

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-04-46

DATE: September 9, 2004

TO: Associate Regional Administrators
State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Electronic Signature Guidance

Letter Summary

- Long-term care providers, that is Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), may implement/accept the use of electronic signatures for their clinical record documentation including the Minimum Data Set (MDS) if this is permitted by state and local law and authorized by the long term care facility's policy.
- A long-term care facility that implements/accepts the use of electronic signatures must have policies in place that identify those who are authorized to sign electronically and have safeguards in place to prevent unauthorized use of electronic signatures.

The purpose of this memorandum is to provide guidance to Regional Office (RO) and State Agency (SA) personnel regarding the use of electronic signatures by certified long-term care providers who have the capability to implement electronic signatures for their clinical records.

Background

The use of electronic medical records appears to be increasing in nursing homes. The Centers for Medicare & Medicaid Services (CMS) has received requests for authorization to use electronic signatures on the MDS and the individual health 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 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. Some States have specific requirements that include 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 the review of the State Operations Manual (SOM), conflicting messages exist in current CMS policy, as guidance requires the need for a hard copy of all MDS forms whether or not the facility's clinical record is entirely electronic. Another reference in the guidance allows the use of electronic signatures rather than a hard copy; the contradiction is noted in the following:

- Appendix PP, Guidance to Surveyors – Long-Term Care Facilities on page PP-76, [42 CFR 483.20(d)] tag F286 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.” Similar language is also found in the guidance for tag F278 on PP-81 [42 CFR 483.20(i)].
- In addition, Appendix R, the Revised Long-Term Care Resident Assessment Instrument User’s Manual, version 2.0, December 2002 with updates through June 2004 on page 1-27, Section 1.18 Reproduction and Maintenance of the Assessments, 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.” Current 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, guidance found in Appendix PP, [42 CFR 483.75(l)(1)], tag F515, Clinical records, references the facility’s “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 in a clinical record including 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. As noted above, the guidance language found in Appendix PP, tag 515, Clinical records currently reflects the use of electronic signatures in the clinical record. Facilities must have written policies in place to ensure that they have proper security measures to protect from the use of an electronic signature by anyone other than to which the electronic signature belongs. The policy must also ensure that access to clinical records is made available to surveyors and others who are authorized by law.

Long-term care facilities that are not capable of maintaining an individual's record electronically must adhere to the current requirements that address 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. In the future, long-term care facilities may be required to conform to a CMS electronic signature standard should CMS adopt one.

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

Effective Date: October 15, 2004

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.

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

/s/
Thomas E. Hamilton