Comment:
Section 1214.B: Each hospital shall provide emergency services which include life-saving procedures when life is in jeopardy. Policies and procedures governing the acceptance and care of emergency patients shall be established. An appropriate record shall be maintained on each person who presents for emergency services.

SRHS recommends the following section in italics be added related to emergency services:
Section 1214.B.4: Emergency services shall be located on the first floor of the hospital to allow for appropriate and timely access.

With the growth in population and the shift to suburban developments, SRHS recommends the following sections in italics be added related to free standing emergency services:
Section 1214.F: All off-campus emergency services must be an extension of an existing hospital's emergency service in the same county, unless the licensee the freestanding emergency service is in a county that does not have a licensed hospital.

Section 1214.F.1: Off-campus emergency services will be surveyed under Regulation 61-16, specifically including 24-hour/7-day per week physician coverage on site.

Section 1214.F.2: An off-campus emergency service must have written agreements with Emergency Medical Services providers and surrounding hospitals regarding serious medical problems, which the off-campus emergency service cannot handle.

Department Response:
Partially Adopted. Department staff have proposed amendments for Emergency Services and Freestanding Emergency Services. See Section 1201.D.

Name	Section
Spartanburg Regional Healthcare Systems	**1222**

Comment:
Section 1222.A.1: Quality and Patient Safety
With the rapidly evolving changes in technology and the need for licensees to adapt to those changes in technology and service locations, in order to ensure patient safety and quality of care, all licensees providing cardiovascular care must be in compliance with the most recent ACC/AHA/SCAI Guideline for Coronary Artery Revascularization publication.

Section 1222.A.2: Cardiac catheterization providers without prior licensure in South Carolina must meet the minimum procedure volumes as identified by the American College of Cardiology as best practice within 3 years of initiation of services. Documentation of volumes must be reported in the Joint Annual Reports.

Section 1222.A.3: Individuals performing procedures must meet the minimum competencies identified in the current version of the ACC, AHA, SCAI Training Guidance for Interventional Cardiology.

Section 1222.A.4: Licensees must provide documentation of oversight, reporting, and monitoring to national organizations and/or registries as part of the annual licensing inspection.

Section 1222.B: Cardiac catheterizations laboratory services shall only be provided under the control of a board certified or board eligible physician.

Section 1222.B.1: Licensees providing interventional cardiac catheterization laboratory services without onsite open-heart surgery shall secure and maintain a formal transfer agreement with a hospital performing open heart surgery.

Section 1222.B.2: Licensees providing emergent interventional cardiac catheterization laboratories shall also provide primary interventional cardiac catheterization laboratory services within 12 months of commencement of emergent interventional cardiac catheterization laboratory services. These services must be available 24-hour/7-day per week.

Section 1222.B.4: All licensees performing cardiac catheterization laboratory services shall be accredited by hospital accreditation or other nationally recognized cardiovascular accrediting agency.

Section 1222.C: Open heart surgery services shall be available and accessible on-site 24-hour/7-day per week, for emergency purposes and must be under the control of a board certified or board eligible physician.

Section 1222.C.1: All licensees performing open heart surgery services shall be accredited by hospital accreditation or other nationally recognized cardiovascular accrediting agency.

Section 1222.C.2: Each open heart surgery program shall provide, at a minimum, the following: a total of 4 segregated/private beds for cardiac care in an ICU; a telemetry unit proximate to the ICU; an acute renal dialysis service; a cardiac rehabilitation service; a minimum of 2 operating rooms equipped and available as needed for open heart surgery; an in-house cardiac catheterization service; and an available and accessible supply of blood and platelets, through an in-house supply or through affiliation with an established blood bank network.

Section 1222.C.3: Each licensee performing open heart surgery shall perform the minimum number of open heart surgery cases identified by the most recent ACC/AHA/SCAI Guideline for Coronary Artery Revascularization publication on an annual basis by the end of the third year of operation. This may be demonstrated by the number of surgeries reported on the most recent Joint Annual Report.

Section 1222.C.4: New open heart surgery services shall only be licensed if existing open heart surgery services are located no closer than a 60-minute travel time within South Carolina.

Department Response:
Not Adopted. The proposed amendments to the regulation address quality and safety of care of all areas in the hospital. At this time, Department staff determined the addition of standards specific to cardiovascular care services is unnecessary to ensure the safe and adequate treatment for persons served in South Carolina hospitals. Moreover, Department staff have concerns that incorporation of volume standards prescribed by the State Health Plan would be inconsistent with the General Assembly's intent in eliminating CON requirements for the establishment and offering of health services in hospitals.

Name	Section
Spartanburg Regional Heathcare Systems	**1300**

Comment:
SRHS is the licensed Level III Regional Perinatal Center providing care in DHEC's Perinatal Region II which is comprised of Spartanburg, Cherokee, Union, and Chester Counties. SRHS supports DHEC's regionalization system to provide care to our State's most critically ill infants. The March of Dimes as well as the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists also support regionalized neonatal intensive care and have guidelines in place to ensure quality care. Furthermore, the existing regionalization system enables the RPCs to maintain quality outcomes by having an adequate number of infants in its care.

SRHS also recommends that the actual verbiage included in the licensing regulations be updated to remain consistent with and reflect the most current edition of Guidelines for Prenatal Care, published by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists.

Department Response:
Not Adopted. Department staff have determined to revise this section at a later date. Additional input from the community and stakeholders will be needed. Department staff's plan with respect to revising the perinatal sections will be forthcoming.

Name	Section
Dr. Robin Lacroix, SC Children's Hospital Collaborative	**1306.C**

Comment:
C. <u>Subspecialty Perinatal Center with Neonatal Intensive Care Unit (Level III).</u> In addition to complying with all requirements of Sections 1306.A through 1306.B, Level III hospitals shall provide all aspects of perinatal care, including intensive care and a range of continuously available subspecialty consultation as recommended in the most recent edition of the Guidelines for Perinatal Care (GPC) by the American Academy of Pediatrics (AAP) and The American College of Obstetricians and Gynecologists. Level III hospitals shall provide care for mothers and infants at less than 32 weeks gestation, estimated fetal weight less than 1500 grams, and anticipated complex medical or surgical conditions for mother or infant that may require sub-specialty services. Level III hospitals shall also provide care for infants born at less than 32 weeks of gestation and weigh less than 1500 grams at birth or have actual or anticipated complex medical or surgical conditions regardless of gestational age. Level III hospital care shall include expertise in neonatology and maternal-fetal medicine. Level III neonatal intensive care units (NICUs) shall include continuously available personnel (neonatologists, neonatal nurses, and respiratory therapists) and equipment available to provide life support as long as needed. Level III facilities shall provide ongoing assisted ventilation for periods longer than 24 hours, which may include conventional ventilation, high frequency ventilation, and inhaled nitric oxide. Level III hospitals shall provide services and care for women and fetuses at high risk, both admitted and transferred to the facility. Level III hospitals shall have advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise, social services, and pastoral care. Pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity shall also be readily available in Level III hospitals. Level III hospitals shall have the capability to perform advanced imaging with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography. Level III hospitals shall also have the capability to perform major surgery on site or at a closely related institution.

A board-certified or board-eligible neonatologist shall be in the hospital or on site within 30 minutes, 24 hours a day. A board-certified maternal-fetal medicine specialist (perinatologist) shall be available for supervision and consultation, 24 hours a day. Perinatal consultation requirements may be met via telemedicine arrangements with a RPC. In addition to the Level II capabilities, Level III hospitals shall have the staffing and technical capability to manage high-risk obstetric and complex neonatal patients, including neonates requiring prolonged ventilatory support, surgical intervention, or 24-hour availability of multispecialty management. Hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually, calculated over the previous three years, and at least an average of 100 neonate admissions, calculated over the previous three years, who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery based on individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. To receive a Level III designation, a hospital must have no less than an average of 1500 deliveries annually, calculated over the previous three years, and must have no less than an average of 100 neonate admissions annually, calculated over the previous three years, who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery based on individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. To be included in a hospital's calculation of average annual neonate admissions as a maternal transfer, the mother must be admitted to the hospital, transferred to a higher level perinatal hospital, and give birth to a neonate who weighs less than 1500 grams each, requires ventilatory support for over twenty-four (24) hours, or requires surgery based on individual hospital statistics. The NICU budget shall include support for outcomes measurement, including data collection and membership in a multi-institutional collaborative quality improvement data base. Level III hospitals shall collect data to assess outcomes within their facility and to compare with other hospitals within their level. Hospitals at this level shall not provide additional care or services designated only for RPC's, or perform neonatal transport, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

Department Response:
Not Adopted. Department staff have determined to revise this section at a later date. Additional input from the community and stakeholders will be needed. Department staff's plan with respect to revising the perinatal sections will be forthcoming.

Name	Section
Summerville Medical Center	**1306.C**

Comment:
MUSC's proposed amendments to the language in 1306(C) appear to be designed to do one thing--prevent SMC from offering Level III NICU services. While MUSC claims that its volume-centric proposed amendments to 1306(c) are to promote better outcomes in terms of morbidity and mortality in the Level III NICU setting, it is strange that MUSC has never before suggested any such changes to 1306(C) until SMC decided to apply for Level III status. In other words, MUSC had no problem with the outcomes of the other low volume NICU providers in the state until a high volume delivery provider proposed adding a NICU in its service area. As such, MUSC's proposed amendments, which are not based on solid ground, should be rejected.

Recently, I had the opportunity to serve as a witness in a case brought by MUSC against SMC's CON application to establish a 6 bassinet Level III NICU. My testimony included many of the facts and issues discussed in this letter. As you may or may not know, on August 7, 2023,

the South Carolina Administrative Law Court upheld the Court's decision and concluded that "the Court is not inclined to impose a VLBW threshold standard on SMC or find that its neonatal outcomes for VLBW babies will be determined by treatment outcomes." Final Order, ¶ 318, p. 83. The judge heard testimony from both MUSC and SMC regarding neonatal outcomes, threshold volumes, quality control, and leadership factors, and determined that SMC's wholistic position was more reasonable than MUSC's volume-centric approach, so we would ask that DHEC take that into account when considering MUSC's proposed amendments.

More to the point, I ask that DHEC amend the current language in section 1306(C) regarding the management of 100 neonatal admissions and replace it with the standard in the South Carolina Health Plan, which allows DHEC to approve a CON application for Level III NICU when the Level II provider can demonstrate 1,500 births and 2,500 Level II patients days in the previous 12 months.

Department Response:
Not Adopted. Department staff have determined to revise this section at a later date. Additional input from the community and stakeholders will be needed. Department staff's plan with respect to revising the perinatal sections will be forthcoming.

Name	Section
Tidelands Health	**1306.C**

Comment:
Tidelands Health supports South Carolina's system of perinatal regionalization, which centralizes care of the most at-risk premature babies in high-volume regional neonatal intensive care units. This approach has been shown to result in better outcomes for babies compared to a more fragmented system, particularly when it comes to the most medically fragile babies who require care in Level III neonatal ICUs.
Proliferation of Level III neonatal ICUs would weaken South Carolina's regional perinatal system. We would recommend including the following volume prerequisites for establishing a Level III NICU:
· An average of 1500 deliveries annually, calculated over the previous three years, with no less than an average of 100 neonate admissions annually, calculated over the previous three years, who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery based on individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. To be included in a hospital's calculation of average annual neonate admissions as a maternal transfer, the mother must be admitted to the hospital, transferred to a higher-level perinatal hospital, and give birth to a neonate who weighs less than 1500 grams each, requires ventilatory support for over twenty-four (24) hours, or requires surgery based on individual hospital statistics.

Department Response:
Not Adopted. Department staff have determined to revise this section at a later date. Additional input from the community and stakeholders will be needed. Department staff's plan with respect to revising the perinatal sections will be forthcoming.

Name	Section
Summerville Medical Center	**1306.C**

Comment:

Summerville Medical Center ("SMC") proposes the following amendments to S.C. Regulation 61-16 § 1306(C):

C. Subspecialty Perinatal Center with Neonatal Intensive Care Unit (Level III). In addition to complying with all requirements of Sections 1306.A through 1306.B, Level III hospitals shall provide all aspects of perinatal care, including intensive care and a range of continuously available subspecialty consultation as recommended in the most recent edition of the Guidelines for Perinatal Care (GPC) by the American Academy of Pediatrics (AAP) and The American College of Obstetricians and Gynecologists. Level III hospitals shall provide care for mothers and infants at less than 32 weeks gestation, estimated fetal weight less than 1500 grams, and anticipated complex medical or surgical conditions for mother or infant that may require sub-specialty services. Level III hospitals shall also provide care for infants born at less than 32 weeks of gestation and weigh less than 1500 grams at birth or have actual or anticipated complex medical or surgical conditions regardless of gestational age. Level III hospital care shall include expertise in neonatology and maternal-fetal medicine. Level III neonatal intensive care units (NICUs) shall include continuously available personnel (neonatologists, neonatal nurses, and respiratory therapists) and equipment available to provide life support as long as needed. Level III facilities shall provide ongoing assisted ventilation for periods longer than 24 hours, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide. Level III hospitals shall provide services and care for women and fetuses at high risk, both admitted and transferred to the facility. Level III hospitals shall have advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise, social services, and pastoral care. Pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity shall also be readily available in Level III hospitals. Level III hospitals shall have the capability to perform advanced imaging with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography.

Level III hospitals shall also have the capability to perform major surgery on site or at a closely related institution.

A board-certified or board-eligible neonatologist shall be in the hospital or on site within 30 minutes, 24 hours a day. A board-certified maternal-fetal medicine specialist (perinatologist) shall be available for supervision and consultation, 24 hours a day. Perinatal consultation requirements may be met via telemedicine arrangements with a RPC. In addition to the Level II capabilities, Level III hospitals shall have the staffing and technical capability to manage high-risk obstetric and complex neonatal patients, including neonates requiring prolonged ventilatory support, surgical intervention, or 24-hour availability of multispecialty management. Hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually, calculated over the previous three years, and shall have managed at least an average of 2,500 patients days as a Level II program over a three year period prior to being licensed as a Level III program. The NICU budget shall include support for outcomes measurement, including data collection and membership in a multi-institutional collaborative quality improvement data base. Level III hospitals shall collect data to assess outcomes within their facility and to compare with other hospitals within their level. Hospitals at this level shall not provide additional care or services designated only for RPC's, or perform neonatal transport, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

Department Response:

Not Adopted. Department staff have determined to revise this section at a later date. Additional input from the community and stakeholders will be needed. Department staff's plan with respect to revising the perinatal sections will be forthcoming.

Name	Section
Jerry Davis	1306.C

Comment:
My letter requests that DHEC amend Section 1306 (C) related to Level III neonatal intensive care unit to remove the arbitrary 100 very low birth weight volume requirement of 100 which serves to basically restricts competition and access to care by virtually preventing any additional, otherwise qualified hospitals, from achieving a Level III designation.

It is essential that this much-needed aspect of care is provided to our community. The anticipated growth in our area justifies the need. The following additional considerations also validate the need for an additional Level III NICU in the eight-county Low Country Perinatal Region.

· Currently, all NICU beds in Region V are located at one hospital (MUSC, Regional Perinatal Center). This distance requires travel times of 30 to 60 minutes and places our infants are risk due to dealing with travel congestion.

· Flooding in downtown presents many challenges for patients and families.

· The new women and children's expansion at our community hospital, Summerville Medical Center, was built and staffed to address the community need for Level Ill NICU.

· The Summerville Medical Center delivers approximately 2,700 babies annually.

· Additional beds would improve access to a higher level of NICU services closer to home and would prevent new parents from being separated from their newborns.

Department Response:
Not Adopted. Department staff have determined to revise this section at a later date. Additional input from the community and stakeholders will be needed. Department staff's plan with respect to revising the perinatal sections will be forthcoming.

Name	Section
Katie McCravy, Summerville Rotary Club	1306.C

Comment:
The Summerville Rotary Club recognizes the great need for additional medical facilities in Dorchester and Berkeley Counties. Our community is one of the fastest growing areas in South Carolina. This letter requests that DHEC amend Section 1306 (C) related to Level III neonatal intensive care unit to remove the arbitrary 100 very low birth weight volume requirement of 100 which serves to basically restricts competition and access to care by virtually preventing any additional, otherwise qualified hospitals, from achieving a Level III designation.

It is essential that this much-needed aspect of care is provided to our community. The anticipated growth in our area justifies the need. The following additional considerations also validate the need for an additional Level III NICU in the eight-county Low Country Perinatal Region.

· Currently, all NICU beds in Region V are located at one hospital (MUSC, Regional Perinatal Center). This distance requires travel times of 30 to 60 minutes and places our infants are risk due to dealing with travel congestion.

· Flooding in downtown presents many challenges for patients and families.

· The new women and children's expansion at our community hospital, Summerville Medical Center, was built and staffed to address the community need for Level Ill NICU.

· The Summerville Medical Center delivers approximately 2,700 babies annually.

· Additional beds would improve access to a higher level of NICU services closer to home and would prevent new parents from being separated from their newborns.

Department Response:
Not Adopted. Department staff have determined to revise this section at a later date. Additional input from the community and stakeholders will be needed. Department staff's plan with respect to revising the perinatal sections will be forthcoming.

Name	Section
East Cooper Medical Center	**1306.C**

Comment:
For these reasons and with the goal of providing the latest in evidence-based medicine to our most fragile patients, the Department should strongly consider modifying Regulation 61-16 Section 1306(C) related to Subspecialty Perinatal Center with Neonatal Intensive Care Unit (Level III). The use of volume-based criteria for the development of Level III NICUs should be dropped or otherwise modified to a projection of 50 higher risk12 neonatal admissions annually after three years of operation. For growing Level II providers that are ready, from a volume perspective, to advance their level of care to better serve their population, projections for annual admissions are better calculated as a percentage of live births following national benchmarks set forth by the VON, CDC and March of Dimes. Quality requirements listed above should be emphasized above all other requirements. In the end as growth occurs, regionalization will be preserved, access to care maintained, and an evidence-based medicine road map will be provided to units growing in their level of capability, their level of care, benefitting all South Carolinians.

Department response:
Not Adopted. Department staff have determined to revise this section at a later date. Additional input from the community and stakeholders will be needed. Department staff's plan with respect to revising the perinatal sections will be forthcoming.

Name	Section
Sullivan Consulting	**1306.C**

Comment:
I recommend that this section of regulation be amended to:
"To be licensed as a Level III NICU, a facility must have birth volumes of at least 1,500 babies and 2,500 Level II neonatal patient days in the previous 12 months, in addition to the other requirements set forth in S.C. Code Ann. Reg. 61-15 § 1300 et seq."

Department Response:
Not Adopted. Department staff have determined to revise this section at a later date. Additional input from the community and stakeholders will be needed. Department staff's plan with respect to revising the perinatal sections will be forthcoming.

Name	Section
Greater Summerville Dorchester County Chamber of Commerce	**1306.C**

Comment:
The Greater Summerville/Dorchester County Chamber of Commerce's Board of Directors recognizes the great need for additional medical facilities in Dorchester and Berkeley Counties. Our community is one of the fastest growing areas in South Carolina. This letter requests that DHEC amend Section 1306 (C) related to Level III neonatal intensive care unit to remove the arbitrary 100 very low birth weight volume requirement of 100 which serves to basically restricts competition and access to care by virtually preventing any additional, otherwise qualified hospitals, from achieving a Level III designation.

It is essential that this much-needed aspect of care is provided to our community. The anticipated growth in our area justifies the need. The following additional considerations also validate the need for an additional Level III NICU in the eight-county Low Country Perinatal Region.

• Currently, all NICU beds in Region V are at located at one hospital (MUSC, Regional Perinatal Center).

• Flooding in downtown presents many challenges for patients and families.

• The new women and children's expansion at our community hospital, Summerville Medical Center, was built and staffed to address the community need for Level Ill NICU.

• The Summerville Medical Center delivers approximately 2,700 babies annually.

• Additional beds would improve access to a higher level of NICU services closer to home and would prevent new parents from being separated from their newborns.

Department Response:
Not Adopted. Department staff have determined to revise this section at a later date. Additional input from the community and stakeholders will be needed. Department staff's plan with respect to revising the perinatal sections will be forthcoming.

Name	Section
Trident Medical Center	**1806**

Comment:
<u>Regulation 61-16 Section 1806 Waste Management, Section {El</u>
Trident Medical Center would request the following language to Section E:

"The hospital shall have policies for the use and disposal of sharps. The hospital shall use sharps containers capable of maintaining their impermeability after waste treatment to avoid subsequent physical injuries during final disposal. Disposable syringes with needles, including sterile sharps that are being discarded, scalpel blades, and other sharp items must be placed into puncture-resistant containers located as close as practical to the point of use."

There have been different interpretations about the definition for sharps related to vials. DHEC is currently considering vials as a "potential sharp" and therefore is considered as infectious waste. We have checked with colleagues from multiple other states and determined that South

Carolina is one of the few that takes this stance. I recommend that this section be revised to further define empty, intact vials as non-infectious waste.

Department Response:
Not Adopted. In interpreting R. 61-16, Department staff have deferred to other relevant law including Regulation 61-105, *Infectious Waste Management Regulation*, which defines sharps. R. 61-105, Section E.1.a - Sharps is any discarded article that may cause puncture or cuts, including but not limited to: needles, syringes, Pasteur pipettes, lancets, broken glass or other broken materials, and scalpel blades.

Name	Section
Spartanburg Regional Heathcare Systems	**1902**

Comment:
The references in this section specifically relate to hospitals. However, as technology evolves, so does the delivery of care. SRHS recommends this section be updated to differentiate design and construction for activities that occur in a hospital as well as ambulatory and outpatient settings. Within each area, care must be given to apply the most reasonable building standards to ensure patient safety but to also control costs rather than the highest simply due to location.

We appreciate the effort and time the Department will spend in updating this Regulation and thank you for your consideration of our comments. Quality and safe patient care is vital for our state. If you have any questions or would like to speak further regarding our recommendations, please do not hesitate to contact me at 864.560.6078. We welcome the opportunity to work together with the Department to streamline the regulatory process as we both share the common goal of continued high-quality, safe healthcare for the citizens of South Carolina.

Department Response:
Acknowledged. See Section 1902.

Name	Section
Tidelands Health	**2200**

Comment:
Tidelands Health would recommend DHEC highlight specific standards it would use to handle issues not addressed by regulation. For example, would DHEC use Joint Commission or DNV standards to supplement areas not covered by regulation. The "best practices" standard is overly vague.

Department Response:
Department staff proposes removing Section 2200.

(x) ACTION/DECISION
( ) INFORMATION

Date: November 9, 2023

To: S.C. Board of Health and Environmental Control

From: Healthcare Quality

Re: Notice of Proposed Regulation Amending R. 61-91, Standards for Licensing Ambulatory Surgical Facilities.

I. Introduction

Healthcare Quality proposes the attached Notice of Proposed Regulation amending R. 61-91, Standards for Licensing Ambulatory Surgical Facilities for publication in the November 24, 2023, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Sections 44-7-250 and 44-7-260(A)(4), which requires the Department of Health and Environmental Control ("Department") to establish and enforce the minimum standards for the licensure, maintenance, and operation of ambulatory surgical facilities to ensure the safe and appropriate treatment of persons served in this state. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. In accordance with 2023 Act No. 20 (S.164), the Department proposes amending R.61-91 to promulgate regulations concerning the provision of uncompensated indigent/charity care required pursuant to S.C. Code Section 44-7-266(C), including related definitions, licensure requirements, reporting requirements, and enforcement. Additionally, the Department proposes amending the regulation to address the required quality of care, services, and treatment provided by facilities and to prescribe the manner and method of fee payments.

2. The Department had a Notice of Drafting published in the August 25, 2023 *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received public comments from eight parties by September 25, 2023, the close of the public comment period. Attachment C presents a summary of these public comments received and Department responses.

3. Department staff conducted a virtual stakeholder meeting on September 13, 2023, to receive comments on the proposed amendments. No comments were offered during the meeting.

4. Appropriate Department staff conducted an internal review of the proposed amendments on October 17, 2023.

III. Request for Approval

Healthcare Quality respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the November 24, 2023 *State Register*.

Gwen C. Thompson
Deputy Director
Healthcare Quality

Kristen Juarez Kollu
Director, Provider Services Division
Bureau of Healthcare Systems and Services
Healthcare Quality

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the August 25, 2023 *State Register*
C. Summary of Public Comments Received and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R. 61-91, Standards for Licensing Ambulatory Surgical Facilities.

November 9, 2023

Document No. _____

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 1976 Code Sections 44-7-110 through 44-7-394

R. 61-91, Standards for Licensing Ambulatory Surgical Facilities

Preamble:

Pursuant to S.C. Code Sections 44-7-250 and 44-7-260(A)(4), the Department establishes and enforces the minimum standards for the licensure, maintenance, and operation of ambulatory surgical facilities to ensure the safe and appropriate treatment of persons served in this state. In accordance with 2023 Act No. 20 (S.164), the Department proposes amending R.61-91 to promulgate regulations concerning the provision of uncompensated indigent/charity care required pursuant to S.C. Code Section 44-7-266(B) and -(C), including related definitions, licensure requirements, reporting requirements, and enforcement. Additionally, the Department proposes amending the regulation to address the required quality of care, services, and treatment provided by facilities and to prescribe the manner and method of fee payments. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Department had a Notice of Drafting published in the August 25, 2023 South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments

Section	Type of Change	Purpose
101	Reorganization	Recodification of definitions due to additions of new definition.
101.B, 101.J, 101.M, 101.N, 101.W, 101.X, 101.Z, 101.AA, 101.MM, 101.NN, 101.HHH, 101.III, 101.JJJ	Addition	Added definitions for clarity.
103.G	Addition	Added requirement to make payment of fees before the Department's issuance of a license.
103.H	Revision	Revised for clarification.
103.N.1 and 103.N.2	Addition	Language added in accordance with ACT 20.
202.F and 202.G	Addition	Inspection and Construction fees added for clarification.
401.A and 402.B	Revision	Revised to clarify requirements for policies and procedures, the time period for reviewing policies and procedures, and their accessibility to staff.
503	Addition	The governing body section added to address quality of care, services and treatment provided by facilities.
504, 505, 506, 507, 508, and 509	Reorganization	Recodification of section due to addition of section 503.
601.B.7	Addition	Added "with adverse reaction" to be consistent with other regulations.
801.D	Addition	Added a new section for transfer agreements.
804.B	Addition	Added to be consistent with federal regulation and to address quality of care.
804.C	Reorganization	Recodified due to the addition of 804.B.
901.A	Deletion	Deletion of incorrect reference to SC Code.
1201.A	Addition	Added emergency equipment requirements.
1504.E	Addition	Added requirement concerning collection, transportation, and storage of contaminated equipment.
1601.C	Addition	Added requirements concerning governing body involvement with the quality improvement program to be consistent with

		federal regulations and to address quality of care.
2006.E	Revision	Revised the minimum toilet fixture requirement.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments to Healthcare Quality; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; HQRegs@dhec.sc.gov, or the Public Comment Form at https://forms.office.com/g/9VMEXLWtq0. To be considered, the Department must receive the comment(s) by 5:00 p.m. on December 27, 2023, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments during its February 8, 2024, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: http://www.scdhec.gov/Agenda.

The Department publishes a Monthly Regulation Development Update tracking the status of its proposed new regulations, amendments, and repeals and providing links to associated State Register documents at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/.

Preliminary Fiscal Impact Statement

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any requirements of this regulation.

Statement of Need and Reasonableness

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: Regulation 61-91, *Standards for Licensing Ambulatory Surgical Facilities*

Purpose: The Department proposes promulgating provisions concerning uncompensated indigent/charity requirements set forth in S.C. Code Section 44-7-266(C). *See* 2023 Act No. 20 (S.164). The Department is further proposing amendments related to quality of care, services and treatment provided by ambulatory surgical facilities and the manner and method of fee payments.

Legal Authority: 1976 Code Sections 44-7-250 and 44-7-260(A)(4)

Plan for Implementation: The amendments will take legal effect upon General Assembly approval and upon publication in the State Register. Department personnel will then take appropriate steps to inform the regulated community of the amendments. Additionally, a copy of the regulation will be posted on the

Department's website, accessible at www.scdhec.gov/regulations-table. Printed copies may also be requested, for a fee, from the Department's Freedom of Information Office.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The proposed amendments are required to implement newly enacted statutory requirements concerning uncompensated indigent/charity care set forth in S.C. Code Section 44-7-266(C). Further, the proposed amendments will further provide for the quality of care, services, and treatment offered and provided at ambulatory surgical facilities in this State. Many of the proposed amendments relating to quality of care are consistent with the conditions of coverage set forth in Federal Regulation for participation in the Medicare (*see* 42 C.F.R Part 416), which are applicable to a substantial amount of existing facilities. Finally, the proposed amendments relating to fees update the manner and method of fees such that there are more convenient and efficient transactions with the Department.

DETERMINATION OF COSTS AND BENEFITS:

Implementation of these proposed amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any inherent requirements of these proposed amendments. There are no anticipated additional costs to the regulated community.

UNCERTAINTIES OF ESTIMATES:

None

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The proposed amendments will have no effect on the environment of this State. These regulations contribute to the Department's function of protecting public welfare and promoting safety and wellbeing for patients receiving care and treatment from ambulatory surgical facilities.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment. If the proposed revision is not implemented, the regulation will be maintained in its current form; the benefits of the proposed amendments herein will not be realized.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(A)(3)(h):

These revised regulations are updated to implement new statutory requirements concerning uncompensated indigent/charity care, and to ensure the safety and wellbeing of patients of ambulatory surgical facilities.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-91. Standards for Licensing Ambulatory Surgical Facilities.

Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394

SECTION 100

DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS

101. Definitions.

For the purpose of these standards, the following definitions shall apply:

A. Administrator. The individual designated by the facility licensee to have the authority and responsibility to manage the facility.

B. Adjusted Gross Revenue. Total Gross Revenue minus Medicaid and Medicare contractual adjustments only and bad debt.

~~B~~C. Administering Medication. The direct application of a single dose or multi-dose of medication to the body of a patient by injection, ingestion, or any other means.

~~C~~D. Advance Directive. A written statement such as a living will, a durable power of attorney for health care, or a do-not-resuscitate order relating to the provision of health care when the individual is incapacitated. The exercise by a patient of self-determination that encompasses making choices regarding life-sustaining treatment (including resuscitative services).

~~D~~E. Advanced Practice Registered Nurse. An individual who has official recognition as such by the S.C. State Board of Nursing.

~~E~~F. Ambulatory Surgical Facility. A facility organized and administered for the purpose of performing surgical procedures and/or endoscopy for which patients are scheduled to arrive, receive surgery, and be discharged on the same day.

1. The owner or operator shall make the facility available to other providers who comprise an organized professional staff, *i.e.*, an open medical staff (see Section 101.BB).

2. This definition does not apply to any facility used as an office or clinic for the private practice of licensed healthcare professionals (see Section 101.JJ).

~~F~~G. Anesthesiologist's Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

~~G~~H. Anesthesiologist. A physician who has completed a residency in anesthesiology.

~~H~~I. Anesthetic Agent. Any drug or combination of drugs administered parenterally or inhaled with the purpose of creating conscious or deep sedation.

J. Bad Debt. The amount a party has an obligation to pay, but that is considered uncollectible. Bad debt represents the portion of a patient's account not expected to be collected from the patient or other responsible party (the patient's portion). The patient's portion of a bill should not be categorized as bad debt for medically indigent patients. Bad debt must be differentiated from charity services. Patient charges

otherwise eligible for classification as charity care should only be treated as bad debt if all conditions of your facility's charity care criteria are not met.

~~I~~K. Certified Nursing Assistant. A person whose duties are assigned by a licensed nurse and who has successfully completed a state-approved training program or course with a curriculum prescribed by the South Carolina Department of Health and Human Services, holds a certificate of training from that program or course and is listed on the South Carolina Registry of Certified Nurse Aides.

~~J~~L. Certified Registered Nurse Anesthetist. A registered nurse who is authorized to practice as a certified registered nurse anesthetist by the S. C. State Board of Nursing.

M. Charity Care. Any unpaid charges for services to patients as defined in S.C. Code Ann. Section 44-6-5(5). Only the portion of a patient's account that meets the facility's charity care criteria is recognized as charity.

N. Contractual Adjustments. Any charges that are not paid by third-party payers and cannot be billed to the patient pursuant to contractual agreements. Contractual adjustments for Medicare, Medicaid and other payers should be captured separately.

~~K~~O. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act and the S.C. Controlled Substances Act.

~~L~~P. Consultation. A visit by Department representatives who will provide information to the licensee in order to facilitate compliance with these regulations.

~~M~~Q. Dentist. An individual currently licensed by the S.C. Board of Dentistry to practice dentistry.

~~N~~R. Department. The S.C. Department of Health and Environmental Control (DHEC).

~~O~~S. Direct Care Staff Member. An individual who provides care, treatment, surgery, and/or services, or performs procedures for a patient.

~~P~~T. Endoscopy. Visual inspection of any cavity of the body by means of an endoscope.

~~Q~~U. Existing Facility. A facility that was in operation and/or one that began the construction or renovation of a building, for the purpose of operating the facility, prior to the promulgation of this regulation. The licensing standards governing new facilities apply if and when an existing facility is not continuously operated and licensed under this regulation.

