



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-07-37

DATE: September 14, 2007

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Hospital and Laboratory Verbal Order Authentication Requirements Guidance

Memorandum Summary

- This memorandum provides guidance on how separate hospital and laboratory requirements related to verbal order authentication are to be applied.
- These regulations do not conflict.

Under Clinical Laboratory Improvement Amendment (CLIA) regulations, a laboratory must solicit written or electronic authorization for verbal test orders **within 30 days** of the laboratory's receipt of the order, or the laboratory must maintain documentation of its efforts to obtain authorization. For CLIA purposes, the State Agency (SA) and Regional Office (RO) laboratory surveyors assess compliance with 42 CFR 493.1241(b) in CLIA laboratories by looking at their standard operating procedures. Centers for Medicare & Medicaid Services (CMS)-approved laboratory accrediting organizations are also reminded that they are required to enforce their CLIA-equivalent requirements at the condition level.

SA and RO *hospital* surveyors assess compliance with the hospital conditions of participation (CoPs) by looking at the hospitals' standard operating procedures. The revised Medical Record Services CoP at 42 CFR 482.24(c)(1)(iii) requires verbal orders to be subsequently authenticated in the medical record **within 48 hours**, unless there is a State law that specifies a different timeframe for verbal order authentication. This requirement applies to verbal orders associated with both inpatients and outpatients.

It is possible that a hospital verbal order for a laboratory test could be authenticated in compliance with the CLIA standard, but nonetheless be out of compliance with the hospital Medical Record Services requirement (for instance, authentication of a verbal order 96 hours after being given). Because CLIA laboratories – even if physically situated in a hospital – are surveyed for compliance only with CLIA regulations, the laboratory would not be cited for a deficiency by a CLIA survey team.

However, hospital surveyors conducting a survey would cite the hospital's inpatient or outpatient recordkeeping for deficiencies under the Medical Record Services CoP if the lab order originated for a patient during a hospital inpatient stay or hospital outpatient clinic visit and no State law otherwise permitted a delay of that length.

Additional guidance on the interpretation of the revised Hospital CoPs, including the revisions concerning verbal orders, is under development and will be forthcoming.

Questions regarding verbal order authentication requirements in the hospital CoPs should be addressed to David Eddinger at david.eddinger@cms.hhs.gov. Questions regarding verbal order authentication requirements in the CLIA regulations should be addressed to Judy Yost at judith.yost@cms.hhs.gov.

Effective Date: Immediately. The State agencies should disseminate this information within 30 days of the date this memorandum.

Training: The information contained in this announcement should be shared with all survey and certification staff, surveyors, and their managers.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management