

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-14

DATE: January 13, 2005

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Electronic Signature Guidance - Clarification

Letter Summary

- Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs) may implement the use of electronic signatures for clinical record documentation whether or not the clinical record is entirely electronic. Included in this policy clarification is the Minimum Data Set (MDS), provided that state and local laws and the long-term care facility's policy permits.
- A long-term care facility that implements the use of electronic signatures must have policies in place that identify those who are authorized to sign electronically and security safeguards to prevent unauthorized use of electronic signatures.

This memorandum replaces S&C-04-46 dated September 9, 2004 that provided guidance to Regional Office (RO) and State Agency (SA) personnel regarding the use of electronic signatures.

The intent of this clarification is to inform certified long-term care providers who have the capability to implement electronic signatures for their MDS documentation that they may do so whether or not the clinical record is entirely electronic.

Background

The Centers for Medicare & Medicaid Services (CMS) has received requests for authorization to use electronic signatures on the MDS and the clinical record. Demand for the use of electronic signatures and current CMS requirements to retain hard copies of the MDS and clinical record has raised operational issues and concerns by both facility staff and authorized reviewers.

CMS has adopted the current hospital guidelines for electronic medical records and electronic signatures for other providers that do not have specific regulations governing the use of electronic signatures, such as Rural Health Clinics and Federally Qualified Health Centers. In addition, some states have specific requirements for the use of electronic signatures. A few states do not address electronic signatures in their statutes or regulations, but may permit the use of electronic signatures with approval from fiscal intermediaries or state authorities.

Discussion

Based on a review of the State Operations Manual (SOM), conflicting messages exist in current CMS policy. Some of our existing guidance requires the need for a hard copy of all MDS forms whether or not the facility is able to document signatures electronically, while another reference in the guidance allows the use of electronic signatures rather than a hard copy. Specifically:

- Appendix PP (Guidance to Surveyors – Long-Term Care Facilities) guidance regarding 42 CFR 483.20(d) states, “Whether or not the facility’s clinical record system is entirely electronic, a hard copy of all MDS forms, including the signatures of the facility staff attesting to the accuracy and completion of the records must be maintained in the resident’s clinical record.”
- Appendix PP guidance regarding 42 CFR 483.20(i) states, “Whether the MDS forms are manually completed or computer-generated following data entry, each individual assessor is responsible for certifying the accuracy of responses on the forms relative to the resident’s condition and discharge status. Manually completed forms are signed and dated by each individual assessor the day they complete their portion(s) of the MDS record. When MDS forms are completed directly on the facility’s computer (e.g., no paper form has been manually completed), then each individual assessor signs and dates a computer generated hard copy, after they review it for accuracy of the portion(s) they completed. Back dating completion dates is not acceptable.”
- Appendix R, (Revised Long-Term Care Resident Assessment Instrument User’s Manual, version 2.0, December 2002) with updates through June 2004 states, “Until such time as CMS adopts an electronic signature standard that is compatible with pending HIPAA requirements for electronic signature, all facilities are required to sign and retain hard copies of the MDS.” Another policy found in the RAI Manual states, “There is no requirement to maintain two copies of the form in the resident’s record (the hand written and computer-generated MDS). Either a hand written or a computer-generated form is equally acceptable.”
- However, Appendix PP guidance regarding 42 CFR 483.75(l)(1) states, “In cases in which facilities have created the option for an individual’s record to be maintained by computer, rather than a hard copy, electronic signatures are acceptable.” Further guidance provides an example of how the facility may set up a system with safeguards to prevent unauthorized access to an individual’s record maintained by computer.

Decision

Nursing homes may use electronic signatures on the MDS when permitted to do so by state and local law and when this is authorized by the long-term care facility's policy. Facilities must have written policies in place to ensure that they have proper security measures to protect use of an electronic signature by anyone other than to which the electronic signature belongs. The policy must also ensure that access to a hard copy of clinical records is made available to surveyors and others who are authorized access to clinical records by law.

Long-term care facilities that are not capable of maintaining the MDS signatures electronically must adhere to the current requirements addressing the need for either a hand-written copy or a computer-generated form. All state licensure and state practice regulations continue to apply to certified long-term care facilities. Where state law is more restrictive than federal requirements, the provider needs to apply the state law standard.

For questions regarding this memo, please contact Rosemary Dunn at (410) 786-1372 or e-mail at Rdunn@cms.hhs.gov.

Effective Date: The information contained in this memorandum clarifies current policy and must be implemented no later than 30 days after issuance of this memorandum.

Training: The information contained in this announcement should be shared with all survey and certification staff, their managers, the RO/state training coordinators, and all long-term care providers.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)