~~R~~V. Facility. An ambulatory surgical facility licensed by the Department.

W. Gross Indigent and Charity Care Patient Charges. The total uncompensated charges for patients who qualify as indigent or charity under the relevant definitions.

X. Gross Patient Revenue. Includes charges generated by all patients at full-established rates before provisions for contractual and other adjustments are applied. Include any revenue forgone for provision of care for indigent/charity patients at full-established rates.

~~S~~Y. Health Assessment. An evaluation of the health status of a staff member or volunteer by a physician, physician assistant, or advanced practice registered nurse, or by a registered nurse, pursuant to standing orders approved by a physician, as evidenced by the physician's signature in accordance with facility policy.

Z. Indigent and Charity Care Write-Offs. Unpaid charges for indigent and charity care cases should be related only to the provision of ambulatory surgical facility services that are licensed and regulated by the Department. Unpaid charges from other lines of business should not be included.

AA. Indigent Care. Any unpaid charges for services to medically indigent patients as defined in S.C. Code Ann. Section 44-6-5(5). Unpaid charges for patients who were eligible for Medicare, Medicaid, Third Party, or patients provided other free care are not included in Indigent Care.

~~T~~BB. Inspection. A visit by Department representative(s) for the purpose of determining compliance with this regulation.

~~U~~CC. Investigation. A visit by Department representative(s) to a licensed or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to this regulation.

~~V~~DD. Initial License. A license granted to a new facility.

~~W~~EE. Legally Authorized Healthcare Provider. An individual authorized by law and currently licensed in S.C. to provide specific medical care, treatment, procedures, surgery, and/or services to patients. Examples of individuals who may be authorized by law to provide the aforementioned care, treatment, procedures, surgery, and/or services may include, but are not limited to, advanced practice registered nurses, and physician assistants.

~~X~~FF. Legend Drug.

1. A drug required by federal law to be labeled with any of the following statements prior to being dispensed or delivered:

a. "Caution: Federal law prohibits dispensing without prescription";

b. "Rx only."

2. A drug required by federal or state law to be dispensed pursuant to a prescription drug order or restricted to use by practitioners only;

3. Any drug products designated by the S.C. Board of Pharmacy to be a public health threat; or

4. Any prescribed compounded prescription within the meaning of the Pharmacy Act.

~~Y~~GG. License. A certificate issued by the Department to an Ambulatory Surgical Facility to provide care, treatment, procedures, surgery, and/or services.

~~Z~~HH. Licensed Nurse. An individual currently licensed by the S.C. State Board of Nursing as a registered nurse or licensed practical nurse.

~~AA~~II. Licensee. The individual, corporation, organization, or public entity that has received a license to provide care, treatment, procedures, surgery, and/or services at a facility and with whom rests the ultimate responsibility for compliance with this regulation.

~~BB~~JJ. New Facility. All buildings or portions of buildings, new and existing, that are:

1. Being licensed for the first time;

2. Providing a different service that requires a change in the type of license;

3. Being licensed after the previous licensee's license has been revoked, suspended, or after the previous licensee has voluntarily surrendered the license and the facility has not continuously operated.

~~CC~~KK. Open Medical Staff. Members of the medical staff, which includes physicians, dentists, or podiatrists, of an ambulatory surgical facility, that have individually submitted application to the facility, and subsequently been approved to perform surgery/procedures in accordance with criteria established by the facility for approving qualified applicants.

~~DD~~LL. Operating Room. A room in which surgery is performed.

MM. Other Free Care. Other uncompensated care provided as a result of employee discounts, administrative adjustments, courtesy discounts, small bill write-offs, or other similar write-offs not based on a patient's inability to pay. Should not include amounts properly classified as "contractual adjustments."

NN. Other Revenue. Other revenues or gains are derived from services other than providing services to patients. This may include revenues shared with the facility from another organizational entity.

~~EE~~OO. Nonlegend Medication. A medication that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws of this State and the Federal government.

~~FF~~PP. Pharmacist. An individual currently registered as such by the S.C. Board of Pharmacy.

~~GG~~QQ. Physical Examination. An examination of a patient by a physician or physician assistant that addresses those issues identified in Section 802 of this regulation.

~~HH~~RR. Physician. An individual currently licensed as such by the S.C. Board of Medical Examiners.

~~H~~SS. Physician Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

~~JJ~~TT. Podiatrist. An individual currently licensed as such by the S.C. Board of Podiatry Examiners.

~~KK~~UU. Private Practice. An individually-licensed physician or group of licensed physicians who practice together at a certain location/address in a legally-constituted professional corporation, association, or partnership; patient encounters in the office or clinic are for the purpose of diagnosis and treatment, and not limited primarily to the performance of surgery and related care, treatment, procedures, and/or services.

~~LL~~VV. Procedure Room. A room where procedures not requiring general anesthesia can be safely performed.

~~MM~~WW. Quality Improvement Program. The process used by a facility to examine its methods and practices of providing care, treatment, procedures, surgery, and/or services, identify the ways to improve its performance, and take actions that result in higher quality of care, treatment, procedures, surgery, and/or services for the facility's patients.

~~NN~~XX. Recovery Area. An area used for the recovery of patients.

~~OO~~YY. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a 36-month period. The time-period determinant of repeat violation status is not interrupted by ownership changes.

~~PP~~ZZ. Responsible Party. A person who is authorized by law to make decisions on behalf of a patient, including, but not limited to, a court-appointed guardian or conservator, or person with a health care power of attorney or other durable power of attorney.

~~QQ~~AAA. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding its authority to operate.

~~RR~~BBB. Same Day. A period of time not to exceed twenty-four (24) hours after admission.

~~SS~~CCC. Staff Member. An adult who is a compensated employee of the facility on either a full or part-time basis.

~~TT~~DDD. Surgery. Treatment of conditions by operative means involving incision, whether with a scalpel or a laser, followed by removal or repair of an organ or other tissue.

~~UU~~EEE. Surgical Suite. An area that includes one or more operating rooms and a recovery area.

~~VV~~FFF. Surgical Technologist. An individual who meets one of the requirements listed in 1976 Code Section 44-7-380(B)(1)(a) – (d) to practice surgical technology in South Carolina.

~~WW~~GGG. Suspension of License. An action by the Department requiring a facility to cease operation for a period of time or to require a facility to cease admitting patients until such time as the Department rescinds that restriction.

HHH. Total Expenses. The sum of resources consumed in fulfillment of a facility's ongoing major or central operations. Expenses may result from current expenditures, incurring obligations to make future expenditures, or consuming resources obtained from previous expenditures. Expenses related to activities shared with entities other than the ambulatory surgical facility should be allocated between the entities. The expense component not allocated to the ambulatory surgical facility should not be included in the report. Appropriate matching of revenues and expenses excluded from the report should be made. Do not include bad debt as a total expense, but as a deduction from revenue.

III. Total Gross Revenue. The total revenue for the facility from all patient revenue and from other revenues or gains derived from services other than providing services to patients.

JJJ. Total Indigent and Charity Compensation. Funds provided by all public and private sources that are earmarked as compensation to offset uncompensated charges from indigent or charity care cases.

102. References.

The following publications/standards are referenced in this regulation:

A.Departmental:

1. R.61-4, *Controlled Substances*;

2. R.61-12, *Standards for Licensing Abortion Clinics*;

3. R.61-16, *Standards for Licensing Hospitals and Institutional General Infirmaries*;

4. R.61-20, *Communicable Diseases*;

5. R.61-25, *Retail Food Establishments*;

6. R.61-58, *State Primary Drinking Water Regulations*;

7. R.61-63, *Title A, Rules and Regulations for Radioactive Materials*;

8. R.61-64, *X-Rays, (Title B)*;

9. R.61-67, *Standards for Wastewater Facility Construction*;

10. R.61-105, *Infectious Waste Management Regulations*;

11. Guidelines for Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings.

B. Non-Departmental:

1. American Association of Blood Banks;

2. American National Standards Institute (ANSI);

3. American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE);

4. Bloodborne Pathogens Standards, Occupational Safety and Health Act (OSHA) of 1970;

5. Civil Rights Act of 1964;

6. Centers for Disease Control and Prevention (CDC);

7. International Building Code (IBC);

8. National Fire Protection Association (NFPA);

103. License Requirements (II).

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise/market) as an ambulatory surgical facility in S.C. without first obtaining a license from the Department. No such party shall provide care, treatment, procedures, surgery, and/or services to patients prior to the effective date of licensure. Upon the Department's determination that such party provides care, treatment, procedures, surgery, and/or services without a Department-issued license, the party shall cease operation immediately and ensure safety, health, and well-being of the patients. Current or previous violations of the S.C. Code and/or Department regulations may jeopardize the issuance of a license or licensing of another facility or addition to an existing facility owned or operated by the violating licensee. (I)

B. Compliance. An initial license shall not be issued to a proposed facility that has not been previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed facility is in substantial compliance with the licensing standards. In the event a licensee who already has a facility/activity licensed by the Department makes application for another facility or increase in licensed capacity, the currently licensed facility/activity shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility or an amended license to the existing facility. A copy of the licensing standards shall be maintained at the facility and accessible to all staff members. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations.

C. Compliance with Structural Standards. Facilities possessing a license issued prior to January 1, 2016 are considered in compliance with Section 1703 without modification of its licensed structure.

D. Licensed Capacity. No facility that has been licensed for a set number of operating rooms or procedure rooms shall exceed that number of operating or procedure rooms or establish new care, treatment, procedures, surgery, and/or services without first obtaining authorization from the Department. (I)

E. Issuance and Terms of License.

1. A license is issued by the Department and shall be posted in a conspicuous place in a public area within the facility.

2. The issuance of a license does not guarantee adequacy of individual care, treatment, procedures, surgery, and/or services, personal safety, fire safety, or the well-being of any patient or occupant of a facility.

3. A license is not assignable or transferable and is subject to revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this State.

4. A license shall be effective for a specified facility, at a specific location(s), for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the Department notifies the licensee of a change in that status.

5. Facilities owned by the same entity but not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, *e.g.*, interstate highways, shall not be considered as dividing otherwise adjoining or contiguous property.

6. Separate licenses are not required, but may be issued, for separate buildings on the same or adjoining grounds where a single level or type of care is provided.

7. Multiple types of facilities on the same premises shall be licensed separately even though owned by the same entity.

8. A facility shall provide only the care, treatment, procedures, surgery, and/or services of which it is capable and equipped to provide, and has been authorized by the Department to provide pursuant to the definition in Section 101.E of this regulation.

9. Abortions shall not be performed in an ambulatory surgical facility unless it is also licensed as an abortion clinic pursuant to R.61-12.

F. Facility Name. No proposed facility shall be named nor shall any existing facility have its name changed to the same or similar name as any other facility licensed in S.C. The Department shall determine if names are similar. If the facility is part of a "chain operation" it shall then have the geographic area in which it is located as part of its name.

G.Application. Applicants for a license shall submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application includes the applicant's oath, assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall be signed by the owner(s) if an individual or partnership; in the case of a corporation, by two of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in the event his or her address is different from that of the facility, and the names of the persons in control of the facility. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with these regulations. Corporations or partnerships shall be registered with the S.C. Office of the Secretary of State. Applicants shall make payment of all outstanding fees (initial licensure fees, annual licensure fees, inspection fees, construction fees, etc.) prior to the Department's issuance of a license.

H.Fees. The initial and annual license fee shall be $150.00 per operating/procedure room or $600.00, whichever is greater. ~~Such fee shall be made payable by check or money order to the Department and is not refundable. The Department may charge a fee for plan reviews, construction inspections and licensing inspections.~~ All fees are non-refundable and shall be made payable to the Department via a secured portal or specific website.

I. Late Fee. Failure to submit a renewal application after the license expiration date may result in a late fee of 25% of the licensing fee amount, in addition to the licensing fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time-period specified by the Department may result in an enforcement action.

J. License Renewal. To renew a license, an applicant shall file an application with the Department and pay a license fee. If the license renewal is delayed due to enforcement action, the renewal license shall be issued only when the matter has been resolved satisfactorily by the Department or when the adjudicatory process is completed, whichever is applicable. If an application is denied, a portion of the fee shall be refunded based upon the remaining months of the licensure year.

K.Change of License.

1. A facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

a. Change of ownership;

b. Reallocation of types of operating or procedure rooms as shown on the license;

c. Change of facility location from one geographic site to another;

d. The addition or replacement of a surgical suite or any part thereof, or the deletion of operating or procedure rooms.

2. Changes in facility name or address (as notified by the post office) shall be accomplished by application or by letter from the licensee.

L. An ambulatory surgical facility license shall not be required for, nor shall such a license be issued to:

1. Facilities operated by the federal government;

2. Ambulatory surgical services or procedures provided in licensed hospitals (such services remain within the purview of R.61-16);

3. Private practices (see Section 101.JJ).

M. Exceptions to Licensing Standards. The Department has the authority to make exceptions to these standards where it is determined that the health, safety, and well-being of the patients are not compromised, and provided the standard is not specifically required by statute.

N. Indigent/Charity Care. Any Facility established or constructed after May 16, 2023, and which did not require a Certificate of Need, must provide indigent charity care as described below in Section 103.N.2 after it has been in operation for two calendar years:

1. Annual Reports: After being in operation for two calendar years, a Facility subject to Section 103.N shall submit annual reports in a form prescribed by the Department and located on the Department's website. Further, a Facility subject to Section 103.N shall submit the annual reports by a deadline set by the Department and indicated on the Department's website. The annual reports shall include, but not be limited to the following information:

a. Gross patient revenue;

b. Medicare contractual adjustments;

c. Medicaid contractual adjustments;

d. Other contractual adjustments;

e. Bad debt;

f. Indigent care gross charges;

g. Indigent care compensation;

h. Charity care gross charges;

i. Charity care compensation;

j. Other free care;

k. Other revenue; and

l. Total expenses.

2.Indigent/Charity Care requirements:

a. If the Facility provides care to Medicaid beneficiaries, it must provide uncompensated indigent/charity care to the underinsured or medically indigent in an amount equal to or greater than 2% of its adjusted gross revenue; or

b. If the Facility does not provide care to Medicaid beneficiaries, it must provide uncompensated indigent/charity care to the underinsured or medically indigent in an amount equal to or greater than 3% of its adjusted gross revenue.

c. Noncompliance with Section 103.N.2.a or -b shall result in a monetary penalty in the amount of the difference between the services which the Facility is required to provide and the amount it actually provided.

SECTION 200

ENFORCING REGULATIONS

201. General.

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

202. Inspections/Investigations.

A. An inspection shall be conducted prior to initial licensing of a facility and subsequent inspections conducted as deemed appropriate by the Department. Other regulatory-related inspections may be considered in determining the appropriateness of Department inspections, e.g., Joint Commission on Accreditation of Health Care Organizations (JCAHO), Accreditation Association for Ambulatory Health Care (AAAHC), American Osteopathic Association (AOA), American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) inspections.

B. All facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by the Department.

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records, and have the authority to require the facility to make photocopies of those documents required in the course of inspections or investigations. Photocopies shall be used for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. (II)

D. A facility found noncompliant with the standards of this regulation shall submit an acceptable written plan of correction to the Department that shall be signed by the administrator and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;

2. The actions taken to prevent recurrences (actual and similar);

3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the facility response, shall be made available upon written request with the redaction of the names of those individuals in the report as provided by § 44-7-310 and 315 of the S.C. Code Ann. (2002).

F. Inspection Fees. The Facility shall pay the inspection fee for initial, relocation, routine inspection, and routine follow-up. The Facility shall pay a fee for unit increase of service modification or follow-up.

Initial/Relocation Inspection Fee	Calculated - $350 + $45 per operating, endoscopy, and procedure room
Initial/Relocation Follow-Up Fee	Calculated - $200 + $45 per operating, endoscopy, and procedure room
Routine Inspection Fee	Calculated - $350 + $45 per operating, endoscopy, and procedure room
Routine Follow-Up Fee	Calculated - $350 + $45 per operating, endoscopy, and procedure room
Unit Increase or Service Modification Fee	Calculated - $200 + $45 per operating, endoscopy, and procedure room
Unit Increase of Service Modification Follow-Up Fee	Calculated - $200 + $45 per operating, endoscopy, and procedure room

G. Construction Fees. The Facility shall pay the following inspection fees during the construction phase of the project.

Construction Inspection Fees	
Plan Inspection	
Total Project Cost	Fee
< $10,001	$750
$10,001 -$100,000	$1,500
$100,001 - $500,00	$2,000
> $500,000	$2,500 plus $100 for each additional $100,000 in project costs
Site Inspection	$500

SECTION 300

ENFORCEMENT ACTIONS

301. General.

When the Department determines that a facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice to the licensee, may impose a mandatory penalty and/or deny, suspend, and/or revoke its license.

302. Violation Classifications.

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of the persons in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time established by the Department may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety, or well-being of persons in the facility. The citation of a Class II violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. The notations "(I)" or "(II)", placed within sections of this regulation, indicate that those standards are considered Class I or II violations, if they are not met, respectively. Standards not so annotated are considered Class III violations.

E. In arriving at a decision to take enforcement actions, the Department shall consider the following factors: specific conditions and their impact or potential impact on health, safety, or well-being of the patients; efforts by the facility to correct cited violations; behavior of the licensee that reflects negatively on the licensee's character, such as illegal or illicit activities; overall conditions; history of compliance; and any other pertinent factors that may be applicable to current statutes and regulations.

F. When a decision is made to impose monetary penalties, the following schedule shall be used as a guide to determine the dollar amount:

Frequency of violation of standard within a 36-month period:

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$ 500 - 1,500	$ 300 - 800	$ 100 - 300
2nd	1,000 - 3,000	500 - 1,500	300 - 800
3rd	2,000 - 5,000	1,000 - 3,000	500 - 1,500
4th	5,000	2,000 - 5,000	1,000 - 3,000
5th	7,500	5,000	2,000 - 5,000
6th	10,000	7,500	5,000

G. Any enforcement action taken by the Department may be appealed in a manner pursuant to the Administrative Procedures Act, 1976 Code Section 1-23-310, et seq.

SECTION 400

POLICIES AND PROCEDURES

401. General (II).

A. The Facility shall maintain and adhere to ~~P~~policies and procedures addressing each section of this regulation regarding care, treatment, procedures, surgery, and/or services, patient rights, and the operation of the facility ~~shall be developed and implemented, and revised as required in order to accurately reflect actual facility operation~~. The policies and procedures shall follow current accepted standards of medical and surgical practice to ensure services are provided in a manner which protects the health and safety of patients. The Facility shall be in full compliance with the policies and procedures. ~~The licensee shall establish a time period for review of all policies and procedures. These policies and procedures shall be accessible in each facility at all times, either by hard copy or electronically.~~

B. ~~Policies and procedures shall describe the means by which the facility shall assure that the standards described in this regulation that the licensee has agreed to meet, as confirmed by signature on the application for licensing, will be met (see Section 1601.B).~~ The Facility shall establish a time period for review, not to exceed two (2) years, of all policies and procedures, and such reviews shall be documented. The Facility shall ensure all policies and procedures are accessible to staff at all times, either by hard copy or electronically.

SECTION 500

STAFF

501. General (II).

A. A facility shall be fully staffed in sufficient numbers and training as required by this Section at all times a patient is in the facility or the facility is open to accept patients, in order to:

1. Effectively meet the needs and condition of the patients, to include the demands of effective emergency on-site action that might arise;

2. Properly operate equipment in accordance with the equipment manufacturer's recommendations;

3. Adhere to current professional organizational standards;

4. Comply with all local, state, and federal laws.

B. The facility shall provide additional staff members if the Department determines that the facility staff on duty is inadequate to provide appropriate care, treatment, procedures, surgery, and/or services to the patients of a facility.

C. All staff members shall be assigned duties and responsibilities in accordance with the individual's capability that shall be in writing and be reviewed on an annual basis by the staff member and supervisor.

D. There shall be accurate current information maintained regarding all staff members of the facility, to include at least an address, phone number, and health and personal/work/training background. For those staff members who are licensed/certified, a copy of the license/certificate shall be available for review.

E. Direct care staff members of the facility shall not have a prior conviction or have pled no contest (nolo contendere) within the last 10 years for child or adult abuse, neglect, exploitation, or mistreatment, or for sexual assault or assault with a deadly weapon. Facilities may take certain considerations into account regarding criminal records when making hiring decisions, i.e., discretion may be exercised regarding

convictions/nolo contendere pleas occurring more than 10 years ago and may determine that an applicant, who would otherwise be disqualified, could be hired. (I)

F. A staff member shall not have an active dependency on a psychoactive substance(s) that would impair his or her ability to perform assigned duties. (I)

502. Administrator (II).

A.The facility shall have an administrator who shall be capable of meeting the responsibilities of operating the facility to ensure that it is in compliance with these regulations, and shall demonstrate adequate knowledge of these regulations. An administrator appointed subsequent to the promulgation of this regulation shall be a registered nurse or shall have a baccalaureate or associate degree with at least three years experience in a health-related field within the past five years.

B.A staff member shall be designated, by name or position, in writing, to act in the absence of the administrator.

503. Control (I).

The Facility must have a governing body designated in writing by the licensee that assumes full responsibility for determining, implementing, and monitoring policies governing the Facility's total operations. The governing body has oversight and accountability for the quality improvement program, and ensures that Facility policies and programs are administered so as to provide quality health care in a safe environment.

~~503~~504. Medical Director (II).

A.There shall be a medical director of the facility who is a physician.

B.The administrator and medical director may be the same individual.

~~504~~505. Medical Staff (I).

A.Physicians, dentists, and podiatrists performing surgery and/or procedures shall be appropriately licensed to perform these functions as well as adequately trained in any special requirements that are necessary to perform such surgery/procedures, including being board certified or board eligible.

B.Privileges for each physician, dentist, and podiatrist performing surgery/procedures shall be in accordance with criteria that the facility has established and approved.

C.There shall be a roster of medical staff having surgery, procedures, and anesthesia privileges at the facility, specifying the privileges and limitations of each and a current listing of all types of surgery and/or procedures offered by the facility.

D.A physician shall be physically present or available within 30 minutes until all patients have departed the premises.

E. There shall be at least one physician on staff who has admitting privileges at one or more hospitals.

~~505~~506. Nursing Staff (I).

A. An adequate number of licensed nurses shall be on duty to meet the total nursing needs of patients.

B. At least one registered nurse shall be on duty whenever patients are present in the facility.

C. Nursing staff shall be assigned to duties consistent with their scope of practice as determined through their licensure and educational preparation.

~~506~~507. Advanced Cardiac Life Support (I).

A. An individual who possesses a valid Advanced Cardiac Life Support credential shall be on duty in the facility whenever patients are present in the facility.

B. An individual who possesses a valid Pediatric Advanced Life Support credential shall be on duty in the facility whenever pediatric patients are present in the facility.

~~507~~508. Inservice Training (II).

A. Training for the tasks each staff member performs shall be conducted in order to provide the care, treatment, procedures, surgery, and/or services delineated in Sections 501.A and 800.

B. The following training shall be provided to staff members by appropriate resources, e.g., licensed or registered persons, video tapes, books, *etc.*, to all staff members in context with their job duties and responsibilities, prior to patient contact and at a frequency determined by the facility, but at least annually:

1. Cause, effect, transmission, prevention, and elimination of infections, to include management and care of persons with contagious and/or communicable disease, *e.g.*, hepatitis, tuberculosis, HIV infection;

2. OSHA standards regarding bloodborne pathogens;

3. Confidentiality of patient information and records and the protection of patient rights;

4. Emergency procedures and disaster preparedness within 24 hours of their first day on the job in the facility (see Section 1200).

5. Fire response training within 24 hours of their first day on the job in the facility (see Section 1303);

6. Aseptic techniques such as handwashing and scrubbing practices, proper gowning and masking, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of equipment and supplies.

C. All licensed nurses shall possess a valid cardio-pulmonary resuscitation (CPR) certificate within three months from the first day on the job in the facility; a staff member with a valid CPR certificate shall be on duty whenever patients are present in the facility.

D. All newly-hired staff members shall be oriented to acquaint them with the facility organization and physical plant, specific duties and responsibilities of staff members, and patients' needs.

~~508~~509. Health Status (I).

A. All staff members who have contact with patients shall have, within 12 months prior to initial patient contact, a health assessment as defined in Section 101.R.

B. The health assessment shall include a tuberculin skin test as described in Sections 1505 and 1506.

C. If a staff member is working at multiple facilities operated by the same licensee, copies of records for tuberculin skin testing and the pre-employment health assessment shall be acceptable at each facility. (II)

SECTION 600

REPORTING

601. Accidents/Incidents (II).

A. The licensee shall report a record of each accident and/or incident occurring at the facility to the Department within five (5) days of occurrence. Reports submitted to the Department shall contain only: facility name, license number, type of accident/incident, date of accident/incident occurred, number of patients directly injured or affected, patient medical record identification number, patient age and sex, number of staff directly injured or affected, number of visitors directly injured or affected, witness(es) name(s), identified cause of accident/incident, internal investigation results if cause unknown, a brief description of the accident/incident including location where occurred, and treatment of injuries. The report retained by the facility, in addition to the minimum reported to the Department, shall contain: names of patient(s), staff, and/or visitor(s), the injuries and treatment associated with each patient, staff, and/or visitor. Records of all accidents and incidents shall be retained by the facility for ten (10) years after the patient stops receiving services at the facility.

B. The licensee shall report each accident and/or incident resulting in unexpected death or serious injury to the next of kin or party responsible for each affected individual at the earliest practicable hour, not exceeding twenty-four (24) hours. The licensee shall notify the Department immediately, not to exceed twenty-four (24) hours, via telephone, email or facsimile. The licensee shall submit a report of the licensee's investigation of the accident and/or incident to the Department within five (5) days. Accidents and/or incidents requiring reporting include, but are not limited to,:

1. Abuse, Neglect or Exploitation (Confirmed);

2. Abuse, Neglect or Exploitation (Suspected);

3. Criminal event against patient;

4. Death;

5. Fall resulting in fracture of bone or joint;

6. Hospitalization as a result of accident/incident;

7. Medication ~~E~~error with adverse reaction;

8. Procedures on wrong person;

9. Procedures on wrong site;

10. Severe burn;

11. Severe hematoma;

12. Severe laceration;

13. Attempted suicide; or

14. Anesthesia apparatus malfunction.

602. Fire/Disasters (II).

A. The Department shall be notified immediately via telephone, email or facsimile regarding any fire in the facility, and followed by a complete written report, to include fire department reports, if any, to be submitted within a time-period determined by the facility, but not to exceed seventy-two (72) hours from the occurrence of the fire.

B. Any natural disaster that requires displacement of the patients or jeopardizes or potentially jeopardizes the safety of the patients, shall be reported to the Department via telephone, email or facsimile immediately, with a complete written report submitted within a time-period as determined by the facility, but not to exceed seventy-two (72) hours.

C. Where a required fire protection system is out of service, the facility shall notify the fire department and the fire code official immediately, and where required by the fire code official, the building shall either be evacuated or the facility shall provide an approved fire watch for all occupants left unprotected by the shut down until the fire protection system has been returned to service, as applicable to Division of Health Facilities Construction (DHFC) Guidelines Manual.

603. Communicable Diseases (I).

All cases of diseases that are required to be reported to the appropriate county health department shall be accomplished in accordance with R.61-20.

604. Administrator Change.

The Department shall be notified in writing by the licensee within 10 days of any change in administrator. The notice shall include at a minimum the name of the newly-appointed individual, documented qualifications as required by Section 502, and the effective date of the appointment.

605. Joint Annual Report.

Facilities shall complete and return a "Joint Annual Report" to the Department's Planning and Certificate of Need Division within the time-period specified by that division.

606. Accounting of Controlled Substances (I).

Any facility registered with the Department's Bureau of Drug Control and the federal Drug Enforcement Agency shall report any theft or loss of controlled substances to local law enforcement and to the Bureau of Drug Control within three working days of the discovery of the loss/theft. Any facility permitted by the S.C. Board of Pharmacy shall report the loss or theft of drugs or devices within three working days of the discovery of the loss/theft.

607. Facility Closure.

A. Prior to the permanent closure of a facility, the Department shall be notified in writing of the intent to close and the effective closure date. Within 10 days of the closure, the facility shall notify the Department of the provisions for the maintenance of the records. On the date of closure, the current original license shall be returned to the Department.

B. In instances where a facility temporarily closes, the Department shall be given written notice within a reasonable time in advance of closure. At a minimum this notification shall include, but not be limited to: the reason for the temporary closure, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards to the facility prior to its reopening. If the facility is closed for a period longer than one year, and there is a desire to re-open, the facility shall re-apply to the Department and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

608. Zero Census.

In instances when there have been no patients in a facility for any reason, for a period of 90 days or more, the facility shall notify the Department in writing no later than the 100th day following the date of the last procedure/surgery performed. At the time of that notification, the Department shall consider, upon appropriate review of the situation, the necessity of inspecting the facility prior to any new and/or re-admissions to the facility. The facility shall still apply and pay the licensing fee to keep the license active despite being at zero census or temporarily closed. If the facility has no patients for a period longer than one year, and there is a desire to re-open, the facility shall re-apply to the Department and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

SECTION 700

PATIENT RECORDS

701. Content (II).

A. The facility shall initiate and maintain an organized record for each patient. The record shall contain: sufficient documented information to identify the patient; the person responsible for each patient; the description of the diagnosis and the care, treatment, procedures, surgery, and/or services provided, to include the course of action taken and results; and the response and reaction to the care, treatment, procedures, surgery, and/or services provided. All entries shall be indelibly written, authenticated by the author, and dated.

B. Specific entries/documentation shall include at a minimum:

1. Consultations by physicians or other legally authorized healthcare providers;

2. Physical examination report, including pertinent medical history;

3. Orders and recommendations for all care, treatment, procedures, surgery, and/or services from physicians or other legally authorized healthcare providers, completed prior to, or at the time of patient arrival at the facility, and subsequently, as warranted;

4. Care, treatment, procedures, surgery, and/or services provided;

5. Record of administration of each dose of medication;

6. Medications administered and procedures followed if an error is made;

7. Special procedures and preventive measures performed, *e.g.*, isolation for symptoms of tuberculosis;

8. Notes of observation during recovery, to include vital signs pre- and post-operative;

9. Discharge summary, including condition at discharge or transfer, instructions for self-care and instructions for obtaining postoperative emergency care;

10. Special information, *e.g.*, allergies, *etc*. Documentation regarding organ donation shall be included in the record at the patient's request;

11. Signed informed consent;

12. If applicable, anesthesia records of pertinent preoperative and postoperative reports including pre-anesthesia evaluation, type of anesthesia, technique and dosage used, and post-anesthesia follow-up note;

13. Operative report (dictated or written into the record after surgery/procedure) to include at least:

a. Description of findings;

b. Techniques utilized to perform procedure/surgery;

c. Specimens removed, if applicable;

d. Primary surgeon and assistants.

14. Reports of all laboratory, radiological, and diagnostic procedures along with tests performed and the results appropriately authenticated.

C. Except as required by law, patient records may contain written and interpretative findings and reports of diagnostic studies, tests, and procedures, *e.g.*, interpretations of imaging technology and video tapes without the medium itself.

702. Authentication.

A. Each document generated by a user shall be separately authenticated.

B. Written signatures or initials and electronic signatures or computer-generated signature codes are acceptable as authentication.

C. In order for a facility to employ electronic signatures or computer-generated signature codes for authentication purposes, staff shall be identified who are authorized to authenticate patient records utilizing electronic or computer-generated signatures.

1. At a minimum, the facility shall provide authentication safeguards to ensure confidentiality, including, but not limited to, the following:

a. Each user shall be assigned a unique identifier that is generated through a confidential code;

b. The facility shall certify in writing that each identifier is kept strictly confidential. This certification shall include a user's commitment to terminate his or her use of an assigned identifier if it is found that the identifier has been misused, meaning that the user has allowed another person(s) to use his or her personally-assigned identifier, or that the identifier has otherwise been inappropriately utilized;

c. The user shall certify in writing that he or she is the only person with access to the identifier and the only person authorized to use the signature code.

2. The authentication system shall include a verification process to insure that the content of authenticated entries is accurate. The verification process shall include, at a minimum, the following provisions:

a. Blanks, gaps, obvious contradictory statements, or other documentation that require the attention of the authorized user shall be considered authenticated until reviewed and corrected by the user and a revised report issued;

b. Opportunity shall be provided for the user to verify that the document is accurate and that the signature has been properly recorded.

3. A user may terminate authorization for use of electronic or computer-generated signature upon written notice to the individual responsible for the maintenance of patient records.

D. The use of rubber stamp signature is acceptable under the following conditions:

1. The individual whose signature the rubber stamp represents shall be the only individual who has possession of and utilizes the stamp;

2. The individual places in the administrative offices of the facility a signed statement indicating that he or she is the only individual who has possession of and shall utilize the stamp;

3. Rubber stamp signatures are not permitted on orders for medications listed as "controlled substances" pursuant to R.61-4.

703. Record Maintenance.

A. The licensee shall provide accommodations, space, supplies, and equipment adequate for the protection, security, and storage of patient records.

