

<b>CMS Guidance Document</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Survey and Certification Policy Letter</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
EO Guidance No: 0040	<b>Date: August 23, 2007</b>
<b>Planned Web Site Address</b> <a href="http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage">http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage</a>	<b>Release planned:</b> <b>September 6, 2007</b>

**PROGRAM AREA: Survey and Certification**

**SUBJECT:** Hospital and Laboratory Verbal Order Authentication Requirements Guidance

**APPLIES TO:** State Survey Agency and Regional Office Surveyors; all Medicare- and Medicaid-certified hospitals and CLIA laboratories.

**I. SUMMARY OF CHANGES:**

- This memorandum provides guidance on how separate hospital and laboratory requirements related to verbal order authentication are to be applied.

**II. CHANGES IN POLICY INSTRUCTIONS:**

STATUS: R=REVISED, N=NEW, D=DELETED.

Status	Chapter / Section / Subsection / Title
R	Pub 100-07/Appendix A–Hospitals

**III. CLEARANCES:**

Clearance & Point of Contact (POC)	Name/Telephone/Component
Senior Official Clearance	Dennis Smith (410) 786-3870/Center for Medicaid and State Operations (CMSO)
Agency POC	Tracey Mummert (410) 786-3398/CMSO/Survey and Certification Group <a href="mailto:tracey.mummert@cms.hhs.gov">tracey.mummert@cms.hhs.gov</a>

**IV. TYPE (Check appropriate boxes for type of guidance)**

<input type="checkbox"/>	<b>Audit Guide</b>
<input type="checkbox"/>	<b>Change Request</b>
<input type="checkbox"/>	<b>HPMS</b>
<input type="checkbox"/>	<b>Joint Signature Memorandum</b>
<input type="checkbox"/>	<b>Manual Transmittal</b>
<input type="checkbox"/>	<b>State Medicaid Director Letters</b>
<input checked="" type="checkbox"/>	<b>Other – Survey and Certification Policy Letter</b>

**V. STATUTORY OR REGULATORY AUTHORITY:** 42 CFR 493.1241(b), Laboratory Requirements - Standard: Test request, and 42 CFR 482.24(c)(1)(iii), Conditions of Participation for Hospitals, Medical Record Services.



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-07-XX

**DATE:**

**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](mailto: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](mailto: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