

May 19, 1993

MEMORANDUM

TO: Administrators of facilities and activities
Licensed by DHEC Division of Health Licensing

FROM: Alan Samuels, Director
Division of Health Licensing

SUBJECT: Use of electronic signatures in records
and advanced technologies for records
storage.

Technology advances faster than regulations can be revised. Developments in electronic computer and other technologies have prompted questions about how they can be applied, particularly with regard to licensing standards related to records of activities and facilities.

Meetings with representatives of the South Carolina Hospital Association resulted in mutually acceptable positions on medical records storage and the use of computer key or electronic signatures on medical records. While preparing to communicate this to hospitals, we realized that these positions may be applicable to all records maintained by all activities which we license.

Therefore, so as not to impede progress, efficiency, and effectiveness, the following position will be applied as part of our regulatory process.

A. Use of electronic signatures in records:

1. Written signatures or initials and electronic signatures or computer generated signature codes are acceptable as authentication.
2. To employ electronic signatures or computer-generated signature codes for authentication purposes, the facility/service's governing body (and medical staff, if applicable) must adopt a written policy that permits authentication by electronic or computer-generated signature. The policy shall identify those categories of the medical staff, allied health staff, or other personnel who are authorized to authenticate records using electronic or computer generated signatures.

3. At a minimum, the policy shall include adequate safeguards to insure authenticity and confidentiality, including, but not limited to the following:
 - a. Each user must be assigned a unique identifier which is generated through a confidential code.
 - b. The facility/service must certify in writing that each identifier is kept strictly confidential. This certification must include a commitment to terminate an individual's use of an assigned identifier if it is found that the identifier has been misused.
"Misused" shall mean that the user has allowed another person or persons to use his or her personally assigned identifier, or that the identifier has otherwise been inappropriately used.
 - c. The user must 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.
 - d. The facility/service must monitor the use of identifiers periodically, and take corrective action as needed. The monitoring process shall be described in the policy.
4. The 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. No report or other document which contains blanks, gaps, obvious contradictory statements, or other items which require the attention of the authorized user may be considered authenticated until it is reviewed and corrected by the user and a revised report issued.
 - b. The system must make an opportunity available to the user to verify that the document is accurate and that the signature has been properly recorded.
 - c. The facility/service must, as part of its quality assurance activities, periodically sample records generated by the system to verify the accuracy and integrity of the system.

5. A user may terminate authorization for use of electronic computer-generated signature upon written notice to the person who has been designated by the activity/service's policy as having the authority to act upon the notice.
 6. Each report/record/entry generated by a user must be separately authenticated and dated.
 7. Policies and procedures must be consistent with the provisions of the Pharmacy Practice Act, SC Board of Pharmacy regulations and Regulation 61-4, South Carolina Controlled Substances Regulation.
 8. Our licensing regulations generally state that records shall contain the orders for medication and treatment written in ink and signed and dated by the prescriber. Facilities/services which accept electronic signatures or computer-generated signature codes will not be considered out of compliance with the regulations as long as a system as described above is in place, in writing and in practice.
- B. Advanced technologies for medical records storage:
1. Our regulations also generally outline the requirements for the storage of records.
 2. So long as records are stored and retained in accordance with the provisions of the various licensing regulations, the medium in which those records are stored is a facility decision. In other words, storage technologies, such as "optical disk", "microfiche", and others may be substituted for "microfilm."
- C. These issues will be addressed in future amendments to regulations.

AS/DG/ms

cc: C. Douglas Chavous, SC Board of Pharmacy
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