B. When a patient is transferred to an emergency facility, a transfer summary to include, at a minimum, the diagnosis and medication administration record, shall accompany the patient to the receiving facility at the time of transfer or forwarded immediately after the transfer. Documentation of the information forwarded shall be maintained in the facility's patient record. (I)

C. The patient record is confidential. Records containing protected or confidential health information shall be made available only to individuals granted access to that information, in accordance with state and federal laws. The facility shall have a written policy designating the persons allowed to access confidential patient information. (II)

D.Records generated by organizations or individuals contracted by the facility for care, treatment, procedures, surgery, and/or services shall be maintained by the facility that has admitted the patient. Appropriate information shall be provided to assure continuity of care.

E. The facility shall determine the medium in which information is stored. The information shall be readily retrievable and accessible by facility staff, as needed, and for regulatory compliance inspections.

F. Upon discharge of a patient, the record shall be completed within 60 days and filed in an inactive/closed file maintained by the licensee. Prior to the closing of a facility for any reason, the licensee shall arrange for preservation of records to ensure compliance with these regulations and other applicable law. The licensee shall notify the Department, in writing, describing these arrangements and the location of the records.

G.Records of patients shall be maintained for at least six years following the discharge of the patient. Other documents required by the regulation, *e.g.*, fire drills, shall be retained at least 12 months or until the next Department inspection, whichever is longer.

H.Patient records are the property of the facility; the original record shall not be removed without court order. (II)

SECTION 800

CARE/TREATMENT/PROCEDURES/SURGERY/SERVICES

801. General (I).

A.Care, treatment, procedures, surgery, and/or services shall be provided, given, or performed effectively and safely in accordance with orders from physicians or other legally authorized healthcare providers, and precautions shall be taken for patients with special conditions, *e.g.*, pacemakers, pregnancy, Alzheimer's disease, etc., and/or for those who may be susceptible to deleterious effects as a result of the treatment.

B.The facility shall comply with all current federal, state, and local laws and regulations related to patient care, treatment, procedures, surgery, and/or services, and protection.

C.When a facility engages a source other than the facility to provide services normally provided by the facility, *e.g.*, staffing, training, food service, maintenance, housekeeping, there shall be a written agreement with the source that describes how and when the services are to be provided, the exact services to be provided, and a statement that these services are to be provided by qualified individuals. The source shall comply with this regulation in regard to patient care, treatment, procedures, surgery, and/or services, confidentiality, and rights. (II)

D. The Facility shall have a written transfer agreement with one (1) or more hospitals that provides reasonable assurance that transfer of patients will be made between the hospital and the facility. The transfer agreement shall be dated and signed by authorized officials who are a party to the agreement. The agreement shall be updated following a change of Administrator; the agreement shall be updated following changes in licensee or at any other time as deemed advisable to maintain or further improve continuity of care.

802. Physical Examination (I).

A.A preoperative history and physical examination, pertaining to the procedure to be performed, shall be completed by a physician or legally authorized healthcare provider no earlier than 14 days prior to surgery/procedure, or 30 days prior to surgery/procedure with the condition that, on the day of surgery/procedure, the physician or legally authorized healthcare provider documents no notable changes in the original history and physical examination. If notable changes are discovered at that time, a history and physical examination shall be completed. A discharge summary from a health care facility that includes a history and physical examination may be acceptable as the preoperative history and physical examination, provided the summary is within the time requirements of this section, and is reviewed by the physician or legally authorized healthcare provider performing the surgery/procedure.

B.If a patient or potential patient has a communicable disease, a physician or other legally authorized healthcare provider shall insure that the facility has the capability to provide adequate care and prevent the spread of the disease, and that the staff members are adequately trained and qualified to manage the patient, or transfer the patient to an appropriate facility, if necessary.

803. Surgical Services.

If surgical services are provided, a current listing of all types of surgical services offered by the facility shall be available.

804. Anesthesia Services (I).

A.Anesthesia shall be administered only by:

1. An anesthesiologist;

2. A physician, other than an anesthesiologist, or dentist, or podiatrist who is qualified to administer anesthesia pursuant to the S.C. Code of Laws;

3. A certified registered nurse anesthetist; or

4. An anesthesiologist's assistant.

B. Immediately before surgery:

1. A physician must examine the patient to evaluate the risk of the procedure to be performed; and

2. A physician, certified registered nurse anesthetist, or anesthesiologist's assistant must examine the patient to evaluate the risk of anesthesia.

~~B~~C.. After the administration of a general anesthetic, a patient shall be attended by a physician until the patient may be safely placed under post-operative/procedure supervision by the nursing staff who shall then attend the patient until he or she has regained full consciousness, or until the effects of the anesthetic have sufficiently subsided for the patient to be able to summon aid when needed.

805. Laboratory Services (II).

A.Each facility shall provide or make arrangements for obtaining laboratory services required in connection with the surgery/procedure to be performed.

B. Should the facility conduct tests that involve human specimens by utilizing any laboratory equipment such as finger-stick glucose, hemoglobin, monitoring devices, *etc.*, for the purpose of providing information for the diagnosis, prevention, or treatment of disease or impairment, or assessment of health, the facility shall obtain a Certificate of Waiver from the Clinical Laboratories Improvement Amendments (CLIA) Program through the Department's CLIA Program.

C. Laboratory supplies shall not be expired.

D. A pathologist shall examine all surgical specimens except for those types of specimens that the medical staff has determined and documented do not require examination.

806. Radiology Services (II).

A. Each facility shall have the capability of providing or obtaining diagnostic radiology services in connection with the surgery/procedure to be performed.

B. Those facilities where radiological equipment and materials are used shall be in compliance with R.61-63 and R.61-64.

807. Adverse Conditions (I).

Patients in whom any adverse condition exists or in whom a complication is known or suspected to have occurred during or after the performance of the operative procedure shall remain in the facility until the condition/complication is eliminated, as determined by the physician, and the patient is stabilized. Patients requiring care for periods in excess of those set forth in Section 101.RR shall be transferred to a hospital.

808. Patient Instruction (I).

Written instructions shall be issued to all patients upon discharge and shall include, at a minimum, the following:

A. Signs and symptoms of possible complications;

B. Telephone number of the facility or the attending physician or other knowledgeable professional staff member from the facility should any complication occur or question arise;

C. An emergency telephone number should any complication occur. It shall be the responsibility of the attending physician to arrange for needed care;

D. Limitations regarding activities, foods, *etc.*;

E. Date for follow-up or return visit, if applicable.

SECTION 900

RIGHTS AND ASSURANCES

901. General (II).

A.The facility shall comply with all current federal, state, and local laws and regulations concerning patient care, treatment, procedures, surgery, and/or services, patient rights and protections, and privacy and disclosure requirements~~, *e.g.*, § 44-81-10, *et seq.*, S.C. Code Ann. (2002)~~.

B.The facility shall comply with all relevant federal, state, and local laws and regulations concerning discrimination, *e.g.*, Title VII, Section 601 of the Civil Rights Act of 1964, and insure that there is no discrimination with regard to source of payment in the recruitment, location of patient, acceptance or provision of services to patients or potential patients, provided that payment offered is not less than the cost of providing services.

C.The facility shall develop and post in a conspicuous place in a public area of the facility a grievance/complaint procedure to be exercised on behalf of the patients that includes the address and phone number of the Department and a provision prohibiting retaliation should the grievance right be exercised.

D.Care, treatment, procedures, surgery, and/or services provided by the facility, and the charges for such, shall be delineated in writing. Patients shall be made aware of such charges and services, as verified by the signature of the patient or responsible party.

E. Patients shall be permitted to use the telephone and allowed privacy when making calls.

F. Adequate safeguards shall be provided for protection and storage of patients' personal belongings.

G.Patient rights shall be guaranteed, prominently displayed, and the facility shall inform the patient of these rights, to include, at a minimum:

1. The care, treatment, procedures, surgery, and/or services to be provided;

2. Informed consent for care, treatment, procedures, surgery, and/or services;

3. Respect for the patient's property;

4. Freedom from mental and physical abuse and exploitation;

5. Privacy while being treated and while receiving care;

6. Respect and dignity in receiving care, treatment, procedures, surgery, and/or services;

7. Refusal of treatment. The patient shall be informed of the consequences of refusal of treatment, and the reason shall be reported to the physician and documented in the patient record;

8. Refusal of experimental treatment and drugs. The patient's written consent for participation in research shall be obtained and retained in his or her patient record;

9. Confidentiality and privacy of records. Written consent by the patient shall be obtained prior to release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's responsible party. The facility shall establish policies to govern access and duplication of the patient's record.

H.Except in emergencies, documentation regarding informed consent shall be properly executed prior to surgery/procedure.

SECTION 1000

MEDICATION MANAGEMENT

1001. General (I).

A. Medications, including controlled substances, medical supplies, intravenous solutions, and those items necessary for the rendering of first aid shall be properly managed in accordance with local, state, and federal laws and regulations, to include the securing, storing, and administering of medications, medical supplies, first aid supplies, biologicals and their disposal when discontinued or expired, or at discharge, death, or transfer of a patient.

B. Non-legend medications that can be obtained without a prescription may be retained and labeled as stock in the facility for administration as ordered by a physician or other legally authorized healthcare provider.

C. If controlled substances are to be used, a controlled substances registration from the Department's Bureau of Drug Control and a controlled substance registration from the federal Drug Enforcement Administration (DEA) shall be obtained. The registration(s) shall be displayed in a conspicuous location within the facility.

D. Each facility shall maintain, upon the advice and written approval of the Medical Director or consultant pharmacist, an emergency kit/cart of lifesaving medicines and equipment for the use of physicians or other legally authorized healthcare providers in treating the emergency needs of patients.

1. The kit/cart shall be sealed and stored in such a manner as to prevent unauthorized access and to ensure a proper environment for preservation of the medications within, but in such a manner as to allow immediate access.

2. The exterior of each emergency medication kit/cart shall have displayed the following information:

a. "For Emergency Use Only";

b. Name, address, and telephone number of the consultant pharmacist.

3. Whenever the kit/cart is opened, it shall be restocked and resealed within a reasonable time to prevent risk of harm to a patient.

4. Medications used from the kit/cart shall be replaced pursuant to orders from a physician or other legally authorized healthcare provider according to facility policy.

5. Contents of each section of the kit/cart shall be listed and maintained on or in the kit/cart, and shall correspond to the list. Documentation of monthly checks of expiration dates of medications and supplies is to be retained by the facility for a period of two years or until the Department's next inspection, whichever is longer.

E. Medications shall not be expired.

F. Applicable reference materials published within the previous year shall be available at the facility in order to provide staff members with adequate information concerning medications.

1002. Medication Orders (I).

A.Medications, to include oxygen, shall be administered in the facility to patients only upon orders of a physician or other legally authorized healthcare provider.

B.All orders (including verbal) shall be received only by licensed nurses or authorized healthcare providers, and shall be authenticated and dated by a physician or other legally authorized healthcare provider pursuant to the facility's policies and procedures, but no later than 72 hours after the order is given. Verbal orders received shall include the time of receipt of the order, description of the order, and identification of the physician or other legally authorized healthcare provider and the individual receiving the order.

C.Medications and medical supplies ordered for a specific patient shall not be provided to or administered to any other patient.

1003. Administering Medication (I).

A.Each medication dose administered shall be properly recorded in the patient's record as the medication is administered. The medication administration record shall include the name of the medication, dosage, mode of administration, date, time, and the signature of the individual administering the medication. Initials may be utilized when recording administration, provided identification of the individual's initials is located within the record.

B.Expired medications shall not be administered to patients.

1004. Pharmacy Services (I).

Facilities that maintain stocks of legend medications and biologicals for patient use within the facility shall obtain and maintain from the S.C. Board of Pharmacy a valid, current, nondispensing drug outlet permit, displayed in a conspicuous location in the facility, and have a consultant pharmacist on-call during facility operating hours.

1005. Medication Containers (I).

Medications for each patient shall be dispensed from their original container(s), to include unit dose systems. There shall be no transferring between containers or opening blister packs to remove medications for destruction or adding new medications for administration, except by direction of a pharmacist.

1006. Medication Storage (I).

A.Medications shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, safety and security. Medications shall be stored in accordance with manufacturer's directions and in accordance with all applicable state and federal laws and regulations.

B.Medications shall be properly stored and safeguarded to prevent access by unauthorized persons. Expired or discontinued medications shall not be stored with current medications. Storage areas shall be of sufficient size for clean and orderly storage, and shall be locked when not under direct observation by a licensed healthcare provider. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf-life.

C. Medications requiring refrigeration shall be stored in a refrigerator at the temperature established by the U. S. Pharmacopeia (36 - 46 degrees F.). Food and drinks shall not be stored in the same refrigerator in which medications and biologicals are stored. Blood and blood products may be stored in the same refrigerator with medications and biologicals if stored in a separate compartment from the medications and biologicals.

D. Medications shall be stored:

1. Separately from poisonous substances, blood, or body fluids;

2. In a manner that provides for separation between oral and topical medications;

3. Separately from food.

E. Records shall be maintained of all stock controlled substances that indicate an accounting of all items received and/or administered in such a manner that the disposition of each dose of any particular item may be readily traced. Records shall be maintained for a minimum of two years or until the next inspection by the Department, whichever is longer.

F. Review of medication storage areas shall be conducted by the consultant pharmacist or his or her designee on at least a monthly basis. Records of such reviews shall be retained by the facility for at least two years or until the Department's next inspection, whichever is longer.

1007. Disposition of Medications (I).

A. Medications shall not be retained in stock after the expiration date on the label and no contaminated or deteriorated medications shall be maintained. Expired, damaged, or deteriorated medications and biologicals shall be disposed of in the following manner:

1. When noncontrolled legend medications are destroyed, the following shall be documented: date of destruction, medication name, strength, quantity, mode of destruction, and the names of the individual performing the destruction and a witness. (This shall not be applicable to partial unused doses of medications.) The medications may also be disposed of by returning them to the dispensing pharmacy and obtaining a receipt from the pharmacy.

2. The destruction of controlled substances shall be accomplished pursuant to the requirements of R.61-4.

B. Destruction records shall be retained by the facility for at least two years or until the Department's next inspection, whichever is longer.

SECTION 1100

MEAL SERVICE

1101. General (II).

A. All facilities that prepare food on-site shall be approved by the Department, and shall be regulated, inspected, and graded pursuant to R.61-25.

B. When meals or snacks are catered to a facility, such meals shall be obtained from a food service establishment graded by the Department, pursuant to R.61-25, and there shall be a written executed contract with the food service establishment.

1102. Food Storage (II).

A. All food items shall be stored at a minimum of six inches above the floor on clean surfaces and in such a manner as to be protected from splash and other contamination.

B. Food stored in the refrigerator or freezer shall be covered, labeled, and dated. Prepared food shall not be stored in the refrigerator for more than 72 hours.

1103. Food Equipment and Utensils (II).

The equipment and utensils utilized, and the cleaning, sanitizing, and storage of such shall be in accordance with R.61-25.

1104. Ice and Drinking Water (II).

A. Ice from a water system that is in accordance with R.61-58, shall be available and precautions taken to prevent contamination. The ice scoop shall be stored in a sanitary manner outside of the ice container.

B. Potable drinking water shall be available and accessible to patients at all times.

C. The use of common drinking cups shall be prohibited.

D. Ice delivered to patient areas in bulk shall be in nonporous, covered containers that shall be cleaned after each use.

1105. Equipment (II).

A. Liquid or powder soap in dispensers and sanitary paper towels shall be available at each food service handwash lavatory.

B. The facility shall include a separate handwash sink, convenient to serving, food preparation, and dishwashing areas.

C. All walk-in refrigerators and freezers shall be equipped with opening devices that will permit opening of the door from the inside at all times. (I)

1106. Refuse Storage and Disposal (II).

Refuse storage and disposal shall be in accordance with R.61-25.

SECTION 1200

EMERGENCY PROCEDURES/DISASTER PREPAREDNESS

1201. Emergency Services (I).

A. Appropriate equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer to a hospital. The emergency equipment must meet the following requirements:

1. Be immediately available for use during emergency situations;

2. Be appropriate for the facility's patient population; and

3. Be maintained by appropriate personnel in accordance with manufacturer's instructions.

B. The facility shall have the capability of obtaining blood and blood products to meet emergency situations.

1202. Disaster Preparedness (II).

A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

1203. Emergency Call Numbers (I).

Although the facility may have access to "911," emergency call data shall be immediately available and shall include, at a minimum, the telephone numbers of fire and police departments, ambulance service, and the Poison Control Center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members to be notified in case of emergency.

1204. Continuity of Essential Services (II).

There shall be a written plan to be implemented to assure the continuation of essential patient support services for reasons such as power outage, water shortage, or in the event of the absence of any portion of the staff resulting from inclement weather or other causes.

SECTION 1300

FIRE PREVENTION

1301. Arrangements for Fire Department Response/Protection (I).

A. Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire, *i.e.*, fire plan and evacuation plan.

B. Facilities located outside a service area or range of a public fire department shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department. A copy of the agreement shall be kept on file in the facility.

1302. Tests and Inspections (I).

A. Fire protection and suppression systems shall be maintained and tested in accordance with NFPA 10, 13, 14, 15, 25, 70, 72, and 96.

B. Fire alarm systems shall be maintained in a safe, operable condition in accordance with NFPA 70 and 99 and shall be inspected at least annually.

1303. Fire Response Training (I).

A. Each staff member shall receive training within 24 hours of his or her first day of employment in the facility and at least annually thereafter, addressing at a minimum, the following:

1. Fire plan;

2. Reporting a fire;

3. Use of the fire alarm system, if applicable;

4. Location and use of fire-fighting equipment;

5. Methods of fire containment; and

6. Specific responsibilities, tasks, or duties of each staff member.

B. A plan for the evacuation of patients, staff members, and visitors, to include evacuation routes and procedures in case of fire or other emergencies, shall be established and posted in conspicuous public areas throughout the facility.

1304. Fire Drills (I).

A. An unannounced fire drill shall be conducted at least quarterly for all shifts. Each staff member shall participate in a fire drill at least once each year. Records of drills shall be maintained at the facility, indicating the date, time, shift, description and evaluation of the drill, and the names of staff members directly involved in responding to the drill. If fire drill requirements are mandated by statute or regulation, the provisions of the statute or regulation shall be complied with and shall supersede the requirements of this section.

B. Drills shall be designed and conducted in consideration of and reflecting the content of the fire response training described in Section 1303 above.

SECTION 1400

MAINTENANCE

1401. General (II).

A. The structure, including its component parts and equipment, shall be properly maintained to perform the functions for which it is designed.

B. The facility shall keep its component parts and all equipment in good repair and operating condition and documented.

1402. Equipment (II).

A.Equipment used in the provision of care, treatment, procedures, surgery, and/or services shall meet appropriate specifications and calibrations and shall be monitored and operated in accordance with the manufacturer's guidelines and with local, State, and Federal laws.

B.If utilized, all equipment for the administration of anesthesia shall be readily available, clean or sterile, and operating properly.

1. Anesthesia apparatus shall be equipped with a device to measure the oxygen component of the gas being inhaled by the patient. The device shall emit audible and visual alarms should the proportion of oxygen fall below a safe level. (I)

2. Inspections shall be made prior to each use of the anesthesia equipment, as well as a record of all service and repair performed on all anesthesia machines, vaporizers, and ventilators, shall be maintained and retained for a minimum of two years or until the next Department's inspection, whichever is longer.

1403. Preventive Maintenance of Life Support Equipment (II).

A.A written preventive maintenance program shall be developed and implemented for all life support equipment, to include, but not be limited to:

1. Patient monitoring equipment;

2. Isolated electrical systems;

3. Patient ground systems; and

4. Medical gas systems.

B.This equipment shall be calibrated, if applicable, and/or tested at periodic intervals, but not less than annually, to insure proper operation. After repairs and/or alterations are made to any equipment or system, thorough testing for proper operation shall be accomplished prior to returning it to service. (I)

C.Records shall be maintained on all life support equipment to indicate its history of testing and maintenance.

SECTION 1500

INFECTION CONTROL AND ENVIRONMENT

1501. Staff Practices (I).

Staff and volunteer practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures and practices shall be in compliance with applicable guidelines of the Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; the Centers for Disease Control and Prevention (CDC) Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices and the Hospital Infection Control Practices Advisory Committee; the Department's *Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*, and R.61-105; and other applicable federal, state, and local laws and regulations.

1502. Vaccinations (I).

A.Hepatitis B.

1. All direct care staff who perform tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps shall have the hepatitis B vaccination series unless the vaccine is contraindicated or an individual is offered the series and declines. In either case the decision shall be documented.

2. Each staff member who elects vaccination shall have completed the initial dose of the three-dose series within 30 days of employment.

B.Influenza. All direct care staff shall have an annual influenza vaccination unless contraindicated or offered and declined. In either case the decision shall be documented.

C.MMR and Varicella. All direct care staff shall have been vaccinated or have evidence of immunity for measles, rubella, and varicella prior to patient contact unless contraindicated or offered and declined. In either case the decision shall be documented. Immunity to mumps is recommended.

1503. Live Animals.

Live animals shall not be permitted in facilities.

EXCEPTION: This standard does not apply to patrol dogs accompanying security or police officers, guide dogs, or other service animals accompanying individuals with disabilities.

1504. Sterilization Procedures (I).

A.Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and operating room materials as well as laboratory equipment and supplies. The sterilizing equipment shall have approved control and safety features. The accuracy of instrumentation and equipment shall be tested at least quarterly; periodic calibration and/or preventive maintenance shall be provided as necessary and a history of testing and service maintained.

B.The dates of sterilization and expiration shall be marked on all supplies sterilized in the facility.

EXCEPTION: Facilities may utilize "event-related" methodologies for determining sterile integrity in lieu of "time-related" methods provided there is an established policy and procedure.

C.The facility shall provide for appropriate storage and distribution of sterile supplies and equipment pursuant to facility policies and procedures.

D.Cleaning and disinfection, as needed, of equipment used and/or maintained in each area, appropriate to the area and the equipment's purpose or use, shall be accomplished. A recognized method of monitoring disinfectant performance shall be employed. Disinfectants, *e.g.*, glutraldehyde, Cidex, Sporox, hydrogen peroxide, shall be tested and maintained according to manufacturer's instructions and shall include, at a minimum, a record of readings/testings and change dates of the disinfectant solution.

E. Collection, transportation, and storage of contaminated or used equipment must be performed in a safe manner and in accordance with approved policies and procedures of the Facility.

1505. Tuberculosis Risk Assessment (I).

A. All facilities shall conduct an annual tuberculosis risk assessment in accordance with CDC guidelines (See Section 102.B.6) to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

B. The risk classification, *i.e.*, low risk, medium risk, shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for staff and patients and the frequency of screening. A risk classification shall be determined for the entire facility. In certain settings, *e.g.*, healthcare organizations that encompass multiple sites or types of services, specific areas defined by geography, functional units, patient population, job type, or location within the setting may have separate risk classifications.

1506. Staff Tuberculosis Screening (I).

A. Tuberculosis Status. Prior to date of hire or initial patient contact, the tuberculosis status of direct care staff shall be determined in the following manner in accordance with the applicable risk classification:

B. Low Risk:

1. Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All staff (within three (3) months prior to contact with patients) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic TST or BAMT is not required.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified.

Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case/suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8-10) weeks after that exposure to *M. tuberculosis* ended.

C. Medium Risk:

1. Baseline two-step TST or a single BAMT: All staff (within three (3) months prior to contact with patients) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic testing (with TST or BAMT): Annually, of all staff who have risk of TB exposure and who have previous documented negative results. Instead of participating in periodic testing, staff with documented TB infection (positive TST or BAMT) shall receive a symptom screen annually. This screen shall be accomplished by educating the staff about symptoms of TB disease (including the staff and/or direct care volunteers responses), documenting the questioning of the staff about the presence of symptoms of TB disease, and instructing the staff to report any such symptoms immediately to the administrator or director of nursing. Treatment for latent TB infection (LTBI) shall be considered in accordance with CDC and Department guidelines and, if recommended, treatment completion shall be encouraged.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case/suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8-10) weeks after that exposure to *M. tuberculosis* ended.

D. Baseline Positive or Newly Positive Test Result:

1. Staff with a baseline positive or newly positive test result for *M. tuberculosis* infection (*i.e.*, TST or BAMT) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, *e.g.*, cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). These staff members will be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and will be encouraged to follow the recommendations made by a physician with TB expertise (*i.e.*, the Department's TB Control program).

2. Staff who are known or suspected to have TB disease shall be excluded from work, required to undergo evaluation by a physician or legally authorized healthcare provider, and permitted to return to work only with approval by the Department TB Control program. Repeat chest radiographs are not required unless symptoms or signs of TB diseases develop or unless recommended by a physician or legally authorized healthcare provider.

1507. Housekeeping (II).

The facility and its grounds shall be uncluttered, clean, and free of vermin and offensive odors.

A. Interior housekeeping shall at a minimum include:

1. Cleaning each specific area of the facility (dry sweeping and dusting shall be prohibited in restricted areas as identified in facility policies and procedures);

2. Cleaning of operating/procedure rooms in accordance with established written procedures after each operation/procedure.

B. Exterior housekeeping shall at a minimum include:

1. Cleaning of all exterior areas, *e.g.*, porches and ramps, and removal of safety impediments such as snow and ice;

2. Keeping facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin.

1508. Infectious Waste (I).

Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be disposed of in a manner compliant with OSHA Bloodborne Pathogens Standard, the Department's Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings, and R.61-105.

1509. Clean/Soiled Linen and Surgical Clothing (II).

A.A supply of clean, sanitary linen/surgical clothing shall be available at all times. In order to prevent the contamination of clean linen/surgical clothing by dust or other airborne particles or organisms, it shall be stored and transported in a sanitary manner, *i.e.*, enclosed and covered. Linen/Surgical clothing storage rooms shall be used only for the storage of linen/surgical clothing. Clean linen/Surgical clothing shall not be stored with other items.

B. Soiled linen/Surgical clothing.

1. Provisions shall be made for collecting, transporting, and storing soiled linen and surgical clothing;

2. Soiled linen/Surgical clothing shall be kept in enclosed/covered containers.

SECTION 1600

QUALITY IMPROVEMENT PROGRAM

1601. General (II).

A.There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care, treatment, procedures, surgery, and/or services provided by the facility.

B. The quality improvement program, at a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is systematically, objectively, and regularly accomplished at a frequency as determined by the facility to ensure that policies and procedures and this regulation are met, but not less than every three months;

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Establish ways to measure the quality of patient care and staff performance as well as the degree to which the policies and procedures are followed;

5. Analyze the necessity of care, treatment, procedures, surgery, and/or services rendered;

6. Analyze the effectiveness of the fire plan;

7. Analyze all serious incidents and accidents, to include all patient deaths and significant medication errors;

8. Analyze any other unusual occurrences that threaten the health, safety, or well-being of the patients;

9. At least every three months, review an established percentage of patient records to verify the accuracy and integrity of the system, and take corrective action as needed;

10. Establish a systematic method of obtaining feedback from patients and other interested persons, *e.g.*, family members and peer organizations, as expressed by the level of satisfaction with care, treatment, procedures, surgery, and/or services received.

C. The governing body must ensure the quality improvement program:

1. Is defined, implemented, and maintained by the Facility;

2. Addresses the Facility's priorities and that all improvements are evaluated for effectiveness;

3. Specifies data collection methods, frequency, and details;

4. Clearly establishes its expectations for safety; and

5. Adequately allocates sufficient staff, time, information systems, and training to implement the quality improvement program.

SECTION 1700

DESIGN AND CONSTRUCTION

1701. General (II).

A facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each patient.

1702. Local and State Codes and Standards (II).

Buildings shall comply with pertinent local and state laws, codes, ordinances, and standards with reference to design and construction. No facility shall be licensed unless the Department has assurance that responsible local officials (zoning and building) have approved the facility for code compliance.

1703. Applicable Code Editions (II).

A. Facility design and construction shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to ambulatory surgical facilities.

B. Unless specifically required otherwise by the Department, all facilities shall comply with the construction codes and construction regulations applicable at the time its license was issued.

C. Any facility that closes, has its license revoked, or surrenders its license, and applies for re-licensure at the same site, shall be considered a new building and shall meet the current codes, regulations, and requirements for the building and its essential equipment and systems in effect at the time of application for re-licensing.

1704. Submission of Plans and Specifications.

A. Plans and specifications shall be submitted to the Department for review and approval for new construction, additions or alterations to existing buildings, replacement of major equipment, buildings being licensed for the first time, buildings changing license type, and for facilities increasing occupant load or licensed capacity. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. Unless directed otherwise by the Department, submit

plans at the schematic, design development, and final stages. All plans shall be drawn to scale with the title, stage of submission and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction the owner shall employ a registered architect and/or engineer for observation and inspections. Upon approval of the Department, construction administration may be performed by an entity other than the architect. The Department shall conduct periodic inspections throughout each project.

B. Plans and specifications shall be submitted to the Department for review and approval for projects that have an effect on:

1. The function of a space;

2. The accessibility to or of an area;

3. The structural integrity of the facility;

4. The active and/or passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under an exhaust hood);

5. Doors;

6. Walls;

7. Ceiling system assemblies;

8. Exit corridors;

9. Life safety systems; or

10. That increases the occupant load or licensed capacity of the facility.

C. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written notification, review and re-approval from the Department.

D. Cosmetic changes utilizing paint, wall covering, floor covering, etc., that are required to have a flame-spread rating or other safety criteria shall be documented with copies of the documentation and certifications kept on file at the facility and made available to the Department.

E. Any construction work which violates codes or standards will be required to be brought into compliance. All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by Department.

1705. Construction Inspections.

All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by Department.

SECTION 1800

FIRE PROTECTION EQUIPMENT AND SYSTEMS

1801. Fire Alarms (I).

A.A facility shall include a partial, manual, automatic, supervised fire alarm system. The system shall be arranged to transmit an alarm automatically to a third party by an approved method. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.

B.There must be a fire alarm pull station at each required exit and in or near each nurses station.

C.All fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems must be connected to the main fire alarm system and trigger the system when they are activated.

1802. Gases (I).

Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. “No Smoking” signs shall be posted conspicuously inside the facility and on oxygen cylinders. All cylinders shall be properly secured in place.

SECTION 1900

ELECTRICAL

1901. Signal System.

A.All facilities shall have a signal system consisting of a call button for each bed, bath, toilet and treatment/examination room. A light shall be at or over each patient room door visible from the corridor. There shall be an audio-visual master station in a location continuously monitored by staff.

B.Activation of signal system shall be by pull cord or electronic device. Pull cord shall hang to a maximum of four (4) inches above finished floor.

1902. Emergency Generator Service (I).

A.With concurrence of the local authority having jurisdiction, facilities shall have an emergency generator with a ten (10) second startup and six (6) hour run time based on the maximum load rating of the generator. As a minimum, emergency power shall be provided for but not limited to:

1. Emergency and Exit lighting;

2. Lighting for staff work areas;

3. All lighting and power at patient care areas;

4. Fire alarm telephone and signal systems;

5. At least one (1) elevator where required;

6. Fire pump and associated equipment;

7. Public toilet rooms;

8. All HVAC equipment serving patient areas; and

9. All patient life safety equipment;

EXCEPTION: In endoscopy facilities, an emergency power supply system is not required.

B. An Uninterruptible Power System (UPS) is not acceptable as an alternative to the generator system.

C. In the event of natural disaster or electrical power failure, no new surgery/procedures shall commence, and surgery/procedures in progress shall be concluded as soon as possible.

SECTION 2000

PHYSICAL PLANT

2001. Surgical Suite(s).

The size and design of the surgical suite(s) shall be in accordance with individual programs and this regulation. The following basic elements, designed to ensure no flow of through traffic, shall be incorporated in all facilities:

A. Operating/Procedure Room(s).

1. The number shall depend on the projected caseload and types of procedures to be performed. Rooms shall have adequate space to accommodate necessary equipment and staff.

2. Each operating room shall have a minimum clear area of 180 square feet exclusive of fixed and movable cabinets and shelves. The minimum width shall be 12 feet.

3. Each procedure room shall have a minimum clear area of 140 square feet exclusive of fixed and movable cabinets and shelves. The minimum width shall be 10 feet.

4. Additional clear area may be required as described in the narrative program to accommodate special functions in one or more of these rooms.

5. The facility shall include an emergency communication system connecting with the surgical suite work station.

B. Surgery/Procedure and Recovery Equipment and Supplies

1. Each operating/procedure room shall be completely equipped and supplied for the types of procedures to be performed. (I)

2. The center's medical staff and governing body shall develop policies and procedures to specify the types of emergency equipment required for use in the Ambulatory Surgical Facility's operating room(s). The equipment must meet the following requirements: (I)

(a) Be immediately available for use during emergency situations;

(b) Be appropriate for the facility's patient population; and

(c) Be maintained by appropriate personnel.

C. Surgical/Procedure Service Areas. The facility shall include the following:

1. A work station located to permit visual surveillance of persons entering the surgical/procedure areas and the recovery area;

2. Sterilizing equipment with autoclave(s) conveniently located to serve all operating rooms;

EXCEPTION: Sterilizing equipment is not required in endoscopy facilities; however, a high-level disinfection of equipment is required in such facilities.

3. A medication distribution station provided for storage and preparation of medication to be administered to patients;

4. Scrub facilities provided near the entrance to each operating room. Scrub facilities with foot or knee controls shall be arranged to minimize any incidental splatter on nearby staff or supply carts. At a minimum, the facility shall include the following:

a. Scrub sink with knee, elbow, or foot controls;

b. Soap dispenser.

EXCEPTION: For endoscopy facilities, in lieu of scrub facilities, there shall be a handwash sink in each procedure room that is equipped with valves that can be operated without the use of hands.

5. A soiled workroom for the exclusive use of the surgical suite staff. The soiled workroom shall
contain a clinical sink or equivalent flushing type fixture, waste receptacle, and covered soiled receptacle, unless there is a separate soiled linen storage room;

EXCEPTION: In endoscopy facilities, a designated soiled work area will suffice in lieu of a soiled workroom.

6. A clean workroom when clean materials are assembled within the surgical suite prior to use. The workroom shall contain a work counter, a sink equipped for handwashing and space for clean and sterile supplies;

EXCEPTION: In endoscopy facilities, a designated clean work area will suffice in lieu of a clean workroom.

7. An area for cleaning, testing, and storing anesthesia equipment in accordance with accepted principles of aseptic technique.

EXCEPTION: An anesthesia area is not required in endoscopy facilities.

8. Staff change areas that shall contain adequate dressing space for changing of scrubs and shall contain lockers, showers, toilets, lavatories, and receptacles and facilities for the appropriate disposition of soiled

scrubs; these areas shall be arranged to allow a restricted traffic pattern of authorized staff from outside the surgical suite to change into appropriate attire and enter the surgical suite;

EXCEPTION: Showers and areas for donning of scrub suits and boots are not required in endoscopy facilities.

9. Provisions for emergency eye-washing.

D.Recovery Area. The facility shall include the following:

1. An area for recovery of patients;

2. Handwashing facilities, secured medication storage space, clerical work space, and sufficient storage space for supplies and equipment;

3. At least four feet between beds or stretchers (two feet if next to a wall) and adequate space at the foot of the bed or stretcher as needed for work and staff circulation;

4. Partitions, walls and/or cubicle curtains (on built-in tracks) to afford visual privacy for each patient;

5. Recovery beds or reclining type of vinyl upholstered chairs or recovery stretchers;

6. Equipment for oxygen, resuscitation, and suction.

2002. Soiled Utility Room.

Facilities shall have at least one soiled utility room per floor containing a clinical sink, work counter, waste receptacle and soiled linen receptacle.

2003. Clean Utility Room.

Facilities shall have at least one clean utility room per floor containing a counter with handwashing sink and space for the storage and assembly of supplies for nursing procedures.

2004. Corridors (II).

A.Minimum public corridor width shall be five feet.

B.There shall be at least one corridor that is no less than eight feet clear width between doors from the recovery area and/or operating/procedure rooms and an exit door. In a one-story building or on the ground floor of a multi-story building, if there is less than eight feet clear width, the corridors shall be so arranged as to allow a stretcher to exit from the recovery area or operating rooms directly into the corridor without turning and move to the required exit without having to make a turn. Minimum width shall be five feet.

C.The location of items such as drinking fountains, telephone booths, vending machines, and portable equipment shall not restrict corridor traffic or reduce the required corridor width. (II)

2005. Handrails/Guardrails (II).

The facility shall have handrails on at least one side of each corridor/hallway, and on all stairways, ramps, and porches with two or more steps. Ends of all installed handrails shall return to the wall.

2006. Restrooms (II).

A. There shall be an appropriate number of restrooms in the facility, to accommodate patients, staff, and visitors.

B. The restrooms shall be accessible during all operating hours of the facility.

C. A restroom(s) shall be equipped with at least one toilet fixture, toilet paper installed in a holder, a lavatory supplied with hot and cold running water, liquid or granulated soap, single-use disposable paper towels or electric air dryer, and a covered waste receptacle.

D. The waiting/lobby area must have at least one restroom.

E. The facility shall have toilet fixtures in restrooms for patient use in ample number, located within or adjacent to the recovery area. The minimum requirement is one toilet fixture for every ~~surgical and procedure room~~eight pre-operative and post-operative beds.

F. All toilet fixtures used by patients shall have approved grab bars securely fastened in a usable fashion.

G. Privacy shall be provided at toilet fixtures and urinals.

2007. Janitor's Closets.

A. The facility shall include at least one (1) lockable janitor's closet throughout the facility.

B. Each shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies, *e.g.*, mops.

2008. Storage Areas.

A. Adequate general storage areas shall be provided for patient and staff/volunteer belongings, equipment, and supplies as well as clean linen, soiled linen, wheelchairs, and general supplies and equipment.

B. Soiled linen shall be stored in an enclosed room. This room may also be the soiled workroom.

C. Storage buildings on the premises shall meet the requirements of the current building code regarding distance from the licensed building. Storage in buildings other than on the facility premises shall be secure and accessible. An appropriate controlled environment shall be provided if necessary for storage of items requiring such an environment.

D. Supplies/Equipment shall not be stored directly on the floor. Supplies/Equipment susceptible to water damage/contamination shall not be stored under sinks or other areas with a propensity for water leakage.

E. Chemicals indicated as harmful on the product label, cleaning materials, and supplies shall be safely stored in cabinets or well-lighted closets/rooms.

2009. Elevators (II).

Elevators shall be inspected and tested upon installation, prior to first use, and annually thereafter by a certified elevator inspector.

2010. Telephone Service.

At least one land-line telephone shall be available on each floor of the facility for use by patients and/or visitors for their private, discretionary use; pay phones for this purpose are acceptable

2011. Location.

A.Transportation. The facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B.Parking. The facility shall have a parking area to reasonably satisfy the needs of patients, staff members, and visitors.

C.Access to firefighting equipment. Facilities shall maintain adequate access to and around the building(s) for firefighting equipment. (I)

2012. Incinerators (I).

If the facility has an incinerator, it shall conform to the requirements of the Department.

2013. Furnishings/Equipment (I).

A.The facility shall maintain the physical plant free of fire hazards and impediments to fire prevention.

B.No portable electric or unvented fuel heaters shall be permitted in the facility except as permitted by the State Fire Marshal Regulations.

C.Wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant in accordance with the applicable code in Section 1700.

2014. Water Requirements.

A.The facility shall establish written policies and procedures to prevent waterborne microbial contamination within the water distribution system.

B.The facility shall ensure the practice of hand hygiene to prevent the hand transfer of pathogens, and the use of barrier precautions (e.g. gloves) in accordance with established guidelines.

C.The facility shall eliminate contaminated water or fluid from environmental reservoirs (e.g. in equipment or solutions) wherever possible.

D.The facility shall not place decorative fountains and fish tanks in patient-care areas. If decorative fountains are used in separate public areas, the facility shall ensure they are disinfected in accordance with manufacturer’s instructions and safely maintained.

E. The facility plumbing fixtures that require hot water and are accessible to patients shall be supplied with water which thermostatically controlled to a temperature of at least 100 degrees F. (37.8 degrees C) and not exceeding 125 degrees F. (51.7 degrees C.) at the fixture.

F. The facility shall have a written plan to respond to disruptions in water supply. The plan must include a contingency plan to estimate water demands for the entire facility in advance of significant water disruptions (i.e., those expected to result in extensive and heavy microbial or chemical contamination of the potable water), sewage intrusion, or flooding.

G. When a significant water disruption or an emergency occurs, the facility shall:

1. Adhere to any advisory to boil water issued by the municipal water utility;

2. Alert patients, families, employees, volunteers, students and visitors not to consume water from drinking fountains, ice, or drinks made from municipal tap water, while the advisory is in effect, unless the water has been disinfected;

3. After the advisory is lifted, run faucets and drinking fountains at full flow for greater than 5 minutes, or use high-temperature water flushing or chlorination;

4. All ice and drinks that may have been contaminated must be disposed and storage containers cleaned; and

5. Decontaminate the hot water system as necessary after a disruption in service or a cross-connection with sewer lines has occurred.

H. The facility shall follow appropriate recommendations to prevent cross connection and other sources of contamination of ice for human consumption and to prevent contamination of hydrotherapy equipment and medical equipment connected to water systems (e.g. automated endoscope reprocessors).

I. The facility shall maintain and implement policies and procedures addressing the management of failure of waste water systems.

J. Patient and staff handwashing lavatories and showers, if any, shall include hot and cold water at all times.

2015. Panelboards (II).

The directory shall be labeled to conform to the actual room designations. Clear access of stored materials shall be maintained to the panel. The panelboard directory shall be labeled to conform to the actual room numbers or designations.

2016. Lighting.

A. Spaces occupied by persons, machinery, equipment within buildings, approaches to buildings, and parking lots shall be lighted. (II)

B. The facility shall have adequate artificial light to include sufficient illumination for reading, observation, and activities.

2017. Heating, Ventilation, and Air Conditioning (HVAC) (II).

A.The HVAC system shall be inspected at least once a year by a certified/licensed technician.

B.No HVAC supply or return grill shall be installed within three feet of a smoke detector. (I)

C.Intake air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials.

D.Each bath/restroom shall have either operable windows or have approved mechanical ventilation.

SECTION 2100

SEVERABILITY

2101. General.

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

SECTION 2200

GENERAL

2201. General.

Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

ATTACHMENT B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394

Notice of Drafting:

The Department of Health and Environmental Control ("Department") proposes amending R.61-91, Standards for Licensing Ambulatory Surgical Facilities. Interested persons may submit written comments to the Healthcare Quality Office of Policy and Communications, S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; HQRegs@dhec.sc.gov; or the Healthcare Quality Public Comment Form (https://forms.office.com/g/9VMEXLWtq0). To be considered, the Department must receive comments no later than 5:00 p.m. on September 25, 2023, the close of the Notice of Drafting comment period.

Synopsis:

Pursuant to S.C. Code Sections 44-7-250 and 44-7-260(A)(4), the Department establishes and enforces the minimum standards for the licensure, maintenance, and operation of ambulatory surgical facilities to ensure the safe and appropriate treatment of persons served in this state. In accordance with 2023 Act No. 20 (S.164), the Department proposes amending R.61-91 to promulgate regulations concerning the provision of uncompensated indigent/charity care required pursuant to S.C. Code Section 44-7-266(B) and -(C), including related definitions, licensure requirements, reporting requirements, and enforcement. Additionally, the Department proposes amending the regulation to address the required quality of care, services, and treatment provided by facilities and to prescribe the manner and method of fee payments.

The proposed amendments may also include stylistic changes, which may include corrections for clarity and readability, grammar, punctuation, definitions, references, codification, and overall improvement of the text of the regulation.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

ATTACHMENT C

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

R.61-91, Standards for Licensing Ambulatory Surgical Facilities

As of September 25, 2023, close of the Notice of Drafting comment period:

Name	Section
Surgery Center of Pelham	**General**
Comment: **Consistency with 2023 Act No. 20** **The Surgery Center at Pelham fully supports the Department's efforts to revise the proposed Regulation 61-91 to align with 2023 Act No. 20, including the requirement that ASFs constructed or established after May 16, 2023, must provide uncompensated indigent/charity care in the amount of at least 2% (Medicaid facilities) or 3% (non-Medicaid facilities) of the facility's adjusted gross revenue within 2 calendar years of initiation of services.** **The Surgery Center at Pelham would also recommend that all ASFs constructed or established after May 16, 2023, must accept Medicare.** **Department Response:** **Acknowledged comments about consistency with 2023 Act No. 20. Please see proposed provisions implementing S.C. Code Ann. Section 44-7-266(C) concerning uncompensated indigent/charity care. See Section 101 (Definitions) and Section 103.N.** **Not adopt suggested revision requiring acceptance of Medicare patients. The Department's authority in promulgating regulations is limited to implementation of the State Health Facility Licensure Act, including establishment of basic standards to ensure the safe and adequate treatment of persons served in this State.**	

Name	Section
Ambulatory Surgery Center of Spartanburg	**General**
Comment: **Consistency with 2023 Act No. 20** **The Ambulatory Surgery Center of Spartanburg fully supports the Department's efforts to revise the proposed Regulation 61-91 to align with 2023 Act No. 20, including the requirement that ASFs constructed or established after May 16, 2023, must provide uncompensated indigent/charity care in the amount of at least 2% (Medicaid facilities) or 3% (non-Medicaid facilities) of the facility's adjusted gross revenue within 2 calendar years of initiation of services.** **The Ambulatory Surgery Center of Spartanburg would also recommend that all ASFs constructed or established after May 16, 2023, must accept Medicare.** **Department Response:**	

Acknowledged comments about consistency with 2023 Act No. 20. Please see proposed provisions implementing S.C. Code Ann. Section 44-7-266(C) concerning uncompensated indigent/charity care. See Section 101 (Definitions) and Section 103.N.

Not adopt suggested revision requiring acceptance of Medicare patients. The Department's authority in promulgating regulations is limited to implementation of the State Health Facility Licensure Act, including establishment of basic standards to ensure the safe and adequate treatment of persons served in this State.

Name	Section
SCMA and SCOA	General

Comment:
The SCMA and SCOA urge DHEC to limit its changes to its statutory authority which is, 'basic standards' to 'ensure the safe and adequate treatment of persons served in this State,' and avoid any new or amended requirements that inject 'Certificate of Need like' considerations for ASCs or services provided therein, counter to legislative intent to eliminate such requirements, such as community need standards, distribution, service areas, adverse impact, financial feasibility, cost containment, record of the applicant, or facility minimum volume standards.

Department Response:
Acknowledged.

Name	Section
SCHA	General

Comment:
Indigent/Charity Care and Government Payors SCHA and its member hospitals are concerned that outpatient cardiac catheterization labs will not accept indigent patients in the same quantities as hospital-based cath labs. The net result will be that uninsured and indigent patients will be less likely to receive life-saving care. We believe that outpatient cardiac cath labs should be subject to the same Medicaid and indigent care requirements as new ASFs.
As amended, South Carolina's CON statute requires that any ASF not requiring a CON after the effective date of the Act must provide indigent/charity care in one of the amounts listed below after the ASC has been in operation for two calendar years:

- **If the ASC provides care to Medicaid beneficiaries, it must provide uncompensated indigent/charity care to the underinsured or medically indigent in an amount equal to or greater than 2% of its adjusted gross revenue; or**
- **If the ASC does not provide care to Medicaid beneficiaries, it must provide uncompensated indigent/charity care to the underinsured or medically indigent in an amount equal to or greater than 3% of its adjusted gross revenue.**

As noted above, state law does not require existing ASFs to meet this charity standard. When the CON statute was amended, there were no cardiac catheterization labs located in ASFs. In order to maintain access to cardiac cath labs for Medicaid, uninsured and indigent patients, we strongly encourage DHEC to require all new outpatient catheterization

facilities to meet the indigent/charity care standards. That should apply even to new cath labs added to existing ASFs that are otherwise exempt.

Department Response:
Acknowledged. Please see proposed provisions implementing S.C. Code Ann. Section 44-7-266(C) concerning uncompensated indigent/charity care. See Section 101 (Definitions) and Section 103.N.

Name	Section
MUSC	300

Comment:
MUSC further strongly recommends that DHEC actively engage in post-licensure enforcement of the ASC licensure requirements that it adopts, such that an ASC's failure to achieve and maintain these standards will result in the ASC's surrender or DHEC's revocation of the ASC's license for a significant period of time. In addition to existing ASC licensure standards, DHEC's enforcement priorities further should include cardiac catheterization volume requirements, transfer agreement requirements, and the indigent/charity care requirements set forth in Act No. 20 (now in S.C. Code §44-7-266(C)).

Department Response:
Acknowledged comments regarding enforcement of licensure regulations.

Not adopt recommendations regarding cardiac catheterization requirements. At this time, the Department has declined proposing standards specifically regarding cardiac catheterizations in ASFs. While various types of surgeries and procedures are performed in ASFs, there aren't provisions specifically addressing types of surgeries or procedures. Moreover, the general provisions of the regulation addressing care, treatment, and services cover all the types of surgeries and procedures performed in ASFs. Finally, the Department is hesitant in promulgating regulations requiring volume requirements as this could be inconsistent with the General Assembly's intent in repealing CON for certain facilities and services. See 2023 Act No. 20.

Name	Section
Surgery Center of Pelham	300

Comment:
Section 300 – Enforcement Actions
Section 302. Violation Classifications
Throughout Section 302, the current language regarding what constitutes a violation is vague and can be inconsistently interpreted and therefore applied differently by individual inspectors.
For example:
Section 302.A. Class I violations are those that the Department determines to present an imminent danger…
Section 302.B. Class II violations are those….that the Department determines to have a negative impact….
Section 302.C. Class III violations….against the best practices as interpreted by the Department.

While there are various I, II, and III notations throughout the regulation, it would be helpful for licensees to have all violations consolidated in a specific area. The Surgery Center at Pelham recommends the Department identify specific violations by and within each Class to eliminate any confusion or inconsistency during the inspection process.

Department Response:
Not adopted. The format and notations of class violations are reasonably clear in the current regulation and follows the standard format used for all health licensure facility or service regulations.

Name	Section
Ambulatory Surgery Center of Spartanburg	**300**

Comment:
Section 300 – Enforcement Actions
Section 302. Violation Classifications
Throughout Section 302, the current language regarding what constitutes a violation is vague and can be inconsistently interpreted and therefore applied differently by individual inspectors.
For example:
Section 302.A. Class I violations are those that the Department determines to present an imminent danger…
Section 302.B. Class II violations are those….that the Department determines to have a negative impact….
Section 302.C. Class III violations….against the best practices as interpreted by the Department.
While there are various I, II, and III notations throughout the regulation, it would be helpful for licensees to have all violations consolidated in a specific area. The Ambulatory Surgery Center of Spartanburg recommends the Department identify specific violations by and within each Class to eliminate any confusion or inconsistency during the inspection process.

Department Response:
Not adopted. The format and notations of class violations are reasonably clear in the current regulation and follows the standard format used for all health licensure facility or service regulations.

Name	Section
Ambulatory Surgery Center of Spartanburg	**500**

Comment:
Section 500 – Staff
Section 504. Medical Staff (I)
The Ambulatory Surgery Center of Spartanburg recommends that Section 504.A. be updated to include the requirement physicians performing surgery/procedures are board certified or board eligible.
Physicians, Dentists, and podiatrists performing surgery and/or procedures shall be appropriately licensed to perform those functions as well as adequately trained in any

special requirements that are necessary to perform such surgery/procedures, including being board certified or board eligible.

Department Response:
Adopted. Please see proposed Section 505.A. This suggestion is consistent with guidance provided by the Centers for Medicare & Medicaid Services (CMS) for its ASC conditions for coverage.

Name	Section
Surgery Center at Pelham	500

Comment:
Section 500 – Staff
Section 504. Medical Staff (I)
The Surgery Center at Pelham recommends that Section 504.A. be updated to include the requirement physicians performing surgery/procedures are board certified or board eligible.
Physicians, Dentists, and podiatrists performing surgery and/or procedures shall be appropriately licensed to perform those functions as well as adequately trained in any special requirements that are necessary to perform such surgery/procedures, including being board certified or board eligible.

Department Response:
Adopted. Please see proposed Section 505.A. This suggestion is consistent with guidance provided by CMS for its ASC conditions for coverage.

Name	Section
Prisma Health	600

Comment:
SECTION 600 – REPORTING
601. B. 7. We find the requirement to report all medication errors to be excessive and request that the regulation be amended to specify that only medication errors resulting in serious harm or death be reportable.

Department Response:
Partially adopted. Department staff propose amending Section 601.B.7 to require reporting medication errors with adverse reaction. The proposed language aligns with other licensure regulations.

Name	Section
Surgery Center of Pelham	800

Comment:
The Surgery Center at Pelham recommends that Section 803.A be created to require that for any surgeries or procedures scheduled that general anesthesia time be limited to 4 hours or less duration in order to allow for appropriate recovery time within the nature of an ambulatory surgical facility and consistent with CMS Ambulatory Surgery Center guidelines for duration of service.

Department Response:
Not adopted. At this time, the Department staff determined the existing and proposed provisions relating to care, treatment, and services reasonably ensure the safe and adequate treatment of persons served in ASFs. Moreover, the referenced CMS Ambulatory Surgery Center guideline was not found in the current version of the CMS Medicare Conditions for Coverage. See 42 C.F.R. Part 416.

Name	Section
Ambulatory Surgery Center of Spartanburg	800

Comment:
The Ambulatory Surgery Center of Spartanburg recommends that Section 803.A be created to require that for any surgeries or procedures scheduled that general anesthesia time be limited to 4 hours or less duration in order to allow for appropriate recovery time within the nature of an ambulatory surgical facility and consistent with CMS Ambulatory Surgery Center guidelines for duration of service.

Department Response:
Not adopted. At this time, Department staff have determined the existing and proposed provisions relating to care, treatment, and services reasonably ensure the safe and adequate treatment of persons served in ASFs. Moreover, the referenced CMS Ambulatory Surgery Center guideline was not found in the current version of the CMS Medicare Conditions for Coverage. See 42 C.F.R. Part 416.

Name	Section
Surgery Center at Pelham	800

Comment:
The Surgery Center at Pelham recommends that Section 803.B be created to require that a transfer agreement be in place with a hospital for those surgeries or procedures that require transport to a hospital.

Department Response:
Adopted. See Section 801.D.

Name	Section
Ambulatory Surgery Center of Spartanburg	800

Comment:
The Ambulatory Surgery Center of Spartanburg recommends that Section 803.B be created to require that a transfer agreement be in place with a hospital for those surgeries or procedures that require transport to a hospital.

Department Response:
Adopted. See Section 801.D.

Name	Section
Surgery Center of Pelham	800

Comment:

The Surgery Center at Pelham also recommends the creation of a Cardiovascular Services section with the following regulations:

Cardiovascular Services
1: Quality and Patient Safety
With the rapidly evolving changes in technology and the need for licensees to adapt to those changes in technology and service locations, in order to ensure patient safety and quality of care, all licensees providing cardiovascular care must be in compliance with the most recent ACC/AHA/SCAI Guideline for Coronary Artery Revascularization publication.
2: Individuals performing procedures must meet the minimum competencies identified in the current version of the ACC, AHA, SCAI Training Guidance for Interventional Cardiology.
3: Cardiac catheterizations laboratory services shall only be provided under the control of a board certified or board eligible physician.
4: Licensees providing interventional cardiac catheterization laboratory services without onsite open-heart surgery shall secure and maintain a formal transfer agreement with a hospital performing open heart surgery located within 30 minutes' emergency medical transport time as determined by the DHEC Bureau of EMS and Trauma. For the purposes of this regulation, emergency medical transport time shall mean transport by ground ambulance.
5: Licensees may not provide emergent interventional cardiac catheterization services.
6: Licensees may not provide open heart surgery services.

Department Response:
Not adopted. At this time, Department staff have declined proposing standards specifically regarding cardiovascular care in ASFs. While various types of surgeries and procedures are performed in ASFs, there aren't provisions specifically addressing types of surgeries or procedures. Moreover, the general provisions of the regulation addressing care, treatment, and services cover all the types of surgeries and procedures performed in ASFs.

Name	Section
Ambulatory Surgery Center of Spartanburg	**800**

Comment:
The Ambulatory Surgery Center of Spartanburg also recommends the creation of a Cardiovascular Services section with the following regulations:

Cardiovascular Services
1: Quality and Patient Safety
With the rapidly evolving changes in technology and the need for licensees to adapt to those changes in technology and service locations, in order to ensure patient safety and quality of care, all licensees providing cardiovascular care must be in compliance with the most recent ACC/AHA/SCAI Guideline for Coronary Artery Revascularization publication.
2: Individuals performing procedures must meet the minimum competencies identified in the current version of the ACC, AHA, SCAI Training Guidance for Interventional Cardiology.
3: Cardiac catheterizations laboratory services shall only be provided under the control of a board certified or board eligible physician.
4: Licensees providing interventional cardiac catheterization laboratory services without onsite open-heart surgery shall secure and maintain a formal transfer agreement with a

hospital performing open heart surgery located within 30 minutes' emergency medical transport time as determined by the DHEC Bureau of EMS and Trauma. For the purposes of this regulation, emergency medical transport time shall mean transport by ground ambulance.
5: Licensees may not provide emergent interventional cardiac catheterization services.
6: Licensees may not provide open heart surgery services.

Department Response:
Not adopted. At this time, Department staff have declined proposing standards specifically regarding cardiovascular care in ASFs. While various types of surgeries and procedures are performed in ASFs, there aren't provisions specifically addressing types of surgeries or procedures. Moreover, the general provisions of the regulation addressing care, treatment, and services cover all the types of surgeries and procedures performed in ASFs.

Name	Section
MUSC	**800**

Comment:
Consistent with the S.C. Hospital Association's proposal to codify the CON standards for cardiovascular care contained in the 2020 South Carolina Health Plan in hospital licensing regulations, which MUSC supports, such standards should also be codified, where applicable, in Regulation 61-91 to ensure that certain cardiac catheterization procedures can be performed safely in a non-hospital setting. MUSC strongly believes that if DHEC elects to allow certain cardiac procedures to be performed in an ASC, DHEC must amend Regulation 61-91 to incorporate rigorous cardiac catheterization standards in its ASC licensing regulation, which will most appropriately maintain the clinical and quality standards currently governing cardiac catheterization services.

Specifically, MUSC proposes that, in addition to the applicable CON standards in the 2020 Health Plan, DHEC require that an ASC seeking licensure to perform certain cardiac catheterization procedures is owned, in whole or in part, by a hospital licensed under Regulation 61-16. For non-hospital-owned ASC's, DHEC may grant licensure only if all acute care hospitals which offer cardiac catheterization services and/or PCI services, located within a thirty (30) minute automobile travel time of the proposed ASC, provide a written letter of support to DHEC.

Department Response:
Not adopted. At this time, Department staff have declined proposing standards specifically regarding cardiac catheterizations in ASFs. While various types of surgeries and procedures are performed in ASFs, there aren't provisions specifically addressing types of surgeries or procedures. Moreover, the general provisions of the regulation addressing care, treatment, and services cover all the types of surgeries and procedures performed in ASFs. Finally, Department staff are hesitant in promulgating regulations requiring volume requirements as this could be inconsistent with the General Assembly's intent in repealing CON for certain facilities and services. See 2023 Act No. 20.

Name	Section
SCHA	**800**

Comment:

Earlier this year the General Assembly amended our Certificate of Need ("CON") law to allow physicians to perform cardiovascular services in ambulatory surgery centers and possibly other locations. Our state has long regulated cardiovascular services in the hospital setting, and the absence of appropriate regulations for such services outside a hospital poses significant risk for South Carolina patients. SCHA appreciates DHEC recognizing this concern and opening the ambulatory surgical facility regulation for comment. DHEC should also consider whether Regulation 61-108, Standards for Licensing Freestanding or Mobile Technology, applies to cardiovascular care in South Carolina. If so, DHEC should open those regulations for comment as well. SCHA requests that certain cardiac catheterization procedures and catheterization labs remain hospital-based. Specifically, percutaneous coronary interventions ("PCIs") and comprehensive catheterization laboratories. According to the American College of Cardiology/American Heart Association/SCAI standards, these services and facilities are best provided in hospitals for patient safety reasons. We encourage DHEC to work with the South Carolina Board of Medical Examiners to modify the office-based surgery rules to include regulation of cardiovascular procedures as well.

For patient safety concerns, SCHA recommends that any ASF that performs cardiac catheterizations be required to have a critical care transfer protocol in place.

Department Response:
Not adopted. At this time, Department staff have declined proposing standards specifically regarding cardiac catheterizations in ASFs. While various types of surgeries and procedures are performed in ASFs, there aren't provisions specifically addressing types of surgeries or procedures. Moreover, the general provisions of the regulation addressing care, treatment, and services cover all the types of surgeries and procedures performed in ASFs.

Acknowledge comments regarding consideration of R. 61-108, Standards for Licensing Freestanding or Mobile Technology, and coordinating with other agencies in administering our regulatory responsibilities.

Name	Section
Ambulatory Surgery Center of Spartanburg	**800**

Comment:
Section 803. Surgical Services
Section 803 currently requires that a list of all types of surgical services offered by the facility be available.

The Ambulatory Surgery Center of Spartanburg recommends that Section 803.A be created to require that for any surgeries or procedures scheduled that general anesthesia time be limited to 4 hours or less duration in order to allow for appropriate recovery time within the nature of an ambulatory surgical facility and consistent with CMS Ambulatory Surgery Center guidelines for duration of service.

The Ambulatory Surgery Center of Spartanburg recommends that Section 803.B be created to require that a transfer agreement be in place with a hospital for those surgeries or procedures that require transport to a hospital.

The Ambulatory Surgery Center of Spartanburg also recommends the creation of a Cardiovascular Services section with the following regulations:

Cardiovascular Services
1: Quality and Patient Safety
With the rapidly evolving changes in technology and the need for licensees to adapt to those changes in technology and service locations, in order to ensure patient safety and quality of care, all licensees providing cardiovascular care must be in compliance with the most recent ACC/AHA/SCAI Guideline for Coronary Artery Revascularization publication.
2: Individuals performing procedures must meet the minimum competencies identified in the current version of the ACC, AHA, SCAI Training Guidance for Interventional Cardiology.
3: Cardiac catheterizations laboratory services shall only be provided under the control of a board certified or board eligible physician.
4: Licensees providing interventional cardiac catheterization laboratory services without onsite open-heart surgery shall secure and maintain a formal transfer agreement with a hospital performing open heart surgery located within 30 minutes' emergency medical transport time as determined by the DHEC Bureau of EMS and Trauma. For the purposes of this regulation, emergency medical transport time shall mean transport by ground ambulance.
5: Licensees may not provide emergent interventional cardiac catheterization services.
6: Licensees may not provide open heart surgery services.

Department Response:
Not adopt suggested revision regarding limitation of general anesthesia time to 4 hours or less. At this time, Department staff have determined the existing and proposed provisions relating to care, treatment, and services reasonably ensure the safe and adequate treatment of persons served in ASFs. Moreover, the referenced CMS Ambulatory Surgery Center guideline was not found in the current version of the CMS Medicare Conditions for Coverage. See 42 C.F.R. Part 416.

Adopted suggestion regarding requiring a transfer agreement. See Section 801.D.

Not adopt suggestions regarding cardiovascular services. At this time, Department staff have declined proposing standards specifically regarding cardiovascular services. While various types of surgeries and procedures are performed in ASFs, there aren't provisions specifically addressing types of surgeries or procedures. Moreover, the general provisions of the regulation addressing care, treatment, and services cover all the types of surgeries and procedures performed in ASFs.

Name	Section
McLeod Health	800
Comment: **Cardiovascular Services**	

The absence of regulation of cardiovascular services poses a high risk for South Carolina patients requiring either an emergent or elective cardiac catheterization procedure. Without CON regulations, alternate facilities may be chosen by physicians to perform cardiovascular services. These could be performed in an ASF or other surgical setting. Therefore, McLeod appreciates DHEC opening the ambulatory surgical facility regulation, 61-91, for comment and wishes to strongly voice its concerns.

McLeod requests that cardiac catheterization procedures and catheterization labs remain hospital based. We believe this is particularly true for percutaneous coronary interventions ("PCis") and other comprehensive procedures performed in catheterization laboratories. According to the American College of Cardiology/American Heart Association/SCA standards, these services and facilities are best provided and located in hospitals for patient safety reasons. Based on our obligation to advocate on behalf of patients who may face potential dangers with their health, we believe a change to hospital-based catheterizations pose serious negative medical risks and possibly irreversible outcomes for cardiac patients.
We encourage DHEC to work with the South Carolina Board of Medical Examiners to modify the office-based surgery rules to include regulation of cardiovascular procedures performed there as well.
If DHEC should decide to allow ASFs to perform cardiac catheterization, McLeod Health recommends that any ASF that performs therapeutic and diagnostic cardiac catheterizations be required to have in place appropriate critical care transfer protocols, appropriate critical care transport and transfer agreements with a hospital(s) that is licensed to perform open-heart surgery. These protocols should ensure a patient with a complication can be transferred to a higher level of care within 30 minutes of identified issue.

Department Response:
Not adopt provisions specific to cardiovascular care. At this time, Department staff have declined proposing standards specifically regarding cardiac catheterizations. While various types of surgeries and procedures are performed in ASFs, there aren't provisions specifically addressing types of surgeries or procedures. Moreover, the general provisions of the regulation addressing care, treatment, and services cover all the types of surgeries and procedures performed in ASFs.

Acknowledge comments regarding coordinating with other agencies in administering our regulatory responsibilities.

Name	Section
Surgery Center of Pelham	1600

Comment:
Section 1600 – Quality Improvement Program
The Surgery Center at Pelham recommends the Department rename Section 1600 to Quality and rename Section 1601 from General (II) to Quality Improvement Program. Further, it is recommended that a new section 1602. Clinical Quality be created.

Section 1602. Clinical Quality
With the rapidly evolving changes in technology and the need for licensees to adapt to those changes in technology and service locations, to ensure patient safety and quality of care, all ambulatory surgical facility licensees should be required to report quality measures to CMS quarterly and should be encouraged to participate in the ASC Quality Collaboration program. At a minimum, all licensees should be required to report all infections, all transfers and percent of transfers as well as patients admitted to the hospital from an ambulatory surgical center. Documentation of reporting to CMS must be provided at annual licensure surveys.
https://higherlogicdownload.s3.amazonaws.com/ASCACONNECT/1b34f1a1-0180-4005-9507-902fdf8f242e/UploadedFiles/l1HFV0SLnViPTYPgSQt9_ASC-QC-Implementation-Guide-11.0-February-2023.pdf

In addition, within each CMS diagnostic group, licensees must be in compliance with quality measures as identified by recognized national organizations.

Department Response:
Not Adopted. At this time, Department staff have determined required reporting and participation in the referenced ASF Quality Collaboration Program are unnecessary for the Department's licensing duties which involve the establishment and enforcement of basic standards for maintenance and operation of facilities. However, Department staff have proposed certain amendments regarding the governing bodies' involvement with quality improvement programs. See Section 1601.C.

Name	Section
Ambulatory Surgery Center of Spartanburg	1600

Comment:
Section 1600 – Quality Improvement Program
The Ambulatory Surgery Center of Spartanburg recommends the Department rename Section 1600 to Quality and rename Section 1601 from General (II) to Quality Improvement Program.
Further, it is recommended that a new section 1602. Clinical Quality be created.

Section 1602. Clinical Quality
With the rapidly evolving changes in technology and the need for licensees to adapt to those changes in technology and service locations, to ensure patient safety and quality of care, all ambulatory surgical facility licensees should be required to report quality measures to CMS quarterly and should be encouraged to participate in the ASC Quality Collaboration program. At a minimum, all licensees should be required to report all infections, all transfers and percent of transfers as well as patients admitted to the hospital from an ambulatory surgical center. Documentation of reporting to CMS must be provided at annual licensure surveys.
https://higherlogicdownload.s3.amazonaws.com/ASCACONNECT/1b34f1a1-0180-4005-9507-902fdf8f242e/UploadedFiles/l1HFV0SLnViPTYPgSQt9_ASC-QC-Implementation-Guide-11.0-February-2023.pdf

In addition, within each CMS diagnostic group, licensees must be in compliance with quality measures as identified by recognized national organizations.

Department Response:
Not Adopted. At this time, Department staff have determined required reporting and participation in the referenced ASF Quality Collaboration Program are unnecessary for the Department's licensing duties which involve the establishment and enforcement of basic standards for maintenance and operation of facilities. However, Department staff have proposed certain amendments regarding the governing bodies' involvement with quality improvement programs. See Section 1601.C.

Name	Section
Surgery Center of Pelham	**2000**

Comment:
Section 2000 – Physical Plant
Section 2006. Restrooms (II)
In the current regulations, Section 2006.E requires that the facility shall have toilet fixtures in restrooms for patient use in or adjacent to the recovery area in ample number and further specifies a minimum requirement of one toilet fixture for every surgical and procedure room.

<u>This is not an appropriate ratio given the nature of post-operative care.</u> With the various types of procedures, the varying lengths of procedures, and the uniqueness of each patient in an ambulatory surgery facility, it would be extremely unlikely that all patients in the recovery area would need to use a toilet at the same time.

The Surgery Center at Pelham recommends that the Department remove the sentence and that Section 2006.E. reads "The facility shall have toilet fixtures in restrooms for patient use in ample number, located within or adjacent to the recovery area."

Department Response:
Partially adopted. Department staff propose amending Section 2006.E to require a minimum of one toilet fixture for every eight pre-operative and post-operative beds, which is consistent with the FGI Guidelines.

Name	Section
Ambulatory Surgery Center of Spartanburg	**2000**

Comment:
Section 2000 – Physical Plant
Section 2006. Restrooms (II)
In the current regulations, Section 2006.E requires that the facility shall have toilet fixtures in restrooms for patient use in or adjacent to the recovery area in ample number and further specifies a minimum requirement of one toilet fixture for every surgical and procedure room.

<u>This is not an appropriate ratio given the nature of post-operative care.</u> With the various types of procedures, the varying lengths of procedures, and the uniqueness of each patient in an ambulatory surgery facility, it would be extremely unlikely that all patients in the recovery area would need to use a toilet at the same time.

The Ambulatory Surgery Center of Spartanburg recommends that the Department remove the sentence and that Section 2006.E. reads "The facility shall have toilet fixtures in restrooms for patient use in ample number, located within or adjacent to the recovery area."

Department Response:
Partially adopted. Department staff propose amending Section 2006.E to require a minimum of one toilet fixture for every eight pre-operative and post-operative beds, which is consistent with the FGI Guidelines.

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 9, 2023

(X) ACTION/DECISION
( ) INFORMATION

I. **TITLE**: Request for Placement of Zuranolone in Schedule IV for Controlled Substances in South Carolina

II. **SUBJECT:** Placement of Zuranolone in Schedule IV for Controlled Substances

III. **FACTS:**

Controlled substances are governed by the South Carolina Controlled Substances Act, Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule IV substances are listed in Section 44-53-250 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

South Carolina Section 44-53-160(C) states:

> If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee, and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On August 4, 2023, the United States Food and Drug Administration ("FDA") approved a new drug application ("NDA") for ZURZUVAE (Zuranolone) capsules for the treatment of post-partum depression. The Department of Health and Human Services ("HHS") provided the Drug Enforcement Administration ("DEA") with a scheduling recommendation to place zuranolone and its salts in schedule IV of the Controlled Substances Act. In accordance with the federal Controlled Substances Act ("CSA"), as amended by the Improving Regulatory Transparency for New Medical Therapies Act, the DEA issued an interim final rule placing zuranolone, including its salts, in schedule IV of the federal CSA. This action facilitates the public availability of zuranolone as a schedule IV controlled substance. This rule has an effective date

of October 31, 2023, *Federal Register*, Volume 88, Number 209, pages 74347-74352; *https:// www.govinfo.gov/content/pkg/ FR-2023-10-31/pdf/2023-23982.pdf.*

IV. ANALYSIS:

Zuranolone is a new molecular entity that has not been marketed in the United States or any country. Thus, evidence regarding its diversion, illicit manufacturing, or deliberate ingestion is currently lacking. DEA notes that there are no reports of law enforcement encounters of zuranolone in the National Forensic Laboratory Information System ("NFLIS") Drug database. Zuranolone has sedative effects and is likely to have abuse potential, similar to schedule IV sedatives such as alprazolam. Thus, it is reasonable to assume that zuranolone may be diverted from legitimate channels, used contrary to or without medical advice, and capable of creating hazards to the users and to the safety of the community. In human abuse potential studies, zuranolone produced positive subjective responses that are similar to those produced by alprazolam (schedule IV). Zuranolone produces rewarding effects that are comparable to those produced by schedule IV sedatives; therefore, zuranolone is likely to be abused for its sedative effects contrary to medical advice.

On July 12, 2023, DEA received from HHS a scientific and medical evaluation entitled "Basis for the Recommendation to Control Zuranolone and its Salts in Schedule IV of the Controlled Substances Act" and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of zuranolone, along with HHS's recommendation to control zuranolone and its salts under schedule IV of the federal CSA. In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). DEA concluded that zuranolone meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of the CSA. Pursuant to subsection 811(j), and based on HHS' scheduling recommendation, the approval of the NDA by HHS/FDA, and DEA's determination, DEA issued an interim final rule to schedule zuranolone as a schedule IV controlled substance under the federal CSA.

The federal CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA ("Administrator"), pursuant to 21 U.S.C. 812(b)(4), found that:

1) Zuranolone has a potential for abuse similar to drugs or other substances in schedule IV.

2) Zuranolone has a currently accepted medical use in treatment in the United States.

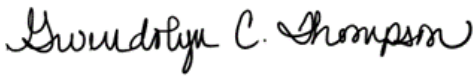
3) Abuse of zuranolone may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III but similar to other substances in schedule IV.

V. RECOMMENDATION:

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing zuranolone and its salts in schedule IV and the amendment of Section 44-53-250 of the South Carolina Controlled Substances Act to include:

( ) Zuranolone

Submitted by:



Lisa Thomson
Director, Bureau of Drug Control

Gwen Thompson
Director for Healthcare Quality

Attachment:
Federal Register, Volume 88, Number 209, October 31, 2023

Nonmetallic Safety Cans for Flammable and Combustible Liquids, Tenth Edition, dated April 29, 2022.

(2) [Reserved]

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–23655 Filed 10–30–23; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA1258]

Schedules of Controlled Substances: Placement of Zuranolone in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule; request for comments.

SUMMARY: On August 4, 2023, the United States Food and Drug Administration approved a new drug application for ZURZUVAE (zuranolone) capsules for the treatment of post-partum depression. The Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place zuranolone and its salts in schedule IV of the Controlled Substances Act (CSA). In accordance with the CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing zuranolone, including its salts, in schedule IV of the CSA. This action facilitates the public availability of zuranolone as a schedule IV controlled substance.

DATES: This rule is effective October 31, 2023. Comments must be submitted electronically or postmarked on or before November 30, 2023.

Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received on or before November 30, 2023.

ADDRESSES: Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference ''Docket No. DEA1258'' on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages commenters to submit comments electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, VA 22152.
- *Hearing requests:* All requests for hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be filed with the DEA Administrator, who will make the determination of whether a hearing will be needed to address such matters of fact and law in the rulemaking. Such requests must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. For informational purposes, a courtesy copy of requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. DEA will make comments available for public inspection online at *https://www.regulations.gov.* Such information includes personal or business identifying information (such as name, address, State or Federal identifiers, etc.) voluntarily submitted by the commenter. In general, all information voluntarily submitted by the commenter, unless clearly marked as Confidential Information in the method described below, will be publicly posted. Comments may be submitted anonymously. The Freedom of Information Act applies to all comments received.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made publicly available should submit two copies of the comment. One copy must be marked ''CONTAINS CONFIDENTIAL INFORMATION'' and should clearly identify all PII or business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked ''TO BE PUBLICLY POSTED'' and must have all claimed confidential PII and business information already redacted. DEA will post only the redacted comment on *https://www.regulations.gov* for public inspection.

For easy reference, an electronic copy of this document and supplemental information to this interim final rule (IFR) are available at *https://www.regulations.gov.*

Request for Hearing or Appearance; Waiver

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559.[1] Interested persons, as defined in 21 CFR 1300.01(b), may file requests for a hearing in conformity with the requirements of 21 CFR 1308.44(a) and 1316.47(a), and such requests must:

(1) state with particularity the interest of the person in the proceeding;

(2) state with particularity the objections or issues concerning which the person desires to be heard; and

[1] 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D.

(3) state briefly the position of the person with regarding to the objections or issues.

Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing in conformity with the requirements of 21 CFR 1308.44©, together with a written statement of position on the matters of fact and law involved in any hearing.[2]

All requests for hearings and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above. The decision whether a hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator. If a hearing is needed, DEA will publish a notice of hearing on the proposed rulemaking in the **Federal Register**.[3] Further, once the Administrator determines a hearing is needed to address such matters of fact and law in rulemaking, she will then designate an Administrative Law Judge (ALJ) to preside over the hearing. The ALJ's functions shall commence upon designation, as provided in 21 CFR 1316.52.

In accordance with 21 U.S.C. 811 and 812, the purpose of a hearing would be to determine whether zuranolone meets the statutory criteria for placement in schedule IV.

Background and Legal Authority

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (section 2(b) of Pub. L. 114–89), DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the Food and Drug Administration (FDA). As provided in 21 U.S.C. 811(j), this expedited scheduling is required where both of the following conditions apply: (1) The Secretary of the Department of Health and Human Services (HHS) has advised DEA that a New Drug Application (NDA) has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system (CNS), and that it appears that such drug has an abuse potential; and (2) the Secretary of HHS recommends that DEA control the drug in schedule II, III, IV, or V pursuant to 21 U.S.C. 811(a) and (b). In these circumstances, DEA is required to issue an interim final rule (IFR) controlling the drug within 90 days.

Subsection 811(j)(2) states that the 90-day timeframe starts the later of (1) the date DEA receives HHS's scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Subsection 811(j)(3) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause therefore. Thus, the purpose of subsection 811(j) is to speed the process by which DEA schedules newly approved drugs that are currently either in schedule I or not controlled (but which have sufficient abuse potential to warrant control) so that such drugs may be marketed without undue delay following FDA approval.[4]

Subsection 811(j)(3) further provides that the IFR shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, DEA must issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811(b) through (d), and 812(b).

Zuranolone (chemically known as 1-[2-[(3*R*,5*R*,8*R*,9*R*,10*S*,13*S*,14*S*,17*S*)-3-hydroxy-3,13-dimethyl-2,4,5,6,7,8,9,10,11,12,14,15,16,17-tetradecahydro-1*H*-cyclopenta[*a*]phenanthren-17-yl]-2-oxoethyl]pyrazole-4-carbonitrile) is a new molecular entity with CNS activity. Zuranolone is a positive allosteric modulator of gamma-aminobutyric acid type A ($GABA_A$) receptors and an inhibitory neurosteroid substance that shares structural features and a pharmacological mechanism of action with progesterone, alfaxalone (schedule IV), and brexanolone (allopregnanolone, schedule IV).

On December 5, 2022, Sage Therapeutics, Inc. submitted an NDA for zuranolone to FDA. On August 4, 2023, FDA approved the NDA for zuranolone to be marketed as a prescription drug (ZURZUVAE, capsule) for the treatment of post-partum depression. DEA received notification that FDA approved the NDA on the same date. Pursuant to its FDA-approved prescription drug labeling, ZURZUVAE, 50 mg, is to be administered orally once in the evening with fat-consuming food for 14 days. The dose may be reduced for patients who cannot tolerate 50 mg.

Determination To Schedule Zuranolone

On July 12, 2023, DEA received from HHS a scientific and medical evaluation entitled ''Basis for the Recommendation to Control Zuranolone and its Salts in Schedule IV of the Controlled Substances Act'' and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of zuranolone, along with HHS's recommendation to control zuranolone and its salts under schedule IV of the CSA.

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). DEA concluded that zuranolone meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of the CSA.

Pursuant to subsection 811(j), and based on HHS's scheduling recommendation, the approval of the NDA by HHS/FDA, and DEA's determination, DEA is issuing this IFR to schedule zuranolone as a schedule IV controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its scheduling action. Please note that both DEA and HHS analyses are available in their entirety under ''Supporting Documents'' in the public docket for this IFR at *https://www.regulations.gov,* under Docket Number ''DEA1258.'' Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

1. Its Actual or Relative Potential for Abuse

Zuranolone is a new molecular entity that has not been marketed in the United States or any country. Thus, evidence regarding its diversion, illicit manufacturing, or deliberate ingestion is currently lacking. DEA notes that there are no reports of law enforcement encounters of zuranolone in the National Forensic Laboratory Information System (NFLIS)-Drug database.[5] Zuranolone has sedative effects and is likely to have abuse potential, similar to schedule IV sedatives such as alprazolam. Thus, it is reasonable to assume that zuranolone may be diverted from legitimate channels, used contrary to or without

[2] 21 CFR 1316.49.

[3] 21 CFR 1308.44(b), 1316.53.

[4] Given the parameters of subsection 811(j), in DEA's view, it would not apply to a reformulation of a drug containing a substance currently in schedules II through V for which an NDA has recently been approved.

[5] NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle more than 96% of an estimated 1 million distinct annual State and local drug analysis cases. NFLIS-Drug includes drug chemistry results from completed analyses only. While NFLIS-Drug data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332 (Dec. 12, 2011). NFLIS data were queried on August 30, 2023.

medical advice, and capable of creating hazards to the users and to the safety of the community. In human abuse potential studies, zuranolone produced positive subjective responses that are similar to those produced by alprazolam (schedule IV). Zuranolone produces rewarding effects that are comparable to those produced by schedule IV sedatives; therefore, zuranolone is likely to be abused for its sedative effects contrary to medical advice.

2. Scientific Evidence of Its Pharmacological Effects, If Known

Zuranolone is a selective neuroactive steroid that potentiates synaptic (γ subunit-containing) and extra synaptic (δ-subunit containing) $GABA_A$ receptor activity. Zuranolone acts on $GABA_A$ receptors to enhance the effects of GABA, a major inhibitory neurotransmitter in the CNS. Zuranolone acts directly through the $GABA_A$ receptor-channel complex to increase the probability that the channel will enter into naturally occurring open states of relatively long duration and allow the influx of chloride. Zuranolone was found to potentiate GABA-evoked current in cells expressing human $GABA_A$ receptor subtypes. HHS noted that these data are consistent with a mechanism of action of zuranolone that is similar to other schedule IV neurosteroids (*e.g.,* brexanolone) as a positive allosteric modulator of $GABA_A$ sites.

In animal studies, zuranolone's effect on the general behavioral profile in male rats showed that it produced behavioral activities, such as decreased activity, ataxia, hypersensitivity to touch and/or sound, and impaired righting reflex at supratherapeutic plasma concentrations. The observations were generally limited to the highest dose test (22.5 mg/kg), although some animals exhibited slight impairments at the lower doses tested (3 and 10 mg/kg).

In a drug discrimination study using male rats trained to discriminate midazolam and saline, intraperitoneally administered zuranolone (0.1, 0.3, 0.5, 1, and 3 mg/kg) produced dose-dependent effects and full substitution to midazolam discriminative stimulus effect at the highest dose tested when considering lever presses over the entire session and not just the first reinforcer (75 percent). However, 3 mg/kg zuranolone produced behavioral impairment, such that only five of ten rodents completed the session. In female rats, intraperitoneally administered zuranolone (0.1, 0.3, 0.5, 1, and 2 mg/kg) also produced dose-dependent effects and full substitution to midazolam discriminative stimulus effect at the highest dose tested when considering lever presses over the entire session and not just the first reinforcer (72.5 percent).

Zuranolone reinforcing properties were assessed by determining whether self-administration behavior was maintained when the drug was substituted for cocaine (schedule II). As stated by HHS in their scientific and medical evaluation, the study found that the selected doses of zuranolone did not maintain robust self-administration in animals with a previous history of cocaine self-administration.

In clinical trials, zuranolone produced significantly greater mean drug liking than placebo. The low (30 mg) and middle (60 mg) doses of zuranolone produced significantly less mean drug liking scores than both alprazolam (schedule IV) doses (1.5 and 3 mg). However, the highest dose of zuranolone produced mean drug liking scores that were similar to both doses of alprazolam (schedule IV).

Zuranolone produced euphoria-related adverse events that are supportive of zuranolone having an abuse potential. However, the abuse-related treatment emergent AE profile of zuranolone was slightly lower than that of alprazolam (a schedule IV benzodiazepine) at a supratherapeutic dose of zuranolone.

Zuranolone produced incidence of euphoria-related adverse events supportive of its abuse potential in animals and humans similar to those of benzodiazepines in schedule IV. These data are consistent with the fact that both drugs share a common mechanism of action involving positive allosteric modulation of the $GABA_A$ receptors.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

Zuranolone, chemically known as 1-[2-[(3*R*,5*R*,8*R*,9*R*,10*S*,13*S*,14*S*,17*S*)-3-hydroxy-3,13-dimethyl-2,4,5,6,7,8,9,10,11,12,14,15,16,17-tetradecahydro-1*H*-cyclopenta[*a*]phenanthren-17-yl]-2-oxoethyl]pyrazole-4-carbonitrile, is a new molecular entity.

Zuranolone is a drug product formulated as 20, 25, and 30 mg colored hard-gelatin capsules. The powder is white to off-white in color. Zuranolone is available as an immediate-release formulation and is absorbed with a time to maximum effect of approximately 6 hours and a half-life of 20 hours.

As discussed in the background section, zuranolone has an accepted medical use in the United States.

4. Its History and Current Pattern of Abuse

There is no information on the history and current pattern of abuse for zuranolone, since it has not been marketed, legally or illegally, in the United States or any other country. There is no evidence of diversion of zuranolone that has been distributed for research, such as for clinical trials. Data from preclinical and clinical studies indicate that the abuse potential of zuranolone is similar to that of schedule IV sedatives, including benzodiazepines. Consistent with the fact that zuranolone is a new molecular entity, the NFLIS-Drug database had no records of encounters by law enforcement.

In summary, pharmacological data on zuranolone show that it produces abuse-related effects and has an abuse potential similar to that of schedule IV CNS depressants.

5. The Scope, Duration, and Significance of Abuse

A search by DEA of the NFLIS-Drug database found no evidence of law enforcement encounters of zuranolone in the United States. Data from preclinical and clinical studies showed that zuranolone has an abuse potential that is similar to that of schedule IV sedatives, including benzodiazepines. Upon availability of zuranolone in the market, it is likely to be abused.

6. What, if any, Risk There Is to the Public Health

Zuranolone's abuse potential, similar to that of schedule IV sedatives, is an indication of its public health risk. As such, upon availability for marketing, it is likely to pose risk to public health comparable to schedule IV positive allosteric modulators of the $GABA_A$ receptor such as brexanolone and benzodiazepines. According to evaluation of public health risks conducted by HHS, the most observed adverse effects were somnolence, dizziness, and sedation. An overdose of zuranolone could result in sedation with or without respiratory depression or other severe adverse effects. Two simulated driving studies demonstrated impairment approximately 9 hours after nighttime administration.

Concomitant use with other CNS depressants such as alcohol may potentiate the impairment of psychomotor performance and cognition. HHS noted that zuranolone is not recommended for chronic administration; it is intended for a 14-day treatment course. This may lessen some public health risks compared to

other drugs that are prescribed for longer durations or in larger quantities.

7. Its Psychic or Physiological Dependence Liability

Zuranolone's psychic and physiological dependence liability was assessed using data from animal physical dependence studies and clinical evaluations of physical dependence, including measures of withdrawal. As described by HHS, data from a physiologic dependence study conducted in rats demonstrated zuranolone did not induce significant withdrawal-related phenotypes at the doses tested; however, zuranolone produced significant toxic effects in dogs, including convulsions and death in the dog toxicity studies. HHS noted the toxic effects in dogs, such as the early mortalities, may be consistent with withdrawal-type effects observed after cessation of chronic dosing of sedative-hypnotic benzodiazepines.

In clinical trials, when zuranolone was administered at therapeutic doses (≤50 mg/day) for a minimum of five days, it produced mild-to-moderate withdrawal-related effects in healthy individuals upon abrupt drug discontinuation, including the following: insomnia, palpitations, decreased appetite, nightmare, nausea, hyperhidrosis, and paranoia. Similar effects were not evident in the patient population. HHS provided caveats for why this may be the case, such as the withdrawal effects may have been obscured by the symptoms of the underlying condition (post-partum depression and major depressive disorder) or inadequate assessment of withdrawal in the various Phase 3 studies. However, based on available data provided by HHS, the withdrawal-related symptoms produced by zuranolone after abrupt drug discontinuation are similar to those that are clinically known for benzodiazepines in schedule IV.

The data taken together suggest that zuranolone maybe produce physical dependence, and the risk of physical dependence and withdrawal syndrome upon drug discontinuation is expected to be more severe for individuals who take a higher than the therapeutic dose of zuranolone for an extended period of time, which may include convulsions based on the dog toxicity studies.

8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA

Zuranolone is not an immediate precursor of any controlled substance, as defined by 21 U.S.C. 802(23).

Conclusion: After considering the scientific and medical evaluation and scheduling recommendation provided by HHS, and its own eight-factor analysis, DEA has determined that these facts and all relevant data constitute substantial evidence of potential for abuse of zuranolone. As such, DEA hereby schedules zuranolone as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V).[6] After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

(1) Zuranolone has a potential for abuse similar to the drugs or other substances in schedule IV.

Zuranolone, a neuroactive steroid, is a positive allosteric modulator of $GABA_A$ receptors and produces sedation in general behavioral studies. In a drug discrimination study in animals, zuranolone produced dose-dependent substitution for midazolam (schedule IV) when considering the full session (partial substitution when considering the first reinforcer), demonstrating it has GABA agonist properties. Zuranolone produced positive subjective responses and euphoria-related adverse events similar to that of alprazolam (schedule IV), and greater than that of placebo in a human abuse potential study.

Furthermore, data from other clinical studies show that zuranolone produced incidence of euphoria-like adverse events in 5 percent of healthy individuals, including euphoric mood, feeling drunk, feeling of relaxation, feeling abnormal, and inappropriate effect compared to no incidence following placebo. Therefore, zuranolone has the potential for abuse similar to alprazolam, midazolam, methohexital, and other substances in schedule IV.

(2) Zuranolone has a currently accepted medical use in treatment in the United States.

FDA approved the NDA for ZURZUVAE (zuranolone) as a treatment for post-partum depression. Thus, zuranolone has a currently accepted medical use in treatment in the United States.

(3) Abuse of zuranolone may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III but similar to other substances in schedule IV.

Zuranolone shares a similar pharmacology profile with brexanolone (schedule IV) and benzodiazepines (schedule IV). Data from a rat physical dependence study demonstrated that discontinuation of chronic administration of zuranolone at the doses tested did not produce physical dependence or withdrawal syndrome. In a dog toxicity study, drug discontinuation after chronic administration at supratherapeutic doses produced convulsions similar to that of benzodiazepines. Further, upon abrupt discontinuation in humans at the therapeutic dose (≤50 mg per day), zuranolone produced mild to moderate withdrawal-like effects in healthy individuals no worse than what is clinically known for schedule IV benzodiazepines. HHS concluded that there would be higher risk of developing physical dependence and withdrawal syndrome and more severe effects after abrupt drug discontinuation in individuals that took more than the therapeutic dose or for an extended duration. Withdrawal symptoms from physical dependence may include convulsions. Zuranolone produced positive subjective responses and euphoria-related adverse events and may produce psychic dependence. Zuranolone may lead to physical or psychological dependence similar to benzodiazepines in schedule IV.

Based on these findings, the Administrator concludes that zuranolone warrants control in schedule IV of the CSA.[7]

Requirements for Handling Zuranolone

Zuranolone is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distributing, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) zuranolone must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. These registration requirements, however, are not applicable to patients (end users) who possess zuranolone pursuant to a lawful prescription.

[6] 21 U.S.C. 812(b).

[7] 21 U.S.C. 812(b)(4).

2. *Disposal of Stocks.* Any person unwilling or unable to obtain a schedule IV registration must surrender all quantities of currently held zuranolone, or may transfer all quantities of currently held zuranolone to a person registered with DEA. Zuranolone is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, state, local, and tribal laws.

3. *Security.* Zuranolone is subject to schedule III–V security requirements for DEA registrants and must be handled and stored in accordance with 21 CFR 1301.71–1301.77, pursuant to 21 U.S.C. 823, 821, 871(b). Non-practitioners handling zuranolone must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93. These requirements, however, are not applicable to patients (end users) who possess zuranolone pursuant to a lawful prescription.

4. *Labeling and Packaging.* All labels and packaging for commercial containers of zuranolone must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of zuranolone must have an initial inventory of all stocks of controlled substances (including zuranolone) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who registers with DEA to handle zuranolone must take an initial inventory of all stocks of controlled substances (including zuranolone) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take inventory of all controlled substances (including zuranolone) on hand every two years, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. These requirements, however, are not applicable to patients (end users) who possess zuranolone pursuant to a lawful prescription.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for zuranolone, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for zuranolone, or products containing zuranolone, must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule IV controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of zuranolone may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act (FDCA), as applicable, and the CSA.

9. *Importation and Exportation.* All importation and exportation of zuranolone must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving zuranolone not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

Section 553 of the APA (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is (1) approved by HHS, under section 505(c) of the FDCA, and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an IFR scheduling the drug within 90 days. As stated in the legal authority section, the 90-day time frame is the later of: (1) the date DEA receives HHS's scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Additionally, subsection 811(j) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause.

Executive Orders 12866, 13563, and 14094, Regulatory Review

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563. E.O. 14094 modernizes the regulatory review process to advance policies that promote the public interest and address national priorities.

Executive Order 12988, Civil Justice Reform

This meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Paperwork Reduction Act

This proposed action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As noted in the above discussion regarding the applicability of the APA, DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this IFR.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this proposed action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the

private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this IFR to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 25, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b) unless otherwise noted.

■ 2. In § 1308.14:

a. Add a new paragraph (c)(60) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

* * * * *	
(60) Zuranolone	2420

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[FR Doc. 2023–23982 Filed 10–30–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–1098]

Designation of Halides of 4-Anilinopiperidine as List I Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is finalizing the modification of the listing of the list I chemical, *N*-phenylpiperidin-4-amine (also known as 4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP) (hereinafter referred to as 4-anilinopiperidine), to include halides of 4-anilinopiperidine. This rule finalizes the modification of the listing of 4-anilinopiperidine as a list I chemical.

DATES: This rule is effective November 30, 2023. Persons currently manufacturing, distributing, importing, or exporting halides of 4-anilinopiperidine or a chemical mixture containing halides of 4-anilinopiperidine, if they are not already registered to handle list I chemicals, must apply on or before November 30, 2023, to continue their business pending final action by DEA on their application.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: The Drug Enforcement Administration (DEA) is extremely concerned with the recent increase in the illicit manufacture and distribution of fentanyl and fentanyl analogues. Therefore, on April 14, 2023, DEA published a Notice of Proposed Rulemaking (NPRM) to include halides of 4-anilinopiperidine as list I chemicals.[1] This rulemaking finalizes that NPRM.

This action subjects handlers of halides of 4-anilinopiperidine to the regulatory provisions of the Controlled Substances Act (CSA) and its implementing regulations regarding list I chemicals. This rulemaking does not establish a threshold for domestic and international transactions of halides of 4-anilinopiperidine. As such, all transactions involving halides of 4-anilinopiperidine, regardless of size, shall be regulated and are subject to control under the CSA. In addition, chemical mixtures containing halides of 4-anilinopiperidine are not exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of halides of 4-anilinopiperidine shall be regulated pursuant to the CSA as list I chemicals.

Legal Authority

The CSA gives the Attorney General the authority to specify, by regulation, chemicals as list I chemicals.[2] A ''list I chemical'' is a chemical that is used in manufacturing a controlled substance in violation of the CSA and is important to the manufacture of the controlled substances.[3] The current list of all listed chemicals is published at 21 CFR 1310.02(a). Pursuant to 28 CFR 0.100(b), the Attorney General has delegated his authority to designate list I chemicals to the Administrator of DEA (Administrator). The DEA regulations set forth the process by which DEA may add a chemical as a listed chemical. As set forth in 21 CFR 1310.02(c), the agency may do so by publishing a final rule in the **Federal Register** following a published notice of proposed rulemaking with at least 30 days for public comments.

Background

DEA previously found that 4-anilinopiperidine is used in the illicit manufacture of the controlled substance fentanyl (a schedule II substance under the CSA) and fentanyl analogues controlled in schedule I of the CSA, and is important to the manufacture of the controlled substance fentanyl and fentanyl analogues, because it cannot be replaced by other chemicals in its respective synthetic pathways that are used in the illicit manufacture of fentanyl and fentanyl analogues.[4] On this basis, DEA previously specified that 4-anilinopiperidine is a list I chemical.[5]

DEA has now found that halides of 4-anilinopiperidine are also used in the illicit manufacture of schedule I controlled substances, such as *para*-fluorofentanyl, *ortho*-fluorofentanyl, and *para*-chlorofentanyl. Accordingly, this action adds halides of 4-anilinopiperidine to the prior listing of 4-anilinopiperidine and thereby subjects handlers of halides of 4-anilinopiperidine to the regulatory provisions of the CSA and its implementing regulations.

[1] 88 FR 22955 (Apr. 14, 2023).

[2] 21 U.S.C. 802(34).

[3] *Id.*

[4] 85 FR 20822 (Apr. 15, 2020).

[5] *Id.*

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 9, 2023

( ) ACTION/DECISION
(X) INFORMATION

I. **TITLE:** Healthcare Quality Administrative and Consent Orders.

II. **SUBJECT:** Healthcare Quality Administrative Orders and Consent Orders for the period of September 1, 2023, through September 30, 2023.

III. **FACTS:** For the period of September 1, 2023, through September 30, 2023, Healthcare Quality reports 6 Consent Orders totaling $9,600 in assessed monetary penalties.

Bureau	Facility, Service, Provider, or Equipment Type	Administrative Orders	Consent Orders	Assessed Penalties	Required Payment
Community Care	Residential Treatment Facility for Children and Adolescents		1	$8,000	$8,000
Healthcare Systems and Services	In-Home Care Provider		1	$300	$300
	Outpatient Facility for Chemically Dependent or Addicted Persons (CDAP)		1	$300	$300
	Adult Day Care		1	$300	$300
	Paramedic		2	$700	$700
TOTAL			**6**	**$9,600**	**$9,600**

Submitted By:

Gwendolyn C. Thompson

_____

Gwen C. Thompson
Deputy Director
Healthcare Quality

HEALTHCARE QUALITY ENFORCEMENT REPORT
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 9, 2023

Bureau of Community Care

Facility Type	Total Number of Licensed Facilities	Total Number of Licensed Beds
Residential Treatment Facility for Children and Adolescents	8	518

1. Broadstep Academy – South Carolina – Hampton (Pickens, 55 beds)

Investigation and Violations: On Jan. 5, 2023, Feb. 8, 2023, Jun. 13, 2023, staff visited the facility to conduct complaint investigations. Staff observed and cited the following violations:

- The Facility failed to implement its policies and procedures regarding resident care, rights and operations of the Facility.
- The Facility failed to immediately report to the Department a serious accident and/or incident.
- The Facility failed to submit a written report of its investigation of a serious accident and/or incident within 5 calendar days.
- The Facility failed to afford a resident the right to be treated with respect and dignity.
- The Facility failed to afford a resident the right to be care for in an atmosphere of sincere interest and concern in which needed support and services were provided.
- The Facility failed to afford residents their right to be free from harm, including abuse.
- The Facility failed maintain the Facility's building components.

Enforcement: The Department notified the Facility via certified mail on July 17, 2023, that an enforcement action was being considered. The Department and the Facility met and agreed to resolve this matter through a Consent Order. The Facility agreed to the assessment of a $8,000 monetary penalty. The Facility has paid the penalty.

Remedial Action: The Facility also agrees to correct the violations that prompted this enforcement action, and to ensure that any other violations are not repeated.

Prior Orders: None in the past five years.

Bureau of Healthcare Systems and Services

Facility Type	Total Number of Licensed Facilities
In-Home Care Provider	952

1. My Father's Touch

Investigation and Violations: The Facility failed to submit a timely renewal application and licensing fees by the license expiration date.

Enforcement: The Department and the Facility decided to resolve the matter through a Consent Order. The Facility paid the $300 monetary penalty.

Remedial Action: none

Prior Orders: None in the past 5 years.

Facility Type	Total Number of Licensed Facilities
Outpatient Facility for Chemically Dependent or Addicted Persons (CDAP)	88

1. Solutions Recovery Counseling - Greenville

Investigation and Violations: The Facility failed to submit a timely renewal application and licensing fees by the license expiration date.

Enforcement: The Department and the Facility decided to resolve the matter through a Consent Order. The Facility paid the $300 monetary penalty.

Remedial Action: none

Prior Orders: None in the past 5 years.

Facility Type	Total Number of Licensed Facilities
Adult Day Care Facility	91

1. Triple E Adult Day Care #3

Investigation and Violations: The Facility failed to submit a timely renewal application and licensing fees by the license expiration date.

Enforcement: The Department and the Facility decided to resolve the matter through a Consent Order. The Facility paid the $300 monetary penalty.

Remedial Action: none

Prior Orders: None in the past 5 years.

Facility Type	Total Number of Licensed Facilities
Paramedic	4,469

1. Josh Orlando

Investigation and Violations: The Department received and opened an investigation on Sept. 29, 2022. The complaint alleged Mr. Orlando assaulted a patient under his care. The Department determined that Mr. Orlando violated the regulation by committing misconduct and failing to provide a patient quality emergency medical treatment.

Enforcement: On Aug. 28, 2023, the Department notified Mr. Orlando that it was considering enforcement action. The parties met on Sept. 12, 2023, for an enforcement conference. Mr. Orlando agreed to the assessment of a $500 monetary penalty and to complete certain classes/courses (see below). Mr. Orlando paid the monetary penalty.

Remedial Action: Mr. Orlando completed the required Professional Ethics and Personal Leadership (PEPL) course and online courses regarding first response, service to self, and creating safe scenes.

Prior Orders: None in the past 5 years.

2. Ander Pregartner

Investigation and Violations: The Department received and opened an investigation on Dec. 29, 2022. The complaint alleged Ms. Pregartner failed to meet patient care standards. The Department determined

that Ms. Pregartner failed to determine the blood glucose level of a patient with a suspected overdose. By failing to do so, the Department concluded Ms. Pregartner failed to provide a patient emergency medical treatment of a quality deemed acceptable by the Department and committed misconduct as defined by the EMS Act and Regulation. Specifically, regarding the misconduct, Department staff concluded Ms. Pregartner disregarded an appropriate order by a physician concerning emergency treatment and created a substantial possibility that death or serious physical harm could result from her actions/inactions.

Enforcement: On Jul. 19, 2023, the Department notified Ms. Pregartner that it was considering enforcement action. The parties met on Aug. 2, 2023, for an enforcement conference. Ms. Pregartner agreed to the assessment of a $200 monetary penalty. Ms. Pregartner paid the monetary penalty.

Remedial Action: Ms. Pregartner completed a NAEMT course focused on Advanced Medical Life Support.

Prior Orders: None in the past 5 years.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
November 9, 2023

_____ ACTION/DECISION

__X__ INFORMATION

1. **TITLE:** Administrative and Consent Orders issued by the Office of Environmental Affairs.

2. **SUBJECT:** Administrative and Consent Orders issued by the Office of Environmental Affairs during the period September 1, 2023, through September 30, 2023.

3. **FACTS:** For the reporting period of September 1, 2023, through September 30, 2023, the Office of Environmental Affairs issued fifty-seven (57) Consent Orders with total assessed civil penalties in the amount of two hundred forty-nine thousand, two hundred seventy dollars ($249,270.00). Also, ten (10) Administrative Orders with total assessed civil penalties in the amount of eleven thousand, thirty-five dollars and eighty-five cents ($11,035.85) were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	2	$11,035.85	7	$34,615.00
Solid Waste	0	0	2	$1,000.00
Hazardous Waste	0	0	3	$26,500.00
Mining	0	0	0	0
Radiological Health	0	0	1	$5,200.00
SUBTOTAL	**2**	**$11,035.85**	**13**	**$67,315.00**
Water				
Recreational Water	0	0	36	$34,355.00
Drinking Water	0	0	0	0
Water Pollution	0	0	2	$19,600.00
SUBTOTAL	**0**	**0**	**38**	**$53,955.00**
Air Quality				
SUBTOTAL	**0**	**0**	**4**	**$117,500.00**
Environmental Health Services				
Onsite Wastewater	8	0	2	$10,500.00
SUBTOTAL	**8**	**0**	**2**	**$10,500.00**
OCRM				
SUBTOTAL	**0**	**0**	**0**	**0**
TOTAL	10	**$11,035.85**	**57**	**$249,270.00**

Submitted by:

Myra C. Reece
Director of Environmental Affairs

ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
November 9, 2023

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

1) Order Type and Number: Administrative Order 22-0278-UST
Order Date: June 9, 2023
Individual/Entity: **Sel Properties, LLC**
Facility: Lancaster Creamery
Location: 1476 Memorial Park Road
Lancaster, SC 29720
Mailing Address: P.O. Box 11641
Columbia, SC 29211
County: Lancaster
Previous Orders: None
Permit/ID Number: 05495
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. Code Ann. § 44-2-10 et seq.; and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.65 (2012 & Supp 2022).

Summary: Sel Properties, LLC (Individual/Entity) owned an underground storage tank (UST) in Lancaster County, South Carolina. On July 14, 2022, the Department conducted a file review and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act, and the South Carolina Underground Storage Tank Regulation as follows: failed to comply with the requirements for the investigation of soil and groundwater cleanup as directed by the Department.

Action: The Individual/Entity is required to submit a monitoring well abandonment report in accordance with the Notice issued on January 28, 2022, by October 13, 2023. The Department has assessed a total civil penalty in the amount of five thousand, thirty-five dollars and eighty-five cents ($5,035.85). The Individual/Entity shall pay a civil penalty in the amount of five thousand, thirty-five dollars and eighty-five cents **($5,035.85)** by October 13, 2023.

Update: None.

2) Order Type and Number: Administrative Order 23-0073-UST
Order Date: August 21, 2023
Individual/Entity: **Pavan Parth, LLC**
Facility: Pavan Food Store 102
Location: 1048 South Main Street
Greenwood, SC 29646
Mailing Address: 115 Lavender Hill Court
Simpsonville, SC 29681

County: Greenwood
Previous Orders: AO 22-0049-UST ($38,150.00)
Permit/ID Number: 04734
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.10(d) and 280.26(f) (2012 & Supp. 2022).

Summary: Pavan Parth, LLC (Individual/Entity) owns underground storage tanks (USTs) in Greenwood County, South Carolina. The Department conducted a routine inspection March 20, 2023, and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: introduced petroleum or petroleum products into an unregistered or unpermitted UST system and received an illegal delivery while USTs are under delivery prohibition.

Action: The Individual/Entity is required to: submit proof the USTs at the Facility contain less than one (1) inch of residue and submit proof the residue removed from the USTs has been disposed of properly. The Department has assessed a total civil penalty in the amount of six thousand dollars ($6,000.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand dollars **($6,000.00)** by October 30, 2023.

Update: None.

3) Order Type and Number: Consent Order 23-0165-UST
Order Date: September 13, 2023
Individual/Entity: **Jackson Jennings**
Facility: Jacksons Grocery
Location: 916 Highway 38 South
Bennettsville, SC 29512
Mailing Address: Same
County: Marlboro
Previous Orders: None
Permit/ID Number: 14741
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.20(c)(1)(ii) (2012 & Supp. 2022).

Summary: Jackson Jennings (Individual/Entity) owns underground storage tanks (USTs) in Marlboro County, South Carolina. The Department conducted a routine inspection on May 22, 2023, and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to demonstrate financial responsibility for an UST system and failed to submit evidence of financial assurance to the Department upon request.

Action: The Individual/Entity corrected all violations prior to the issuance of the

Order. The Department has assessed a total civil penalty in the amount of six hundred dollars ($600.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred dollars **($600.00)** by October 28, 2023.

Update: The Individual/Entity has paid the civil penalty. The Order is closed.

4) Order Type and Number: Consent Order 23-0080-UST
Order Date: September 25, 2023
Individual/Entity: **ARC ATMTPSC001, LLC**
Facility: Citibank NA, Inc.
Location: 11 Ewall Street
Mt. Pleasant, SC 29464
Mailing Address: 2398 East Camelback Road, Suite 1060
Phoenix, AZ 85016
County: Charleston
Previous Orders: None
Permit/ID Number: 18732
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. (2018) and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.40(a), 280.40(a)(2), 280.44(a), 280.45(b)(1), and 280.242(b)(3), (2012 & Supp 2022).

Summary: ARC ATMTPSC001, LLC (Individual/Entity) owns an underground storage tank (USTs) in Charleston County, South Carolina. The Department conducted a routine inspection on February 8, 2023, and issued a New Owner Notice of Alleged Violation on February 16, 2023. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to provide an adequate release detection method for an UST system; failed to properly maintain piping release detection equipment; failed to conduct annual test of automatic line leak detector and/or sump sensors; failed to maintain test results for at least one year; and failed to validate those monthly requirements had been performed.

Action: The Individual/Entity is required to: submit proof, in the form of photographs and/or videos, the sump sensor has been positioned at the bottom of the (STP); submit current passing line leak detector function check test results for all USTs at the Facility; and submit proof a Class A/B operator log has been initiated and is being properly maintained. The Department has assessed a total civil penalty in the amount of five thousand, seven hundred dollars ($5,700.00). The Individual/Entity shall pay a civil penalty in the amount of five thousand, seven hundred dollars **($5,700.00)**.

Update: The Individual/Entity has paid the civil penalty.

5) Order Type and Number: Consent Order 23-0094-UST
Order Date: September 25, 2023
Individual/Entity: **Vivaan Real Estate, LLC**
Facility: Sav Way 4
Location: 349 2nd Street
Cheraw, SC 29520
Mailing Address: 349 Second Street

Chesterfield, SC 29520
County: Chesterfield
Previous Orders: None
Permit/ID Number: 02253
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. and § 44-2-10(A) (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.40(a)(2), (2012 & Supp 2022).

Summary: Vivaan Real Estate, LLC (Individual/Entity) owns underground storage tanks (USTs) in Chesterfield County, South Carolina. On March 31, 2023, the Department conducted a file review of the Facility and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act, and the South Carolina Underground Storage Tank Regulation as follows: failed to properly maintain release detection equipment.

Action: The Individual/Entity is required to: submit proof the line leak detector for the 15,000-gallon kerosene UST has been repaired and/or replaced; submit current passing line leak detector function check test results for the 15,000-gallon kerosene UST; and submit current passing release detection equipment operability test results for the 15,000-gallon kerosene UST. The Department has assessed a total civil penalty in the amount of two thousand, two hundred fifteen dollars ($2,215.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, two hundred fifteen dollars **($2,215.00)** by November 13, 2023.

Update: None.

6) Order Type and Number: Consent Order 23-0196-UST
Order Date: September 25, 2023
Individual/Entity: **Circle K Stores, Inc.**
Facility: Circle K 2705140
Location: 2201 Bush River Road
Columbia, SC 29210
Mailing Address: 1100 Situs Court, Suite 100
Raleigh, NC 27606
County: Lexington
Previous Orders: None
Permit/ID Number: 11165
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. and § 44-2-10(A) (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.10(d), 280.23(b) and 44-2-60(B) (2012 & Supp. 2022).

Summary: Circle K Stores, Inc. (Individual/Entity) owns underground storage tanks (USTs) in Lexington County, South Carolina. The Department conducted a routine compliance inspection on July 27, 2023, and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: introduced petroleum or petroleum products into an unregistered or unpermitted UST system.

Action: The Individual/Entity corrected all violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of eleven thousand, seven hundred dollars ($11,700.00). The Individual/Entity shall pay a civil penalty in the amount of eleven thousand, seven hundred dollars **($11,700.00)**.

Update: The Individual/Entity has paid the civil penalty. The Order is closed.

7) Order Type and Number: Consent Order 23-0117-UST
Order Date: September 26, 2023
Individual/Entity: **Duc Nguyen**
Facility: Lucky Ninety-Nine
Location: 2779 Pageland Highway
Lancaster, SC 29720
Mailing Address: Same
County: Lancaster
Previous Orders: 23-0085-UST ($7,200.00)
Permit/ID Number: 05507
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.20(c)(1)(ii) (2012 & Supp 2022).

Summary: Duc Nguyen (Individual/Entity) owns and operates underground storage tanks (USTs) in Lancaster County, South Carolina. The Department conducted an inspection on May 12, 2023, and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment. This is a repeat violation.

Action: The Individual/Entity is required to: submit proof the obstruction has been removed from the 10,000-gallon regular underground storage tank (UST) and submit passing follow-up overfill prevention equipment operability test results for the 10,000-gallon UST by November 13, 2023. The Department has assessed a penalty in the amount of seven thousand, two hundred dollars ($7,200.00). The Individual/Entity shall pay a civil penalty in the amount of seven thousand, two hundred dollars **($7,200.00)** in accordance with a promissory note.

Update: The Department has received proof the obstruction was removed from the 10,00-gallon regular UST and passing follow-up overfill prevention equipment operability test results for the 10,000-gallon UST. The first civil penalty payment was made in accordance with the promissory note on September 8, 2023.

8) Order Type and Number: Consent Order 23-0203-UST
Order Date: September 27, 2023
Individual/Entity: **Penske Truck Leasing Co., L.P.**
Facility: Penske Truck Leasing Co. L.P. Spartanburg
Location: 747 Simuel Road
Spartanburg, SC 29301
Mailing Address: Route 10 Green Hills, Box 7635

Reading, PA 19603
County: Spartanburg
Previous Orders: None
Permit/ID Number: 19905
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.20(c)(1)(ii) (2012 & Supp. 2022).

Summary: Penske Truck Leasing Co., L.P. (Individual/Entity) owns underground storage tanks (USTs) in Spartanburg County, South Carolina. The Department conducted a routine inspection on August 7, 2023, and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment of an underground storage tank system.

Action: The Individual/Entity corrected all violations prior to issuance of the Order. The Department has assessed a total civil penalty in the amount of three thousand, six hundred dollars ($3,600.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, six hundred dollars **($3,600.00)**.

Update: The Individual/Entity has paid the civil penalty. The Order is closed.

9) Order Type and Number: Consent Order 23-0084-UST
Order Date: September 29, 2023
Individual/Entity: **R.L. Jordan Oil Company of NC, Inc.**
Facility: Hot Spot 6004
Location: 3883 Cross Anchor Road
Enoree, SC 29335
Mailing Address: P.O. Box 2527
Spartanburg, SC 29304
County: Spartanburg
Previous Orders: None
Permit/ID Number: 18193
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.20(c)(1)(ii) (2012 & Supp. 2022).

Summary: R. L. Jordan Oil Company of North Carolina, Inc. (Individual/Entity) owns underground storage tanks (USTs) in Spartanburg County, South Carolina. The Department conducted a routine inspection on April 13, 2023, and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment of an underground storage tank (UST) system.

Action: The Individual/Entity corrected all violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of three thousand, six hundred dollars ($3,600.00). The Individual/Entity shall pay a civil penalty in the

amount of three thousand, six hundred dollars **($3,600.00)**.

Update: The Individual/Entity has paid the civil penalty. The Order is closed.

Solid Waste Enforcement

10) Order Type and Number: Consent Order 23-09-SW
Order Date: September 14, 2023
Individual/Entity: **Arbornature, LLC**
Facility: Arbornature Wood Chipping Facility
Location: Summit Drive
Hilton Head Island, SC 29926
Mailing Address: 76 Leg O' Mutton Road
Hilton Head Island, SC 29926
County: Beaufort
Previous Orders: None
Permit/ID Number: COM-00235
Violations Cited: South Carolina Solid Waste Policy and Management Act of 1991, S.C. Code Ann. §§ 44-96-10 (2018 & Supp. 2021) (Act), the Solid Waste Management: Solid Waste Compost and Mulch Production from Land-clearing Debris, Yard Trimmings, and Organic Residuals Regulation (2002 & Supp. 2014) (Regulation), R.61-107.4, Part III.E.5.b., and Permit # COM-00235 (Permit).

Summary: Arbornature, LLC (Individual/Entity), is responsible for operating a Type One Composting and Wood Chipping facility located in Beaufort County, South Carolina. Based on a file review conducted on September 12, 2022, the Department issued a Notice of Violation. The Individual/Entity has violated the South Carolina Solid Waste Policy and Management Act, the Solid Waste Management: Solid Waste Compost and Mulch Production from Land-clearing Debris, Yard Trimmings, and Organic Residuals Regulation, and Permit COM-00235 as follows: failed to submit an annual report for fiscal year 2022 on, before, or after September 1, 2022.

Action: The Individual/Entity is required to submit an annual report for fiscal year 2022 by October 14, 2023. The Department assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)** by October 14, 2023.

Update: The Department received the annual report on August 28, 2023, and payment of the assessed civil penalty was received on September 5, 2023. The Order is closed.

11) Order Type and Number: Consent Order 23-20-SW
Order Date: September 25, 2023
Individual/Entity: **Victoria H. Walden**
Facility: Bergen Road Site
Location: Tax Map # 001-18-01-007
North Augusta, SC 29841

Mailing Address: 1818 Gregory Lake
North Augusta, SC 29841
County: Aiken
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: South Carolina Solid Waste Policy and Management Act of 1991, S.C. Code Ann. §§ 44-96-10 et seq. (2002 & Supp. 2018); Solid Waste Management: Solid Waste Landfills and Structural Fill, R.61-107.19, Part I.A.8., Part I.B.20., Part I. B.38., Part I.B.53., and Part II.B.1. (Rev. 2008 & Supp. 2016).

Summary: Victoria Walden (Individual/Entity) operated an unpermitted structural fill located in Aiken County, South Carolina. The Department conducted a site visit on April 3, 2023, and determined the Individual/Entity had engaged in Structural Fill activities without a Structural Fill permit from the Department. The Individual/Entity has violated the South Carolina Solid Waste Policy and Management Act, and associated Regulations, as follows: operated a structural fill without a Department-issued permit.

Action: The Individual/Entity is required to: immediately cease receipt and/or transport of solid waste debris onto the Site and complete closure activities to include; applying a two (2) foot thick final earth cover with a three-to-one (3:1) slope; seeding the finished surface area with native grasses or other suitable cover to provide minimum of 75% vegetative cover with no substantial bare spots; recording with the Register of Deeds a notation in the record of ownership of the property that will, in perpetuity, notify any potential purchaser of the property that the land, or a portion thereof, has been filled with solid waste debris; remove all loose solid waste material not compacted during closure activities, dispose of it at a permitted solid waste management facility, and submit disposal receipts to the Department by March 23, 2024. The Department has assessed a total civil penalty in the amount of three thousand dollars ($3,000.00). The Individual/entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)** by November 8, 2023, and pay a suspended penalty in the amount of two thousand, five hundred dollars ($2,500.00) should any requirement of the Order not be met.

Update: None.

Hazardous Waste Enforcement

12) Order Type and Number: Consent Order 23-23-HW
Order Date: September 18, 2023
Individual/Entity: **PSC Custom, LLC d.b.a. Polar Service Center**
Facility: PSC Customer, LLC d.b.a. Polar Service Center
Location: 120 Cedar Springs Road
Spartanburg, SC 29304
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit/ID Number: SCD 088 631 577

Violations Cited: The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2018), and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2021) and South Carolina Solid Waste Management: Used Oil Regulations, 8 S.C. Code Ann. Regs. 61-107.279 (2012 and Supp. 2021).

Summary: PSC Custom, LLC d.b.a. Polar Service Center (Individual/Entity) refurbishes and repairs tank-style semitrailers in Spartanburg County South Carolina. The Department conducted an inspection at the facility on February 23, 2023. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act, the Hazardous Waste Management Regulations and the South Carolina Solid Waste Management: Used Oil Regulations, as follows: failed to manage universal waste lamps in a way that prevents releases of any universal waste or component of a universal waste to the environment; failed to ensure that each lamp or a container or package in which such lamps are contained is labeled with one of the following phrases: "Universal Waste – Lamp(s)," or "Waste Lamp(s)," or "Used Lamp(s)"; failed to clearly label universal waste batteries (i.e., each battery), or a container in which the batteries are contained with any of the following phrases: "Universal Waste -Battery(ies)," or "Waste Battery(ies)," or "Used Battery(ies)"; failed to demonstrate the length of time that the universal waste had been accumulated from the date it becomes a waste; failed to have solvent-contaminated wipes, when accumulated, stored, and transported, contained in non-leaking, closed containers that are labeled ''Excluded Solvent-Contaminated Wipes''; failed to maintain the documentation for name and address of the laundry or dry cleaner that is receiving the solvent-contaminated wipes and description of the process the generator is using to ensure the solvent-contaminated wipes contain no free liquids; to ensure that containers used to store used oil at the facility were closed to prevent spillage or contamination from precipitation; failed to ensure that containers used to store used oil at the facility were labeled with the words "Used Oil"; failed to make accurate hazardous waste determinations; failed to inspect, at least weekly, the central accumulation areas; failed to attempt to make arrangements with the local police department, fire department, other emergency response teams, emergency response contractors, equipment suppliers, and local hospitals; and failed to declare its status annually on, or before January 31st.

Action: The Individual/Entity corrected the violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of eight thousand dollars ($8,000.00). The Individual/Entity shall pay a civil penalty in the amount of eight thousand dollars **($8,000.00)** by October 18, 2023.

Update: None.

13)

Order Type and Number:	Consent Order 23-24-HW
Order Date:	September 25, 2023
Individual/Entity:	**DSM Nutritional Products, LLC**
Facility:	DSM Nutritional Products, LLC
Location:	1416 North Williamsburg Highway Kingstree, SC
Mailing Address:	P.O. Box 5000 Kingstree, SC 29556
County:	Williamsburg
Previous Orders:	None

Permit/ID Number: SCD 083 418 491
Violations Cited: The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2018) and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2021).

Summary: DSM Nutritional Products, LLC (Individual/Entity) is a producer of ingredients and vitamins, carotenoids, and premixes for the agriculture, aquaculture, food, and pharmaceutical industries located in Williamsburg County, South Carolina. The Department conducted an inspection at the facility on March 17, 2023. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: failed to ensure satellite accumulation area storage containers remain closed; failed to mark or label tanks with the words "Hazardous Waste"; failed to receive an extension for hazardous waste to remain onsite for longer than ninety (90) days; failed to inspect tank equipment at least once each operating day and document those inspections; failed to mark or label containers with the word "Hazardous Waste" and an indication of the hazards of the contents; failed to keep containers of universal waste lamps closed; failed to label containers of universal waste lamps with the appropriate verbiage; failed to ensure universal waste is not accumulated for greater than one (1) year; failed to demonstrate the length of time universal waste has been accumulated; failed to ensure all facility personnel take part in an annual review of the initial training; failed to submit a copy of the contingency plan and all revisions and the quick reference guide to all local emergency responders; and failed to maintain a written job description for each position that handles hazardous waste.

Action: The Individual/Entity corrected the violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of eleven thousand, five hundred dollars ($11,500.00). The Individual/Entity is required to pay a civil penalty in the amount of eleven thousand, five hundred dollars **($11,500.00)**.

Update: The Individual/Entity has paid the civil penalty. The Order is closed.

14) Order Type and Number: Consent Order 23-25-HW
Order Date: September 29, 2023
Individual/Entity: **Fort Dearborn Company**
Facility: Fort Dearborn Company
Location: 100 North Woods Drive
Fountain Inn, SC 29644
Mailing Address: Same
County: Greenville
Previous Orders: None.
Permit/ID Number: SCD 982 096 349
Violations Cited: The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2018) and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2021).

Summary: Fort Dearborn Company (Individual/Entity) is a paint label manufacturer located in Greenville County, South Carolina. The Department conducted an inspection at the facility on December 7, 2022. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste

Management Regulations as follows: failed to ensure hazardous waste accumulation at or near the point of generation is under the control of the operator of the process generating waste; failed to ensure containers accumulating waste are closed at all times during accumulation; failed to ensure that excluded solvent-contaminated wipes are in containers that are non-leaking, closed, and labeled with the words "Excluded Solvent-Contaminated Wipes"; failed to maintain the name and address of laundry or dry cleaner of excluded solvent-contaminated wipes and a description of the process the generator is using to ensure the excluded solvent-contaminated wipes contain no free liquids at the point of being laundered or transported off-site for laundering; failed to make an accurate waste determination; failed to manage universal waste lamps in containers that are closed; failed to demonstrate the length of time that universal waste had been accumulating; failed to mark or label container or package with the words "Universal Waste – Lamp(s)" or "Waste Lamp(s)" or "Used Lamp(s)"; failed to maintain and operate the facility to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents; failed to maintain the job title for each position at the facility related to hazardous waste management and the name of the employee filling each positions, a written description for each position, and a written description of the type and amount of introductory and continuing training to be given to each person filling each position; failed to maintain a contingency plan and all revisions at the facility; and failed to submit a copy of the contingency plan and all revisions to all local emergency responders.

Action: The Individual/Entity corrected the violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of seven thousand dollars ($7,000.00). The Individual/Entity is required to pay a civil penalty in the amount of seven thousand dollars **($7,000.00)** in accordance with a promissory note.

Update: The Individual/Entity has paid the first payment in accordance with the promissory note.

Radiological Health Enforcement

15)

Order Type and Number:	Consent Order 23-06-RH
Order Date:	September 25, 2023
Individual/Entity:	**Midlands Orthopedics & Neurosurgery Blanding Street**
Facility:	Midlands Orthopedics & Neurosurgery Blanding Street
Location:	1910 Blanding Street Columbia, SC 29201
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-2040
Violations Cited:	The Atomic Energy and Radiation Control Act, S.C. Code Ann. Laws, § 13-7-10 et seq. (2017): and the South Carolina X-Rays (Title B) Regulations, 6 S. C. Code Ann. Regs. 61-64 (2021).

Summary: Midlands Orthopedics & Neurosurgery Blanding Street (Individual/Entity) is an orthopedic and neurosurgical care clinic located in Richland

County, South Carolina. The Department conducted an inspection on January 10, 2022, and issued a Notice of Alleged Violation. The Individual/Entity has violated the Atomic Energy and Radiation Control Act and the South Carolina X-Rays (Title B) Regulations, as follows: failed to conduct the annual equipment performance test for the C-arm Fluoroscopy unit; and failed to monitor total occupational doses for two (2) physicians.

Action: The Individual/Entity corrected all violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of five thousand, two hundred dollars ($5,200.00). The Individual/Entity shall pay a civil penalty in the amount of five thousand, two hundred dollars **($5,200.00)**.

Updates: The Individual/Entity has paid the civil penalty. The Order is closed.

BUREAU OF WATER

Recreational Waters Enforcement

16)

Order Type and Number:	Consent Order 23-053-RW
Order Date:	September 5, 2023
Individual/Entity:	**Cole LA Rock Hill SC, LLC**
Facility:	LA Fitness Rock Hill
Location:	745 Arden Lane Rock Hill, SC 29732
Mailing Address:	Same
County:	York
Previous Orders:	None
Permit/ID Number:	46-1137B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Cole LA Rock Hill SC, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on April 6, 2023, and June 14, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the waterline tiles were dirty; the water level was too low; the pool rules sign was not legible; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis; and the chlorine level was not within the acceptable range of water quality standards.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

17) Order Type and Number: Consent Order 23-054-RW

Order Date: September 5, 2023
Individual/Entity: **HIHH One, LLC**
Facility: Holiday Inn Express
Location: 2 Tanglewood Drive
Hilton Head, SC 29928
Mailing Address: Same
County: Beaufort
Previous Orders: None
Permit/ID Number: 07-350-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: HIHH One, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Beaufort County, South Carolina. The Department conducted inspections on June 19, 2023, and August 3, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the main drain grates were not visible due to cloudy water; the water level was too high; a light in the pool wall was out of its niche; the chlorine level was not within the acceptable range of water quality standards; the shepherd's crook was not permanently attached to the handle; the pool rules sign was not completely filled out; there were no "Shallow Water – No Diving Allowed" signs posted; there was only one "No Lifeguard On Duty – Swim At Your Own Risk" sign posted; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis; the cyanuric acid level was not recorded weekly in the bound and numbered log book; a ladder was missing rungs; the plaster on the pool floor was deteriorated; the deck was uneven with sharp edges; and skimmer baskets were floating.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

18) Order Type and Number: Consent Order 23-055-RW
Order Date: September 6, 2023
Individual/Entity: **ABI KOA Fort Mill, LLC**
Facility: Charlotte Fort Mill KOA
Location: Route 1, Box 380-A
Fort Mill, SC 29715
Mailing Address: 940 Gold Hill Road
Fort Mill, SC 29708
County: York
Previous Orders: None
Permit/ID Number: 46-033-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: ABI KOA Fort Mill, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on June 12, 2023, July 17, 2023, and August 7, 2023, and violations were issued for failure to properly operate and maintain.

The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats were not properly spaced; the depth marker tiles were not clearly visible; the shepherd's crook was not properly mounted in its designated location; the pool rules sign was not legible and was not completely filled out; the pool operator of record information was not legible; the bound and numbered log book was not maintained on a daily basis; the bound and numbered log book was not maintained a minimum of three times per week by the pool operator of record; and the cyanuric acid levels were not recorded weekly in the bound and numbered log book.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of two thousand forty dollars ($2,040.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand forty dollars **($2,040.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

19)

Order Type and Number:	Consent Order 23-056-RW
Order Date:	September 6, 2023
Individual/Entity:	**Bay View Resort Holdings, LLC**
Facility:	Bayview Resort Tower
Location:	504 North Ocean Boulevard Myrtle Beach, SC 29577
Mailing Address:	Same
County:	Horry
Previous Orders:	None
Permit/ID Number:	26-1490C
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Bay View Resort Holdings, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in Horry County, South Carolina. The Department conducted inspections on July 3, 2023, and July 31, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

20)

Order Type and Number:	Consent Order 23-057-RW
Order Date:	September 6, 2023
Individual/Entity:	**Omkar of Clemson, LLC**
Facility:	Comfort Inn Clemson
Location:	123 Tiger Boulevard Clemson, SC 29631
Mailing Address:	Same
County:	Pickens

Previous Orders:	21-060-RW ($680.00)
Permit/ID Number:	39-045-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Omkar of Clemson, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Pickens County, South Carolina. The Department conducted inspections on May 22, 2023, and July 7, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the depth marker tiles at the water line were not the correct size; the drinking water fountain was not operating; the chlorine level was not within the acceptable range of water quality standards; the life ring was not United States Coast Guard approved; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand six hundred dollars **($1,600.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

21)

Order Type and Number:	Consent Order 23-058-RW
Order Date:	September 7, 2023
Individual/Entity:	**The Preserve at Indigo Run Owners Association, Inc.**
Facility:	The Preserve at Indigo Run
Location:	4 Indigo Run Drive Hilton Head, SC 29926
Mailing Address:	Same
County:	Beaufort
Previous Orders:	None
Permit/ID Number:	07-585-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: The Preserve at Indigo Run Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Beaufort County, South Carolina. The Department conducted inspections on July 10, 2023, and August 17, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the cyanuric acid level was not recorded weekly in the bound and numbered log book; the water level was too high; a light in the pool wall was out of its niche; the life ring and life ring rope were deteriorated; the "Shallow Water – No Diving Allowed" signs were obstructed; the "No Lifeguard On Duty – Swim At Your Own Risk" signs were obstructed; the bound and numbered log book was not maintained a minimum of three times per week by the pool operator of record; and there were chlorine pucks in the skimmer baskets.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

22) Order Type and Number: Consent Order 23-059-RW
Order Date: September 7, 2023
Individual/Entity: **Shree Sadguru Hospitality, LLC**
Facility: Travelodge Santee
Location: 9117 Old #6 Highway
Santee, SC 29142
Mailing Address: Same
County: Orangeburg
Previous Orders: None
Permit/ID Number: 38-075-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Shree Sadguru Hospitality, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Orangeburg County, South Carolina. The Department conducted inspections on June 12, 2023, and August 7, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; a ladder was missing non-slip tread inserts; the pool furniture was not at least four feet from the pool edge; the drinking water fountain and foot rinse shower were not operating; the pool equipment room was not locked; the flow meter was not operating; the pH level was not within the acceptable range of water quality standards; the life ring was deteriorated; there was no pool rules sign on the first inspection, and the pool rules sign was not completely filled out on the second inspection; the letters on the "Shallow Water – No Diving Allowed" signs were not the correct size; the letters on the "No Lifeguard On Duty – Swim At Your Own Risk" signs were not the correct size; the facility could not produce current valid documentation of pool operator certification; the bound and numbered log book was not available for review on the first inspection, and it was not maintained on a daily basis on the second inspection; the plaster on the pool floor was deteriorated; the gate did not self-close and latch; and the life ring did not have a permanently attached rope.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

23) Order Type and Number: Consent Order 23-060-RW
Order Date: September 8, 2023
Individual/Entity: **Serene Hospitality, LLC**
Facility: Hampton Inn & Suites
Location: 1011 East North 1st Street
Seneca, SC 29678
Mailing Address: Same
County: Oconee
Previous Orders: None

Permit/ID Number: 37-1017B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Serene Hospitality, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Oconee County, South Carolina. The Department conducted inspections on June 9, 2023, and July 14, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; the gate did not self-close and latch; a section of the perimeter fence had openings greater than four inches; there was only one "Shallow Water – No Diving Allowed" sign posted on the first inspection and the wording and the letter size was not correct on the the signs posted on the second inspection; there was only one "No Lifeguard On Duty – Swim At Your Own Risk" sign posted; the bound and numbered log book was not available for review on the first inspection and it was not maintained on a daily basis on the second inspection; the chlorine level was not within the acceptable range of water quality standards; and the recirculation and filtration equipment was leaking.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

24) Order Type and Number: Consent Order 23-061-RW
Order Date: September 8, 2023
Individual/Entity: **Windsor Place Owners' Association**
Facility: Windsor Place/Windsor Place II
Location: 65 Ocean Lane
Hilton Head, SC 29928
Mailing Address: Same
County: Beaufort
Previous Orders: None
Permit/ID Number: 07-400-1; 07-1145B; 07-402-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J) & 61-51(K)(1)(c)

Summary: Windsor Place Owners' Association (Individual/Entity) owns and is responsible for the proper operation and maintenance of two pools and a spa located in Beaufort County, South Carolina. The Department conducted inspections of the pools and the spa on June 26, 2023, and a violation was issued for failure to properly operate and maintain pool permit No. 07-400-1; and on June 27, 2023, the Department conducted follow-up inspections of the pools and the spa and violations were issued for re-opening the pools and the spa prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the fill spout was not stainless steel or equivalent and the chlorine level was not within the acceptable range of water quality standards at pool permit No. 07-400-1; and the pools and the spa were operating prior to receiving Department approval.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand two hundred seventy-five

dollars ($1,275.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand two hundred seventy-five dollars **($1,275.00)** in two installment payments. The first installment is due by September 30, 2023. The second installment is due by October 30, 2023.

Update: The first installment of the civil penalty has been paid.

25)

Order Type and Number:	Consent Order 23-062-RW
Order Date:	September 8, 2023
Individual/Entity:	**Jalaram Hotel Gaffney, Inc.**
Facility:	Holiday Inn Express
Location:	1031 Hyatt Street Gaffney, SC 29341
Mailing Address:	9512 Reid Hall Lane Matthews, NC 29105
County:	Cherokee
Previous Orders:	None
Permit/ID Number:	11-1013B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Jalaram Hotel Gaffney, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Cherokee County, South Carolina. The Department conducted inspections on June 27, 2023, and July 19, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the pool rules sign was not completely filled out; the pool operator of record information was not posted to the public; and the bound and numbered log book was not available for review.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

26)

Order Type and Number:	Consent Order 23-063-RW
Order Date:	September 11, 2023
Individual/Entity:	**Imperial Investments-Gaffney, L.L.C.**
Facility:	Hampton Inn
Location:	115 Nancy Creek Road Gaffney, SC 29341
Mailing Address:	330 Research Court, Suite 22 Peach Tree Corners, GA 30092
County:	Cherokee
Previous Orders:	None
Permit/ID Number:	11-024-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Imperial Investments-Gaffney, L.L.C. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Cherokee County, South Carolina. The Department conducted inspections on June 28, 2023, and July 19, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; the cyanuric acid levels were not recorded weekly in the bound and numbered log book; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

27)

Order Type and Number:	Consent Order 23-064-RW
Order Date:	September 12, 2023
Individual/Entity:	**Pointe Gilead Cabana Club, Inc.**
Facility:	Pointe Gilead
Location:	469 Vereen Drive Garden City, SC 29576
Mailing Address:	Same
County:	Horry
Previous Orders:	22-041-RW ($680.00)
Permit/ID Number:	26-F39-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J) & 61-51(K)(1)(c)

Summary: Pointe Gilead Cabana Club, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. On June 5, 2023, and July 24, 2023, the pool was inspected, and a violation was issued for failure to properly operate and maintain; and on July 24, 2023, an additional violation was issued for re-opening the pool prior to receiving Department approval. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; the emergency notification device was not operating; the bound and numbered log book was not maintained on a daily basis; and the pool was operating prior to receiving Department approval.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars **($2,000.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

28)

Order Type and Number:	Consent Order 23-065-RW
Order Date:	September 12, 2023

Individual/Entity: **HPI Mills Gap, LLC**
Facility: The Village at Mills Gap
Location: 100 Mills Gap Road
Boiling Springs, SC 29316
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit/ID Number: 42-1089B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: HPI Mills Gap, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Spartanburg County, South Carolina. The Department conducted inspections on June 8, 2023, and August 16, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the shepherd's crook was missing a bolt; and the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

29) Order Type and Number: Consent Order 23-066-RW
Order Date: September 12, 2023
Individual/Entity: **Welcome Hotels of Fort Mill, Inc.**
Facility: Comfort Inn at the Park Carowinds
Location: 3725 Avenue of the Carolinas
Fort Mill, SC 29708
Mailing Address: Same
County: York
Previous Orders: None
Permit/ID Number: 46-079-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Welcome Hotels of Fort Mill, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on June 7, 2023, and July 12, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine level was not within the acceptable range of water quality standards; there were no "Shallow Water – No Diving Allowed" signs posted; the current pool operator of record information was not posted to the public; the bound and numbered log book was not available for Department review on the first inspection; the bound and numbered log book was not maintained on a daily basis, and was not maintained a minimum of three times per week by the pool operator of record on the second inspection; the letters and

numbers on the depth marker tiles were not the appropriate size; the main drain grates were not visible due to cloudy water; the life ring was deteriorated and did not have a permanently attached rope; the pool rules sign was not completely filled out; the cyanuric acid level was not checked weekly; and the recirculation and filtration system was leaking.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

30)

Order Type and Number:	Consent Order 23-067-RW
Order Date:	September 12, 2023
Individual/Entity:	**SIM Hotel, LLC**
Facility:	Holiday Inn Spartanburg
Location:	160 Simuel Road Spartanburg, SC 29303
Mailing Address:	Same
County:	Spartanburg
Previous Orders:	None
Permit/ID Number:	42-184-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: SIM Hotel, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Spartanburg County, South Carolina. The Department conducted inspections on June 5, 2023, and July 25, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring did not have a permanently attached rope; the shepherd's crook was missing a bolt; the pool rules sign was not completely filled out; the current pool operator of record information was not posted to the public; the log book was not properly bound and numbered and was not maintained on a daily basis; and the letters and numbers on the depth marker tiles were not the appropriate size.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

31)

Order Type and Number:	Consent Order 23-068-RW
Order Date:	September 14, 2023
Individual/Entity:	**Spa on Port Royal Sound Horizontal Property Regime, Inc.**
Facility:	Spa on Port Royal Sound
Location:	239 Beach City Road

Hilton Head Island, SC 29928
Mailing Address: Same
County: Beaufort
Previous Orders: None
Permit/ID Number: 07-275-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Spa on Port Royal Sound Horizontal Property Regime, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Beaufort County, South Carolina. The Department conducted inspections on June 22, 2023, and August 17, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the fill spout was not stainless steel or equivalent; a light in the pool wall was out of its niche; the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; and the cyanuric acid level was not recorded weekly in the bound and numbered log book.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

32) Order Type and Number: Consent Order 23-069-RW
Order Date: September 14, 2023
Individual/Entity: **Sea Oats Villas Homeowners Association, Inc.**
Facility: Sea Oats
Location: 4908 N Ocean Boulevard
North Myrtle Beach, SC 29582
Mailing Address: PO Box 3083
North Myrtle Beach, SC 29582
County: Horry
Previous Orders: None
Permit/ID Number: 26-E57-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Sea Oats Villas Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 21, 2023, and August 3, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the pavers on the deck had settled at the edge of the coping; skimmers were missing weirs; the chlorine level was not within the acceptable range of water quality standards; the emergency notification device was not operational; and there were chlorine sticks in the skimmer baskets**.**

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

33) Order Type and Number: Consent Order 23-070-RW
Order Date: September 14, 2023
Individual/Entity: **Best Western Three D Inn, Inc.**
Facility: Best Western Plus
Location: 9059 Old Number Six Highway
Santee, SC 29142
Mailing Address: P.O. Box 188
Santee, SC 29142
County: Orangeburg
Previous Orders: None
Permit/ID Number: 38-056-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Best Western Three D Inn, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Orangeburg County, South Carolina. The Department conducted inspections on June 13, 2023, and July 26, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: ladders were missing bumpers and non-slip tread inserts; the pool floor was not clean; the waterline tiles were not clean; the pool furniture was not at least four feet from the edge of the pool; there was debris in the skimmer baskets; the chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record; and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book**.**

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

34) Order Type and Number: Consent Order 23-071-RW
Order Date: September 14, 2023
Individual/Entity: **Reflections of Garden City Owners Association, Inc.**
Facility: Reflections Condos
Location: 1520 North Waccamaw Drive
Garden City, SC 29576
Mailing Address: Same
County: Horry
Previous Orders: None
Permit/ID Number: 26- H92-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Reflections of Garden City Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on June 26, 2023, and August 2, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a skimmer was missing a weir; a gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; there was no United States Coast Guard approved life ring; there was no pool rules sign; and the current pool operator of record information was not posted to the public.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

35)

Order Type and Number:	Consent Order 23-072-RW
Order Date:	September 14, 2023
Individual/Entity:	**Woodlands of Clemson Condominium Association, Inc.**
Facility:	Woodlands of Clemson
Location:	833 Old Greenville Highway Clemson, SC 29631
Mailing Address:	Same
County:	Pickens
Previous Orders:	None
Permit/ID Number:	39-1017B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Woodlands of Clemson Condominium Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Pickens County, South Carolina. The Department conducted inspections on May 26, 2023, and July 10, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a skimmer was missing a weir; the drinking water fountain was not operating properly; the foot rinse shower was not operating properly; the pool equipment room was not locked; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring was deteriorated and was not located in the designated location; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

36) Order Type and Number: Consent Order 23-078-RW
Order Date: September 14, 2023
Individual/Entity: **Wave Rider Resort Homeowners Association, Inc.**
Facility: Wave Rider Resort
Location: 1600 S. Ocean Boulevard
Myrtle Beach, SC 29577
Mailing Address: 1860 Village Drive
Surfside Beach, SC 29575
County: Horry
Previous Orders: None
Permit/ID Number: 26-L37-1 & 26-L38-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Wave Rider Resort Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a lazy river and a kiddie pool located in Horry County, South Carolina. The Department conducted inspections on April 28, 2023, June 6, 2023, and July 31, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the plaster on the pool floor was deteriorated; skimmers were missing weirs; the pool equipment room was not locked; there were cracked depth marker tiles; the chlorine and pH levels were not within the acceptable range of water quality standards; the main drain grates were not visible due to cloudy water; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of four thousand eighty dollars ($4,080.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand eighty dollars **($4,080.00)** by November 15, 2023.

Update: None.

37) Order Type and Number: Consent Order 23-073-RW
Order Date: September 18, 2023
Individual/Entity: **MegPan, LLC**
Facility: Florence Inn & Suites
Location: 3821 Bancroft Road
Florence, SC 29501
Mailing Address: Same
County: Florence
Previous Orders: None
Permit/ID Number: 21-127-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: MegPan, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Florence County, South Carolina. The Department conducted inspections on June 8, 2023, and July 20, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the drinking water fountain and the foot rinse shower were not operating; the gate did not self-close and latch; the main drain grates were not visible due to cloudy water; the life ring did not have a

permanently attached rope; there was no shepherd's crook; there was no pool rules sign posted on the first inspection and the sign posted on the second inspection was not completely filled out; only one "Shallow Water – No Diving Allowed" sign was posted; there were no "No Lifeguard On Duty – Swim At Your Own Risk" signs posted; the current pool operator of record information was not posted to the public; the bound and numbered log book was not available for review; and the chlorine level was not within the acceptable range of water quality standards.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

38) Order Type and Number: Consent Order 23-074-RW
Order Date: September 18, 2023
Individual/Entity: **Brayden Owner, LLC**
Facility: The Apartments at Brayden
Location: 1027 Aubrey Lane
Fort Mill, SC 29708
Mailing Address: Same
County: York
Previous Orders: None
Permit/ID Number: 46-1139B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Brayden Owner, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on June 15, 2023, and July 24, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the flow meter was not operating; the chlorine level was not within the acceptable range of water quality standards; the pool rules sign did not have all of the required rules; the current pool operator of record information was not posted to the public; the log book was not properly bound or numbered on the first inspection; the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record on the second inspection; and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book on the second inspection.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

39) Order Type and Number: Consent Order 23-075-RW
Order Date: September 18, 2023
Individual/Entity: **Cat Island Golf Holdings, LLC**

Facility:	Cat Island Club
Location:	390 Islands Causeway Beaufort, SC 29907
Mailing Address:	8 Waveland Avenue Beaufort, SC 29907
County:	Beaufort
Previous Orders:	None
Permit/ID Number:	07-562-1 & 07-563-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Cat Island Golf Holdings, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and a kiddie pool located in Beaufort County, South Carolina. The Department conducted inspections on June 8, 2023, and July 19, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there was algae on the pool wall; a frost proof tile was missing on the pool wall; a light in the pool wall was out of its niche; the chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the life ring was not United States Coast Guard approved; the emergency notification device was not operational; there was no pool rules sign; the bound and numbered log book was not maintained on a daily basis; and the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand three hundred sixty dollars ($1,360.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand three hundred sixty dollars **($1,360.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

40)

Order Type and Number:	Consent Order 23-076-RW
Order Date:	September 18, 2023
Individual/Entity:	**GSM Hotels, LLC**
Facility:	Sleep Inn
Location:	834 Windslow Avenue Gaffney, SC 29341
Mailing Address:	Same
County:	Cherokee
Previous Orders:	None
Permit/ID Number:	11-023-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: GSM Hotels, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Cherokee County, South Carolina. The Department conducted inspections on June 27, 2023, and July 19, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine level was not within the acceptable range of water quality standards; the main drains were not visible due to cloudy water; only one “Shallow Water – No Diving Allowed” sign was posted;

only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; and the disinfection equipment was not operating properly.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

41) Order Type and Number: Consent Order 23-077-RW
Order Date: September 19, 2023
Individual/Entity: **Stones Thrown Council of Co-Owners, Inc.**
Facility: Stones Throw Villas
Location: 43 Folly Field Road
Hilton Head, SC 29928
Mailing Address: Same
County: Beaufort
Previous Orders: None
Permit/ID Number: 07-070-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Stones Thrown Council of Co-Owners, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Beaufort County, South Carolina. The Department conducted inspections on June 8, 2023, and July 25, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats were not properly spaced; there was algae on the pool wall; the pool deck was not clear of hazards; the fill spout was not stainless steel or equivalent; there was debris in the skimmer baskets; the bathrooms were not accessible; the foot rinse shower was not operating properly; the emergency notification device was not operational; the bound and numbered log book was not maintained a minimum of three times per week by the pool operator of record; and the cyanuric acid level was not checked weekly.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

42) Order Type and Number: Consent Order 23-079-RW
Order Date: September 20, 2023
Individual/Entity: **Heritage Hills of Hwy. 123, LLC**
Facility: Heritage Hills
Location: 98 Heritage Hills Drive
Seneca, SC 29678
Mailing Address: 510 Lonesome Pine Trail
Seneca, SC 29678

County:	Oconee
Previous Orders:	None
Permit/ID Number:	37-041-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Heritage Hills of Hwy. 123, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Oconee County, South Carolina. The Department conducted inspections on June 23, 2023, and July 31, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; there was no drinking water fountain; the chlorine level was not within the acceptable range of water quality standards; the life ring was not properly hung in the designated location; the cyanuric acid levels were not recorded weekly in the bound and numbered log book; the bound and numbered log book was not maintained a minimum of three times per week by the pool operator of record; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

43)

Order Type and Number:	Consent Order 23-080-RW
Order Date:	September 20, 2023
Individual/Entity:	**Westbury Park Residential Association, Inc.**
Facility:	Westbury Park
Location:	Chiswick Way Bluffton, SC 29910
Mailing Address:	2 Corpus Christi, Suite 302 Hilton Head Island, SC 29928
County:	Beaufort
Previous Orders:	None
Permit/ID Number:	07-1005B & 07-1006C
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Westbury Park Residential Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and a kiddie pool located in Beaufort County, South Carolina. The Department conducted inspections on July 14, 2023, and August 7, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was not tight and secure; the water level was too high; the backwash pit was flooded; the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the current pool operator of record information was not posted to the public; the pool rules sign did not have all of the required rules; and the bound and numbered log book was not available for review.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand three hundred sixty dollars

($1,360.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand three hundred sixty dollars **($1,360.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

44)

Order Type and Number:	Consent Order 23-081-RW
Order Date:	September 21, 2023
Individual/Entity:	**Watermarke Owners Association, Inc.**
Facility:	Watermarke Luxury Condos
Location:	105 Watermarke Lane Anderson, SC 29625
Mailing Address:	Same
County:	Anderson
Previous Orders:	None
Permit/ID Number:	04-1037B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Watermarke Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Anderson County, South Carolina. The Department conducted inspections on June 23, 2023, and August 11, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the life ring did not have a permanently attached rope; the "Shallow Water – No Diving Allowed" signs posted were in disrepair; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis; the cyanuric acid level was not recorded weekly in the bound and numbered log book; a skimmer lid was cracked; and the emergency notification device was not operational.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

45)

Order Type and Number:	Consent Order 23-082-RW
Order Date:	September 22, 2023
Individual/Entity:	**Calibogue Cay Club Homeowners' Association, Inc.**
Facility:	Calibogue Club
Location:	8 Spartina Court Hilton Head Island, SC 29928
Mailing Address:	1040 William Hilton Parkway Hilton Head Island, SC 29928
County:	Beaufort
Previous Orders:	None
Permit/ID Number:	07-153-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Calibogue Cay Club Homeowners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Beaufort County, South Carolina. The Department conducted inspections on June 27, 2023, and July 25, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats were not properly spaced; the deck was uneven with sharp edges; a skimmer weir was broken; the water level was too high; the fill spout was not stainless steel or equivalent; a gate did not self-close and latch; and only one "Shallow Water – No Diving Allowed" sign was posted.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

46)

Order Type and Number:	Consent Order 23-083-RW
Order Date:	September 25, 2023
Individual/Entity:	**Oyster Landing Homeowner's Association, Inc.**
Facility:	Oyster Landing
Location:	4 Oyster Landing Lane Hilton Head Island, SC 29928
Mailing Address:	59 Oyster Landing Lane Hilton Head Island, SC 29928
County:	Beaufort
Previous Orders:	None
Permit/ID Number:	07-199-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Oyster Landing Homeowner's Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Beaufort County, South Carolina. The Department conducted inspections on June 20 2023, and July 25, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the water level was too high; a gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the life ring was deteriorated on the first inspection; and the life ring did not have a permanently attached rope on the second inspection.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

47) Order Type and Number: Consent Order 23-084-RW

Order Date: September 25, 2023
Individual/Entity: **The Governors Homeowners Association, Inc.**
Facility: Governors
Location: 101 John Rutledge Street
Anderson, SC 29621
Mailing Address: 119 George B Timmerman Drive
Anderson, SC 29621
County: Anderson
Previous Orders: None
Permit/ID Number: 04-083-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: The Governors Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Anderson County, South Carolina. The Department conducted inspections on June 21, 2023, and August 2, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder and handrail were not tight and secure; frost proof tiles were missing on the pool wall; the chlorine level was not within the acceptable range of water quality standards; the emergency notification device was not operational; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

48) Order Type and Number: Consent Order 23-085-RW
Order Date: September 27, 2023
Individual/Entity: **Walnut Creek Residential Homeowners Association, Inc.**
Facility: Walnut Creek
Location: 11459 Walnut Creek Parkway
Lancaster, SC 29720
Mailing Address: 7724 Sea Turtle Way
Lancaster, SC 29720
County: Lancaster
Previous Orders: 22-056-RW ($1,360.00)
Permit/ID Number: 29-1037B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Walnut Creek Residential Homeowners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Lancaster County, South Carolina. The Department conducted inspections on May 22, 2023, and July 31, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a lifeline with floats was not attached to the pool wall; a depth marker tile was cracked; a ladder was missing bumpers; the waterline tiles were dirty; the

coping was chipped; there was debris in the skimmer baskets; the drinking water fountain was not operating properly; the flow meter was not operating properly; the pH level was not within the acceptable range of water quality standards; the shepherd's crook was not permanently attached to the handle; only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; the log book was not properly bound and numbered and was not maintained on a daily basis on the first inspection; the cyanuric acid level was not recorded on a weekly basis in the bound and numbered log book on the second inspection; and there were chlorine sticks in the skimmer baskets.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand six hundred dollars **($1,600.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

49)

Order Type and Number:	Consent Order 23-086-RW
Order Date:	September 28, 2023
Individual/Entity:	**BIF – 1742 SR Blvd, LLC**
Facility:	West Wind Apartments
Location:	320 Broad Street Charleston, SC 29401
Mailing Address:	Same
County:	Charleston
Previous Orders:	None
Permit/ID Number:	10-127-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: BIF – 1742 SR Blvd, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on May 31, 2023, and July 25, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: skimmers were missing weirs; the life ring rope was deteriorated; the bound and numbered log book was not maintained on a daily basis; the lifeline floats were not properly spaced; the deck was uneven with sharp edges; and the equipment room was not locked.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

50)

Order Type and Number:	Consent Order 23-087-RW
Order Date:	September 28, 2023
Individual/Entity:	**Om Shree, LLC**
Facility:	Comfort Suites
Location:	1323 Old Springdale Road

	Rock Hill, SC 29730
Mailing Address:	Same
County:	York
Previous Orders:	None
Permit/ID Number:	46-1099B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Om Shree, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in York County, South Carolina. The Department conducted inspections on March 31, 2023, and May 30, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: depth marker tiles on the deck were broken; the plaster on the pool floor was deteriorated; skimmers were missing weirs; the flow meter was not operating; the chlorine level was not within the acceptable range of water quality standards; the shepherd's crook handle was not the approved length; the log book was not properly bound and numbered; and the gate did not self-close and latch.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

51)

Order Type and Number:	Consent Order 23-088-RW
Order Date:	September 28, 2023
Individual/Entity:	**AHP of Spartanburg, LLC**
Facility:	The Bluffs Apartment Homes
Location:	100 Vanderbilt Lane Spartanburg, SC 29301
Mailing Address:	Same
County:	Spartanburg
Previous Orders:	None
Permit/ID Number:	42-096-1
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: AHP of Spartanburg, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Spartanburg County, South Carolina. The Department conducted inspections on June 15, 2023, and August 1, 2023, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats were not properly spaced; the chlorine level was not within the acceptable range of water quality standards; and the "Shallow Water – No Diving Allowed" signs posted did not have the correct wording.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars ($680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

Update: The civil penalty has been paid and the Consent Order is closed.

Water Pollution Enforcement

52) Order Type and Number: Consent Order 23-040-W
Order Date: September 1, 2023
Individual/Entity: **MHC Carolina LC, Inc.**
Facility: Carolina Landing Campground WWTF
Location: 120 Carolina Landing Drive
Fair Play, SC 29643
Mailing Address: 4300 West Cypress Street, Suite #400
Tampa, FL 33607
County: Oconee
Previous Orders: N/A
Permit/ID Number: SCG570011
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) and the Water Pollution Control Permits Regulation S.C. Code Ann. Regs. 61-9.122.41(a)

Summary: MHC Carolina LC, Inc. (Individual/Entity) owns and is responsible for the Carolina Landing Campground wastewater treatment facility (WWTF) located in Oconee County, South Carolina. The Individual/Entity reported violations of biochemical oxygen demand (BOD), Escherichia coli (E.coli), and ammonia-nitrogen (ammonia) on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation, as follows: failed to comply with the permitted effluent limitations for BOD, E.coli, and ammonia.

Action: The Individual/Entity is required to: submit written notification of the completion date for all corrective actions necessary to resolve the effluent violations by October 2, 2023; conduct a six (6) monitoring event compliance confirmation period upon completion of corrective actions; and implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of twelve thousand, six hundred dollars ($12,600.00). The Individual/Entity shall pay a civil penalty in the amount of twelve thousand, six hundred dollars **($12,600.00)** by October 2, 2023.

Update: The written notification for completion of the corrected actions has been submitted and the civil penalty has been paid.

53) Order Type and Number: Consent Order 23-041-W
Order Date: September 13, 2023
Individual/Entity: **Town of St. Matthews**
Facility: Town of St. Matthews WWTF
Location: 20 Dogwood Acres Trail
St. Matthews, SC 29135
Mailing Address: P.O. Box 172
St. Matthews, SC 29135
County: Calhoun

Previous Orders: N/A
Permit/ID Number: ND0086983
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) and the Water Pollution Control Permits Regulation S.C. Code Ann. Regs. 61-9.122.41(a)

Summary: Town of St Matthews (Individual/Entity) owns and is responsible for a wastewater treatment facility (WWTF) located in Calhoun County, South Carolina. The Individual/Entity reported violations of E.coli on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation, as follows: failed to comply with the permitted effluent limitations for E.coli.

Action: The Individual/Entity is required to: submit written notification of the completion date for all corrective actions necessary to resolve the effluent violations by October 30, 2023; conduct a six (6) monitoring event compliance confirmation period upon completion of corrective actions; and implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of seven thousand dollars ($7,000.00). The Individual/Entity shall pay a civil penalty in the amount of seven thousand dollars **($7,000.00)** by October 30, 2023.

Update: The written notification for completion of the corrected actions has been submitted and the civil penalty has been paid.

BUREAU OF AIR QUALITY

54) Order Type and Number: Consent Order 23-022-A
Order Date: September 5, 2023
Individual/Entity: **Santee Cooper**
Facility: Santee Cooper Cross Generating Station
Location: 553 Cross Station Road
Pineville, SC 29468
Mailing Address: P.O. Box 2946101
Moncks Corner, SC 29461
County: Berkeley
Previous Orders: CO-21-010-A
Permit/ID Number: 0420-0030
Violations Cited: US EPA 40 CFR 63 Subpart UUUUU, S.C. Code Ann. Regs. 61-62.63 Subpart UUUUU, S.C. Code Ann. Regs. 61-62.1, Section II, Permit Requirements, and CO-21-010-A.

Summary: Santee Cooper (Individual/Entity) owns and operates an electricity production station located in Berkeley County, South Carolina. On March 15, 2023, a Department-approved performance test for PM emissions was conducted. The Individual/Entity has violated US EPA and South Carolina Air Pollution Control Regulations, as follows: failed to limit PM emissions to 0.03 lb/MMBtu on March 15, 2023.

Action: The Individual/Entity is required to: henceforth limit PM emissions to 0.03 lb/MMBtu. The Department has assessed a total civil penalty in the amount of eighteen thousand dollars ($18,000.00). The Individual/Entity shall pay a civil penalty in the amount of eighteen thousand dollars **($18,000.00)**.

Update: On April 27, 2023, the Individual/Entity conducted a performance test, demonstrating compliance with the PM limit. The Individual/Entity has paid the civil penalty.

55) Order Type and Number: Consent Order 23-023-A
Order Date: September 13, 2023
Individual/Entity: **Athena Corporation**
Facility: Athena Corporation
Location: 1495 Jenkins Ave
Hardeeville, SC 29927
Mailing Address: P.O. Box 2115
Beaufort, SC 29901
County: Jasper
Previous Orders: None
Permit/ID Number: 1360-0032
Violations Cited: U.S. EPA 40 CFR 70 and S.C. Code Ann. Regs 61-62.70, and S.C. Code Ann. Regs. 61-62.1, Section II, Permit Requirements.

Summary: Athena Corporation (Individual/Entity) manufactures specialty building products at its facility located in Jasper County, South Carolina. On March 31, 2023, Title V Permit 1360-0032 expired, and the renewal application was due no later than September 30, 2022. The Individual/Entity has violated US EPA and South Carolina Air Pollution Control Regulations, as follows: failed to submit a timely Part 70 (Title V) Permit renewal application, or other permit application in lieu of the renewal application, within six months prior to permit expiration.

Action: The Individual/Entity is required to: comply with all terms and conditions of the TV Permit, until such time as the Department issues a new permit. The Department has assessed a total civil penalty in the amount of ten thousand five hundred dollars ($10,500.00). The Individual/Entity shall pay a civil penalty in the amount of ten thousand five hundred dollars **($10,500.00)**.

Update: On July 10, 2023, the Department received a new permit application for a Conditional Major Operating Permit. The application is currently under review by the Department. The Individual/Entity has paid the civil penalty.

56) Order Type and Number: Consent Order 23-024-A
Order Date: September 13, 2023
Individual/Entity: **Rogers Group, Inc.**
Facility: Rogers Group – Lyman Asphalt Plant
Location: 2550 Ballenger Road
Wellford, SC 29835
Mailing Address: 421 Great Circle Road
Nashville, TN 37228

County: Spartanburg
Previous Orders: None
Permit/ID Number: 9900-0090
Violations Cited: US EPA 40 CFR 60 Subpart I, S.C. Code Ann. Regs. 61-62.60 Subpart I, and S.C. Code Ann. Regs. 61-62.1, Section II, Permit Requirements

Summary: Rogers Group, Inc. (Individual/Entity) operates an asphalt plant located in Spartanburg County, South Carolina. On May 31, 2022, and December 1, 2022, Department-approved performance tests for PM emissions were conducted. On February 24, 2023, the Department conducted an inspection. The Individual/Entity has violated US EPA and South Carolina Air Pollution Control Regulations, as follows: failed to limit PM emissions to 0.04 gr/dscf, and failed to record, and maintain on-site, records of weekly inspections and maintenance performed on the water trucks.

Action: The Individual/Entity is required to: henceforth limit PM emissions to 0.04 gr/dscf and comply with all terms and conditions of the Permit. The Department has assessed a total civil penalty in the amount of thirty-six thousand dollars ($36,000.00). The Individual/Entity shall pay a civil penalty in the amount of thirty-six thousand dollars **($36,000.00)**.

Update: On March 9, 2023, the Individual/Entity conducted a Department-approved re-test for PM emissions, demonstrating compliance with the PM emissions limit. The Individual/Entity has paid the civil penalty.

57) Order Type and Number: Consent Order 23-024-A
Order Date: September 29, 2023
Individual/Entity: **Fiber Industries, LLC**
Facility: Fiber Industries, LLC
Location: 1000 East McIver Road
Darlington, SC 29532
Mailing Address: Same
Previous Orders: None
Permit/ID Number: 0820-0079
Violations Cited: U.S. EPA regulations at 40 CFR 63.1315(a), S.C. Code Ann. Regs. 61-62.63.1315(a), U.S. EPA regulations at 40 CFR 63.1330(b), S.C. Code Ann. Regs. 61-62.63.1330(b), U.S. EPA regulations at 40 CFR 63.6655(e)(3), S.C. Code Ann. Regs 61-62.63.6655(e)(3), S.C. Code Ann. Regs. 61-62.1, Section IV.F.1, and S.C. Code Ann. Regs. 61-62.1, Section II, Permit Requirements.

Summary: Fiber Industries, LLC (Individual/Entity) is a polyethylene terephthalate manufacturing facility located in Darlington County, South Carolina. The Individual/Entity performed a Department-approved performance test for nitrogen oxides (NOX) and carbon monoxide (CO) emissions completed on April 7, 2022. The Department also reviewed records and conducted a comprehensive inspection on July 14, 2021. The Individual/Entity has violated US EPA and South Carolina Air Pollution Control Regulations, as follows: failed to properly install, maintain, and operate a flow indicator, or secure the bypass line valve in the non-diverting position and perform a visual inspection of the seal or closure mechanism at least once every month to ensure that the valve is maintained in the non-diverting position and gas stream is not diverted

through the bypass line for 28 days; failed to operate and maintain a steam stripper with a minimum flow rate of 0.04 kilograms (kg) of steam per liter of wastewater feed within the column and a minimum wastewater feed temperature of the steam stripper for a total of 52 days; failed to provide maintenance records at the time of inspection; failed to submit the required source test reports for source tests within 30 days of completion of the tests; exceeded the permitted NOX emissions limit established pursuant to Best Available Control Technology (BACT) and exceeded the permitted CO emissions limit established pursuant to BACT analysis during the source testing; failed to conduct source tests representative of worst case operation no later than 180 days after start up.

Action: The Individual/Entity is required to: conduct a retest for CO and NOX within (60) days of the natural gas fired process heater becoming operational. The Department has assessed a total civil penalty in the amount of fifty-three thousand dollars ($53,000.00). The Individual/Entity shall pay a civil penalty in the amount of fifty-three thousand dollars **($53,000.00)** by October 29, 2023.

Update: None.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

On-Site Wastewater Enforcement

58)

Order Type and Number:	Administrative Order 23-076-OSWW
Order Date:	August 14, 2023
Individual/Entity:	**V&V Investment, LLC**
Facility:	V&V Investment, LLC
Location:	528 McElrath Road Starr, SC 29684
Mailing Address:	P.O. Box 13021 Anderson, SC 29624
County:	Anderson
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: V&V Investment, LLC (Individual/Entity) owns property located in Anderson County, South Carolina. The Department conducted an investigation on June 15, 2023, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The

Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

59) Order Type and Number: Administrative Order 23-072-OSWW
Order Date: August 21, 2023
Individual/Entity: **Pedro Guadalupe Rivera**
Facility: Pedro Guadalupe Rivera
Location: 2305 Vincent Street
Newberry, SC 29108
Mailing Address: Same
County: Newberry
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Pedro Guadalupe Rivera (Individual/Entity) owns property located in Newberry County, South Carolina. The Department conducted an investigation on June 5, 2023, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

60) Order Type and Number: Administrative Order 23-074-OSWW
Order Date: August 21, 2023
Individual/Entity: **Michael McCloskey, Krista Gosland, and Frank Molter**
Facility: Michael McCloskey, Krista Gosland, and Frank Molter
Location: 388 Victor Road
Prosperity, SC 29127
Mailing Address: Same
County: Newberry
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Michael McCloskey, Krista Gosland, and Frank Molter (Individual/Entity) own property located in Newberry County, South Carolina. The Department conducted an investigation on June 27, 2023, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

61)

Order Type and Number:	Administrative Order 23-080-OSWW
Order Date:	August 21, 2023
Individual/Entity:	**Jeramie Green and Tira Green**
Facility:	Jeramie Green and Tira Green
Location:	4404 Davison Road Ravenel, SC 29470
Mailing Address:	Same
County:	Charleston
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Jeramie Green and Tira Green (Individual/Entity) own property located in Charleston County, South Carolina. The Department conducted an investigation on May 9, 2023, and observed domestic wastewater discharging onto the surface of the ground from uncovered areas of the OSWW system. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

62) Order Type and Number: Administrative Order 23-082-OSWW
Order Date: August 21, 2023
Individual/Entity: **Michael Cameron, Sr.**
Facility: Michael Cameron, Sr.
Location: 3214 West Forest Lake Drive
Florence, SC 29501
Mailing Address: Same
County: Florence
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Michael Cameron, Sr. (Individual/Entity) owns property located in Florence County, South Carolina. The Department conducted an investigation on May 12, 2023, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

63) Order Type and Number: Administrative Order 23-083-OSWW
Order Date: August 21, 2023
Individual/Entity: **Wanda Bessant Chestnut, Kenneth Todd, Tommy Todd, Steve Singleton, Kevin Larrimore, and Sharon Brown**
Facility: Wanda Bessant Chestnut, Kenneth Todd, Tommy Todd, Steve Singleton, Kevin Larrimore, and Sharon Brown
Location: 5361 Hampton Road
Conway, SC 29527
Mailing Address: Same
County: Horry
Previous Orders: 23-048-OSWW
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Wanda Bessant Chestnut, Kenneth Todd, Tommy Todd, Steve Singleton, Kevin Larrimore, and Sharon Brown (Individual/Entity) own property located

in Horry County, South Carolina. The Department conducted an investigation on February 22, 2023, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity was referred to the Department's Office of General Counsel for enforcement of the Administrative Order by the courts.

64)

Order Type and Number:	Administrative Order 23-084-OSWW
Order Date:	August 21, 2023
Individual/Entity:	**Estate of Lucille Evans, Jeremiah Riggins, Estate of Kathleen Evans, Althea Johnson, Zachariah Riggins, Jack Evans, Estate of Willie Allgood, John Evans, David Evans, and Charles Evans**
Facility:	Estate of Lucille Evans, Jeremiah Riggins, Estate of Kathleen Evans, Althea Johnson, Zachariah Riggins, Jack Evans, Estate of Willie Allgood, John Evans, David Evans, and Charles Evans
Location:	108 Walker Street Easley, SC 29640
Mailing Address:	Same
County:	Pickens
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: The Estate of Lucille Evans, Jeremiah Riggins, Estate of Kathleen Evans, Althea Johnson, Zachariah Riggins, Jack Evans, Estate of Willie Allgood, John Evans, David Evans, and Charles Evans (Individual/Entity) own property located in Pickens County, South Carolina. The Department conducted an investigation on June 14, 2023, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate

the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

65) Order Type and Number: Administrative Order 23-085-OSWW
Order Date: August 21, 2023
Individual/Entity: **Chasity Lynn Montalvo**
Facility: Chasity Lynn Montalvo
Location: 215 Richey Road
Belton, SC 29627
Mailing Address: Same
County: Anderson
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Chasity Lynn Montalvo (Individual/Entity) owns property located in Anderson County, South Carolina. The Department conducted an investigation on April 24, 2023, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

66) Order Type and Number: Consent Order 23-071-OSWW
Order Date: September 7, 2023
Individual/Entity: **Robert Freeman, d.b.a. Freeman Septic Tank**
Facility: Robert Freeman, d.b.a. Freeman Septic Tank
Location: Lot 6 Carillon Court
Aiken, SC 29803
Mailing Address: 1581 Edgefield Road
North Augusta, SC 29841
County: Aiken
Previous Orders: None

Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Robert Freeman, d.b.a. Freeman Septic Tank, (Individual/Entity) installed an OSWW system on property located in Aiken County, South Carolina. The Department conducted an inspection on April 24, 2023, and observed the OSWW system had already been installed. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to apply for and receive a permit to construct or upgrade the OSWW system before installing the OSWW system.

Action: The Individual/Entity is required to cease and desist installing OSWW systems without a valid permit to construct. The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

67) Order Type and Number: Consent Order 23-066-OSWW
Order Date: September 26, 2023
Individual/Entity: **Lynn W. Laughlin, d.b.a. Lynn Laughlin Backhoe Service**
Facility: Lynn W. Laughlin, d.b.a. Lynn Laughlin Backhoe Service
Location: 320 Shelby Highway
Gaffney, SC 29340
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Lynn W. Laughlin, d.b.a. Lynn Laughlin Backhoe Service, (Individual/Entity) installed OSWW systems on numerous properties located in Spartanburg County, South Carolina. The Department conducted a review of records during January 2023. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that all systems for which the licensee is responsible are constructed, repaired, and cleaned in accordance with S.C. Regulation 61-56 and permits issued by the Department.

Action: The Individual/Entity is required to cease and desist installing OSWW systems without following all requirements of the Permit to Construct and the regulation. The Department has assessed a total civil penalty in the amount of ten thousand dollars ($10,000.00). The Individual/Entity shall pay a civil penalty in the amount of ten thousand dollars **($10,000.00)** by October 27, 2023.

Update: The Individual/Entity has reached out and the Department is working to arrange payment options.

* Unless otherwise specified, “Previous Orders” as listed in this report include orders issued by Environmental Affairs Programs within the last five (5) years.

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 9, 2023

( ) ACTION/DECISION
(X) INFORMATION

I. **TITLE:** Public Health Administrative and Consent Orders.

II. **SUBJECT:** Public Health Administrative Orders and Consent Orders for the period of September 1, 2023, through September 30, 2023.

III. **FACTS:** For the period of September 1, 2023, through September 30, 2023, Public Health reports 0 Administrative Orders and 45 Consent Orders totaling $54,100 in assessed civil penalties.

Permit Type	Administrative Orders	Consent Orders	Assessed Civil Penalties
Retail Food Establishments	0	45	$54,100

Submitted By:

Bentley P. White
Policy Director
Public Health

PUBLIC HEALTH ENFORCEMENT REPORT
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 9, 2023

CONSENT ORDERS (45)

1. Order Type and Number: Consent Order 23-215-FOOD
   Order Date: September 5, 2023
   Individual/Entity: **Charlie's Fine Food Restaurant**
   Facility: Charlie's Fine Food Restaurant
   Location: 226 Cedar Springs Road, Spartanburg, SC 29302
   County: Spartanburg
   Previous Orders: None
   Permit Number: 42-206-04418

   Summary: The Department conducted inspections on April 7, 2023, April 17, 2023, and June 19, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to provide a written plan for the restriction, exclusion and re-instatement of food employees when they have symptoms and/or diseases that are transmissible through food; and failed to ensure that the retail food establishment had written procedures for employees to follow when responding to vomiting or diarrheal events, that involve the discharge of vomitus or fecal matter onto surfaces in the retail food establishment.

   Action: The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

2. Order Type and Number: Consent Order 23-263-FOOD
   Order Date: September 5, 2023
   Individual/Entity: **Bojangles**
   Facility: Bojangles
   Location: 4391 Highway 24, Anderson, SC 29626
   County: Anderson
   Previous Orders: None
   Permit Number: 04-206-04869

   Summary: The Department conducted inspections on May 19, 2023, May 24, 2023, May 31, 2023, and June 6, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep equipment food contact surfaces and utensils clean to sight and touch.

   Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

3. Order Type and Number: Consent Order 23-149-FOOD
   Order Date: September 5, 2023
   Individual/Entity: **Noodles & Company**
   Facility: Noodles & Company

Location: 116 Loyola Drive, Myrtle Beach, SC 29588
County: Horry
Previous Orders: None
Permit Number: 26-206-14541

Summary: The Department conducted inspections on January 5, 2023, April 25, 2023, and May 3, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

4. Order Type and Number: Consent Order 23-265-FOOD
Order Date: September 5, 2023
Individual/Entity: **Up on the Roof**
Facility: Up on the Roof
Location: 314 South McDuffie Street, Anderson, SC 29624
County: Anderson
Previous Orders: None
Permit Number: 04-206-04855

Summary: The Department conducted inspections on May 22, 2023, May 31, 2023, and July 24, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

5. Order Type and Number: Consent Order 23-284-FOOD
Order Date: September 5, 2023
Individual/Entity: **Grande Dunes Members Club**
Facility: Grande Dunes Members Club
Location: 1580 Terra Verde Drive, Myrtle Beach, SC 29579
County: Horry
Previous Orders: None
Permit Number: 26-206-14778

Summary: The Department conducted inspections on March 1, 2023, July 3, 2023, and July 14, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

6. Order Type and Number: Consent Order 23-279-FOOD
   Order Date: September 5, 2023
   Individual/Entity: **TGI Friday's #746**
   Facility: TGI Friday's #746
   Location: 7515 North Kings Highway, Myrtle Beach, SC 29572
   County: Horry
   Previous Orders: None
   Permit Number: 26-206-14482

   Summary: The Department conducted inspections on March 23, 2023, July 18, 2023, and July 27, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

   Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

7. Order Type and Number: Consent Order 23-250-FOOD
   Order Date: September 5, 2023
   Individual/Entity: **Ernesto's Mexican Restaurant**
   Facility: Ernesto's Mexican Restaurant
   Location: 531 Bypass 72 NW, Suite C, Greenwood, SC 29649
   County: Greenwood
   Previous Orders: None
   Permit Number: 24-206-03246

   Summary: The Department conducted inspections on May 30, 2023, June 5, 2023, and June 15, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

   Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

8. Order Type and Number: Consent Order 23-214-FOOD
   Order Date: September 5, 2023
   Individual/Entity: **Southport Bar and Grill**
   Facility: Southport Bar and Grill
   Location: 629 Southport Road, Spartanburg, SC 29376
   County: Spartanburg
   Previous Orders: None
   Permit Number: 42-206-06199

   Summary: The Department conducted inspections on February 15, 2023, February 24, 2023, and June 23, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Department has entered into a payment plan with the Individual/Entity for the civil penalty.

9. Order Type and Number: Consent Order 23-155-FOOD
Order Date: September 5, 2023
Individual/Entity: **Jersey Mike's Subs (Sayebrook)**
Facility: Jersey Mike's Subs (Sayebrook)
Location: 102 Loyola Drive, Unit B, Myrtle Beach, SC 29588
County: Horry
Previous Orders: 23-327-FOOD ($800.00)
Permit Number: 26-206-12355

Summary: The Department conducted an inspection on May 3, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (23-327-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

10. Order Type and Number: Consent Order 23-288-FOOD
Order Date: September 5, 2023
Individual/Entity: **TGI Friday's #745**
Facility: TGI Friday's #745
Location: 500 Highway 17 North, North Myrtle Beach, SC 29582
County: Horry
Previous Orders: 23-112-FOOD ($1,600.00)
Permit Number: 26-206-14483

Summary: The Department conducted an inspection on July 21, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (23-112-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

11. Order Type and Number: Consent Order 22-173-FOOD
Order Date: September 5, 2023
Individual/Entity: **Stevens Farm Produce**
Facility: Stevens Farm Produce
Location: 2245 Highway 701, Loris, SC 29569
County: Horry
Previous Orders: None
Permit Number: Operating Without a Permit

Summary: The Department conducted investigations on April 24, 2023, May 19, 2023, and June 7, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: provided food to the public without a valid permit issued by the Department.

Action: The Department has assessed a total civil penalty in the amount of three thousand dollars ($3,000.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand dollars ($3,000.00). The Department has entered into a payment plan with the Individual/Entity for the civil penalty.

12. Order Type and Number: Consent Order 23-278-FOOD
Order Date: September 6, 2023
Individual/Entity: **McDonald's #07648**
Facility: McDonald's #07648
Location: 4500 Highway 17 Bypass South, Myrtle Beach, SC 29588
County: Horry
Previous Orders: None
Permit Number: 26-206-01135

Summary: The Department conducted inspections on December 30, 2022, January 6, 2023, and July 19, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

13. Order Type and Number: Consent Order 23-225-FOOD
Order Date: September 6, 2023
Individual/Entity: **Ducati's**
Facility: Ducati's
Location: 960 Cipriana Drive, Unit B4, Myrtle Beach, SC 29572
County: Horry
Previous Orders: None
Permit Number: 26-206-12598

Summary: The Department conducted inspections on August 24, 2022, January 18, 2023, and June 12, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

14. Order Type and Number: Consent Order 23-293-FOOD
Order Date: September 6, 2023
Individual/Entity: **Piggly Wiggly #80 Deli**
Facility: Piggly Wiggly #80 Deli
Location: 15 West Ashland Street, Andrews, SC 29510
County: Georgetown
Previous Orders: None
Permit Number: 22-206-06238

Summary: The Department conducted inspections on October 12, 2022, February 6, 2023, and June 14, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

15. Order Type and Number: Consent Order 23-246-FOOD
Order Date: September 6, 2023
Individual/Entity: **Pizza Hyena**
Facility: Pizza Hyena
Location: 13 South Ocean Boulevard, Surfside Beach, SC 29575
County: Horry
Previous Orders: 23-48-FOOD ($1,600.00)
Permit Number: 26-206-13908

Summary: The Department conducted an inspection on July 10, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (23-48-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

16. Order Type and Number: Consent Order 23-285-FOOD
Order Date: September 6, 2023
Individual/Entity: **Burger Fi of NMB**
Facility: Burger Fi of NMB
Location: 801 Main Street, North Myrtle Beach, SC 29582

County: Horry
Previous Orders: 22-242-FOOD ($400.00)
Permit Number: 26-206-13629

Summary: The Department conducted inspections on June 22, 2022, July 11, 2023, and July 20, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (22-242-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure floors, floor coverings, walls, wall coverings, and ceilings were designed, constructed, and installed so they are smooth and easily cleanable; and by failing to ensure that in retail food establishments in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than one (1) thirty-second inch (1 mm).

17. Order Type and Number: Consent Order 23-291-FOOD
Order Date: September 7, 2023
Individual/Entity: **Pizza Palace**
Facility: Pizza Palace
Location: 1314 Leesburg Road, Columbia, SC 29209
County: Richland
Previous Orders: 23-185-FOOD ($800.00)
Permit Number: 40-206-04200

Summary: The Department conducted inspections on March 22, 2022, May 19, 2023, and July 17, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the proper sanitization concentration in a chemical sanitizer used in a manual or mechanical operation during contact times; and failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (23-185-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to maintain the proper sanitization concentration in a chemical sanitizer used in a manual or mechanical operation during contact times.

18. Order Type and Number: Consent Order 23-296-FOOD
Order Date: September 12, 2023
Individual/Entity: **Dataw Island Clubhouse**
Facility: Dataw Island Clubhouse
Location: 100 Dataw Club Road, St. Helena, SC 29920
County: Beaufort

Previous Orders: None
Permit Number: 07-206-00905

Summary: The Department conducted inspections on December 1, 2022, August 2, 2023, and August 11, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

Action: The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

19. Order Type and Number: Consent Order 23-295-FOOD
Order Date: September 12, 2023
Individual/Entity: **Bonefish Grill #0504**
Facility: Bonefish Grill #0504
Location: 4708 Forest Drive, Columbia, SC 29206
County: Richland
Previous Orders: None
Permit Number: 40-206-05553

Summary: The Department conducted inspections on July 12, 2023, July 19, 2023, and July 26, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

20. Order Type and Number: Consent Order 23-209-FOOD
Order Date: September 12, 2023
Individual/Entity: **Wooden Spoon Eatery**
Facility: Wooden Spoon Eatery
Location: 828 Surfside Drive, Surfside Beach, SC 29575
County: Horry
Previous Orders: 22-243-FOOD ($1,000.00)
Permit Number: 26-206-14078

Summary: The Department conducted inspections on January 18, 2023, May 24, 2023, and June 2, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to follow written procedures for preparing and storing raw animal foods when using a non-continuous cooking process.

Action: The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (22-243-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; and by failing to ensure

that at least one employee that has supervisory and management responsibility, the authority to direct and control food preparation and service, the ability to enforce employee health policies, and a frequent presence at the facility shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program.

21. Order Type and Number: Consent Order 23-262-FOOD
Order Date: September 12, 2023
Individual/Entity: **Fazoli's**
Facility: Fazoli's
Location: 7621 Two Notch Road, Columbia, SC 29223
County: Richland
Previous Orders: 22-277-FOOD ($1,600.00); and
23-134-FOOD ($1,000.00)
Permit Number: 40-206-08809

Summary: The Department conducted inspections on June 2, 2023, July 24, 2023, and August 3, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (22-277-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to maintain the premises free of insects, rodents, and other pests. The previous Consent Order (23-134-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to maintain the premises free of insects, rodents, and other pests.

22. Order Type and Number: Consent Order 23-217-FOOD
Order Date: September 12, 2023
Individual/Entity: **3 Amigos Mexican Grill**
Facility: 3 Amigos Mexican Grill
Location: 108 South Catherine Street, Walhalla, SC 29691
County: Oconee
Previous Orders: None
Permit Number: 37-206-01235

Summary: The Department conducted inspections on June 22, 2022, June 24, 2022, July 1, 2022, August 22, 2022, August 31, 2022, June 14, 2023, and June 22, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to properly cool cooked time/temperature control for safety foods; failed to use effective methods to cool cooked time/temperature control for safety foods; and failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Department has assessed a total civil penalty in the amount of four thousand two hundred dollars ($4,200.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand two hundred dollars ($4,200.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

23. Order Type and Number: Consent Order 23-299-FOOD
Order Date: September 19, 2023
Individual/Entity: **Country Cook-In**
Facility: Country Cook-In
Location: 27 East Main Street, Ware Shoals, SC 29692
County: Greenwood
Previous Orders: 23-252-FOOD ($800.00)
Permit Number: 24-206-03296

Summary: The Department conducted an inspection on August 23, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

Action: The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (23-252-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to maintain the premises free of insects, rodents, and other pests; and by failing to sanitize utensils and food contact surfaces of equipment before using, after cleaning.

24. Order Type and Number: Consent Order 23-257-FOOD
Order Date: September 20, 2023
Individual/Entity: **Charleston Sports Pub**
Facility: Charleston Sports Pub
Location: 359 College Avenue, Clemson, SC 29631
County: Pickens
Previous Orders: 22-96-FOOD ($1,000.00);
22-202-FOOD ($2,500.00);
22-307-FOOD ($3,000.00); and
23-09-FOOD ($1,000.00)
Permit Number: 39-206-02077

Summary: The Department conducted an inspection on June 29, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

Action: The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars ($500.00).

Previous Orders: The previous Consent Order (22-96-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

The previous Consent Order (22-202-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to maintain the premises free of insects, rodents, and other pests; by failing to ensure that physical facilities were maintained in good repair; by

failing to clean the physical facilities as often as necessary to keep them clean; by failing to provide individual disposable towels at each hand washing sink or group of adjacent handwashing sinks; by failing to ensure that the handwashing sinks were accessible at all times; and by failing to clean non-food contact surfaces at a frequency to preclude accumulation of soil residues.

The previous Consent Order (22-307-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked; by failing to clean non-food contact surfaces at a frequency to preclude accumulation of soil residues; by failing to clean the physical facilities as often as necessary to keep them clean; and by failing to maintain the premises free of insects, rodents, and other pests.

The previous Consent Order (23-09-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to maintain the premises free of insects, rodents, and other pests.

25. Order Type and Number: Consent Order 23-234-FOOD
Order Date: September 20, 2023
Individual/Entity: **Saltwater Cowboys**
Facility: Saltwater Cowboys
Location: 130 Mill Street, Mount Pleasant, SC 29464
County: Charleston
Previous Orders: None
Permit Number: 10-206-11006

Summary: The Department conducted inspections on June 12, 2023, June 23, 2023, and July 3, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

26. Order Type and Number: Consent Order 23-266-FOOD
Order Date: September 20, 2023
Individual/Entity: **Subway of Belton**
Facility: Subway of Belton
Location: 701 Anderson Street, Belton, SC 29627
County: Anderson
Previous Orders: None
Permit Number: 04-206-02635

Summary: The Department conducted inspections on March 9, 2023, June 29, 2023, and July 5, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

27. Order Type and Number: Consent Order 23-277-FOOD
Order Date: September 20, 2023
Individual/Entity: **Royal Ramen**
Facility: Royal Ramen
Location: 7819 North Kings Highway, Myrtle Beach, SC 29572
County: Horry
Previous Orders: None
Permit Number: 26-206-13937

Summary: The Department conducted inspections on September 7, 2022, March 22, 2023, and July 27, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

28. Order Type and Number: Consent Order 23-256-FOOD
Order Date: September 20, 2023
Individual/Entity: **Taqueria**
Facility: Taqueria
Location: 152 North Pine Street, Batesburg, SC 29006
County: Lexington
Previous Orders: 23-141-FOOD ($1,600.00)
Permit Number: 32-206-05204

Summary: The Department conducted inspections on March 29, 2023, May 24, 2023, July 17, 2023, and July 18, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure employees wash hands after engaging in activities that contaminate their hands; failed to provide individual disposable towels at each hand washing sink or group of adjacent handwashing sinks; and failed to maintain the premises free of insects, rodents, and other pests.

Action: The Department has assessed a total civil penalty in the amount of one thousand five hundred dollars ($1,500.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand five hundred dollars ($1,500.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (23-141-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked; and by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

29. Order Type and Number: Consent Order 23-294-FOOD
Order Date: September 20, 2023
Individual/Entity: **Aguas Frescas Y Frutas Al Pato**
Facility: Aguas Frescas Y Frutas Al Pato
Location: 113 Bent Tree Circle, Gaston, SC 29053
County: Richland
Previous Orders: None
Permit Number: Operating Without a Permit

Summary: The Department conducted investigations on July 21, 2023, and August 12, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: provided food to the public without a valid permit issued by the Department.

Action: The Department has assessed a total civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

30. Order Type and Number: Consent Order 23-142-FOOD
Order Date: September 26, 2023
Individual/Entity: **IHOP #3317**
Facility: IHOP #3317
Location: 100 Legends Drive, Myrtle Beach, SC 29579
County: Horry
Previous Orders: 22-188-FOOD ($1,000.00)
Permit Number: 26-206-11499

Summary: The Department conducted an inspection on April 20, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: obscured, covered, defaced, relocated, or removed the grade decal that was posted by the Department.

Action: The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (22-188-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that equipment is maintained in a state of repair and condition that meets the regulation requirements.

31. Order Type and Number: Consent Order 23-287-FOOD
Order Date: September 26, 2023
Individual/Entity: **Pawleys Island Tavern**
Facility: Pawleys Island Tavern
Location: 10635 Ocean Highway, Pawleys Island, SC 29585
County: Georgetown
Previous Orders: 22-161-FOOD ($1,000.00)
Permit Number: 22-206-05734

Summary: The Department conducted an inspection on July 25, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

Action: The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (22-161-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to maintain the premises free of insects, rodents, and other pests.

32. Order Type and Number: Consent Order 23-115-FOOD
Order Date: September 26, 2023
Individual/Entity: **Quigley's Pint & Plate-MI**
Facility: Quigley's Pint & Plate-MI
Location: 11887 Highway 707, Murrells Inlet, SC 29576
County: Horry
Previous Orders: None
Permit Number: 26-206-14052

Summary: The Department conducted inspections on April 25, 2022, August 22, 2022, and February 23, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

33. Order Type and Number: Consent Order 23-313-FOOD
Order Date: September 26, 2023
Individual/Entity: **Fuddruckers #446**
Facility: Fuddruckers #446
Location: 6100 Wade Hampton Boulevard, Taylors, SC 29687
County: Greenville
Previous Orders: None
Permit Number: 23-206-08787

Summary: The Department conducted inspections on September 14, 2022, August 14, 2023, and August 21, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

34. Order Type and Number: Consent Order 23-151-FOOD
Order Date: September 26, 2023
Individual/Entity: **Fork 'N Links**
Facility: Fork 'N Links
Location: 9408 Highway 707, Myrtle Beach, SC 29588

County: Horry
Previous Orders: None
Permit Number: 26-206-13846

Summary: The Department conducted inspections on March 31, 2023, April 7, 2023, and April 14, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; and failed to ensure that the plumbing system was installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the retail food establishment.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

35. Order Type and Number: Consent Order 23-286-FOOD
Order Date: September 26, 2023
Individual/Entity: **Gios Italian Kitchen**
Facility: Gios Italian Kitchen
Location: 7915 North Kings Highway, Myrtle Beach, SC 29572
County: Horry
Previous Orders: None
Permit Number: 26-206-14145

Summary: The Department conducted inspections on August 2, 2022, December 15, 2022, and July 11, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep shellstock tags or labels attached to the container in which the shellstock are received, until the container is empty; and failed to clearly mark the date by which food shall be consumed on the premises, sold, or discarded when held at a temperature of 41°F or less for a maximum of seven (7) days. This applies only to refrigerated, ready-to-eat, time/temperature control for safety foods prepared and held in a food establishment for more than twenty-four (24) hours.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

36. Order Type and Number: Consent Order 23-315-FOOD
Order Date: September 26, 2023
Individual/Entity: **Fork and Plough**
Facility: Fork and Plough
Location: 1629 East North Street, Greenville, SC 29607
County: Greenville
Previous Orders: None
Permit Number: 23-206-11937

Summary: The Department conducted inspections on October 12, 2021, September 14, 2022, and August 9, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the proper sanitization concentration in a chemical sanitizer used in a manual or mechanical operation during contact times; and failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

Action: The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

37. Order Type and Number: Consent Order 23-277-FOOD
Order Date: September 26, 2023
Individual/Entity: **Piggly Wiggly #183 Deli**
Facility: Piggly Wiggly #183 Deli
Location: 122 Highway 17 North,cSurfside Beach, SC 29575
County: Horry
Previous Orders: 23-49-FOOD ($800.00)
Permit Number: 26-206-12749

Summary: The Department conducted an inspection on July 18, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (23-49-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

38. Order Type and Number: Consent Order 23-276-FOOD
Order Date: September 26, 2023
Individual/Entity: **Scotchman #3222**
Facility: Scotchman #3222
Location: 3065 Dick Pond Road, Myrtle Beach, SC 29588
County: Horry
Previous Orders: None
Permit Number: 26-206-12502

Summary: The Department conducted inspections on July 12, 2023, July 21, 2023, July 28, 2023, and August 7, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that the plumbing system was installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the retail food establishment.

Action: The Department has assessed a total civil penalty in the amount of one thousand six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand six hundred dollars ($1,600.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

39. Order Type and Number: Consent Order 23-158-FOOD
Order Date: September 26, 2023
Individual/Entity: **IHOP Bluffton**

Facility: IHOP Bluffton
Location: 11 Towne Drive, Bluffton, SC 29910
County: Beaufort
Previous Orders: None
Permit Number: 07-206-10780

Summary: The Department conducted inspections on April 12, 2022, November 1, 2022, November 8, 2022, and May 23, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of one thousand six hundred dollars ($1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand six hundred dollars ($1,600.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

40. Order Type and Number: Consent Order 23-290-FOOD
Order Date: September 26, 2023
Individual/Entity: **Cook Out**
Facility: Cook Out
Location: 205 Highway 17 North, North Myrtle Beach, SC 29582
County: Horry
Previous Orders: 22-185-FOOD ($400.00)
Permit Number: 26-206-13549

Summary: The Department conducted inspections on May 20, 2022, November 3, 2022, February 28, 2023, and July 12, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars ($2,000.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.

Previous Orders: The previous Consent Order (22-185-FOOD) was issued when the Individual/Entity violated the South Carolina Retail Food Establishment Regulation by failing to ensure floors, floor coverings, walls, wall coverings, and ceilings were designed, constructed, and installed so they are smooth and easily cleanable.

41. Order Type and Number: Consent Order 23-143-FOOD
Order Date: September 26, 2023
Individual/Entity: **Bojangles #867**
Facility: Bojangles #867
Location: 4207 Main Street, Loris, SC 29569
County: Horry
Previous Orders: None
Permit Number: 26-206-14538

Summary: The Department conducted inspections on January 4, 2023, January 6, 2023, April 17, 2023, April 26, 2023, and May 5, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

Action: The Department has assessed a total civil penalty in the amount of two thousand four hundred dollars ($2,400.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand four hundred dollars ($2,400.00).

42. Order Type and Number: Consent Order 23-194-FOOD
Order Date: September 26, 2023
Individual/Entity: **Big Boy's Country Cooking**
Facility: Big Boy's Country Cooking
Location: 306 East Carolina Avenue, Clinton, SC 29325
County: Laurens
Previous Orders: None
Permit Number: 30-206-01553

Summary: The Department conducted inspections on May 5, 2022, May 5, 2023 (2), May 6, 2023, May 9, 2023 (2), May 11, 2023, May 18, 2023, and May 23, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; failed to convey sewage to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law; and failed to provide equipment sufficient in number and capacity to maintain food temperatures for cooling and heating food and holding cold and hot food.

Action: The Department has assessed a total civil penalty in the amount of four thousand two hundred dollars ($4,200.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand two hundred dollars ($4,200.00). The Department has entered into a payment plan with the Individual/Entity for the civil penalty.

43. Order Type and Number: Consent Order 23-267-FOOD
Order Date: September 26, 2023
Individual/Entity: **Emily's Amish Oven**
Facility: Emily's Amish Oven
Location: 803 Bypass 25 NE, Greenwood, SC 29646
County: Greenwood
Previous Orders: None
Permit Number: 24-206-03308

Summary: The Department conducted inspections on June 16, 2023, June 19, 2023, June 23, 2023, June 30, 2023, July 5, 2023, July 13, 2023, and July 20, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; failed to ensure employees wash hands after engaging in activities that contaminate their hands; failed to ensure that the handwashing sinks were accessible at all times; failed to store foods in a manner to prevent cross contamination; failed to inform consumers of the significantly increased risk of consuming raw animal foods by way of a disclosure

and reminder (using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means); failed to clearly and individually identify with the common name of the material, on all working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies; and failed to provide a test kit or other device that accurately measures the concentration of MG/L of sanitizing solutions.

Action: The Department has assessed a total civil penalty in the amount of four thousand eight hundred dollars ($4,800.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand eight hundred dollars ($4,800.00). The Department has entered into a payment plan with the Individual/Entity for the civil penalty.

44. Order Type and Number: Consent Order 23-249-FOOD
Order Date: September 28, 2023
Individual/Entity: **Kim Brackett and Nathaniel Brackett**
Facility: Pacino's Mediterranean Grill
Location: 3103 Highway 17 Business, Garden City, SC 29576
County: Horry
Previous Orders: None
Permit Number: 26-206-14822

Summary: The Department conducted inspections on January 25, 2023, June 27, 2023, July 7, 2023, and July 14, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure floors, floor coverings, walls, wall coverings, and ceilings were designed, constructed, and installed so they are smooth and easily cleanable; and failed to ensure that in retail food establishments in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than one (1) thirty-second inch (1 mm).

Action: The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars ($400.00).

45. Order Type and Number: Consent Order 23-327-FOOD
Order Date: September 28, 2023
Individual/Entity: **Zaxby's #1302**
Facility: Zaxby's #1302
Location: 100 Strand Market Drive, Myrtle Beach, SC 29588
County: Horry
Previous Orders: None
Permit Number: 26-206-09397

Summary: The Department conducted inspections on December 5, 2022, April 10, 2023, and August 21, 2023. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to provide individual disposable towels at each hand washing sink or group of adjacent handwashing sinks.

Action: The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity has met all requirements of the Order. This Order has been closed.