

## The Importance of the Conditions of Participation for Hospitals

The Centers for Medicare & Medicaid Services (CMS) issued [Transmittal R37SOMA](#) (Transmittal 37) revising the Interpretive Guidelines to Hospitals ([Appendix A](#)) which are located in CMS' State Operations Manual. The revisions within the Interpretive Guidelines to Hospitals "reflect the amended regulations and survey and certification policy issuances concerning the Conditions of Participation [CoPs]."<sup>1</sup>

Healthcare organizations, which include but are not limited to hospitals, hospices, critical access hospitals, skilled nursing facilities and home health agencies, are required to comply with the CoPs if the organization participates in Medicare and Medicaid. The CoPs are the "minimum health and safety standards that providers and suppliers must meet in order to be Medicare and Medicaid certified."<sup>2</sup> In addition, the CoPs provide a foundation for healthcare organizations to improve and protect the quality of care administered to beneficiaries. Thus, failure to comply with CoPs will not only result in non-compliance with [Title 42 Part 482 of the Code of Federal Regulations](#) (CFR), but may also have adverse effects on the quality of care rendered.

### Why Do the CoPs Matter and Why Should it Matter to Me?

It is important for hospital facilities to regularly review the CoPs to ensure ongoing compliance with Medicare and Medicaid standards. Facilities that fail to fulfill standards are "at risk of exposure from private claims based on allegations of abuse and neglect."<sup>3</sup> In addition, when a hospital fails to comply with the CoPs, any claims submitted to Medicare and Medicaid for reimbursement will be false. Hence, not only can CMS deny payment to the facility, but the hospital will also be in violation of the False Claims Act resulting in potential sanctions from governmental enforcement agencies, fines and extensive litigation expenses. Hospitals "should [thus] be mindful as to whether or not their operations are in compliance with CoPs so as to avoid the costly experience of being forced to defend their operations."<sup>4</sup>

All staff members within a hospital facility are strongly encouraged to understand the laws and regulations regarding the CoPs for hospitals as well as those relating specifically to their workplace to minimize risk of regulatory non-compliance. This article summarizes the revised Interpretive Guidelines for Hospitals regarding medical records and utilization reviews in order to provide insight to compliance officers and billing personnel how day-to-day operations can impact the overall standards of their facility. Furthermore, this article will recommend compliance activities that compliance officers and billing personnel may conduct to assist their organization in complying with the CoPs.

---

<sup>1</sup> CMS, Revised Appendix A, "Interpretive Guidelines for Hospitals," [Trans. R37SOMA \(Oct. 17, 2008\)](#).

<sup>2</sup> CMS, "Conditions for Coverage & Conditions for Participation Overview." 9 July 2008. 10 December 2008 <<http://www.cms.hhs.gov/CFCsAndCOPs/>>.

<sup>3</sup> Dahlinghaus, Andrew and Marchica, Jo-Ann. "Compliance with Medicare Conditions of Participation." [HCCA Compliance Today](#) Vol. 9, No. 6. June 2007: 2-4.

<sup>4</sup> Ibid.

## What are the Medical Record Revisions?

Over the past several years CMS issued a number of regulatory revisions that clarified hospitals' responsibilities regarding medical records. The majority of the revisions emphasize the importance of a facility to uphold accurate medical documentation. Under 42 CFR 482.24(c)(1), hospitals should ensure that "[a]ll patient medical record entries [are] legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures." Prior to the release of Transmittal 37, the Interpretive Guidelines to Hospitals stated that "[a]ll entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished."<sup>5</sup> Thus, since the language in the current rule became more specific, CMS updated Interpretive Guidelines to Hospitals to be consistent with the CFR. As a result, CMS discussed in detail the interpretation of legible, complete, dated, timed, and authenticated in order to clarify how facilities can comply with the CoP.

Another provision that was added in the Interpretive Guidelines to Hospitals is section 482.24(c)(1)(iii) which states that "[a]ll verbal orders must be authenticated based upon Federal and State law. If there is no State law that designates a specific time frame for the authentication of verbal orders, verbal orders must be authenticated within 48 hours." The required authentication provides hospitals with "an opportunity to identify a transcription error and potential risk to patient safety."<sup>6</sup>

Through the revisions detailed in Transmittal 37, CMS reiterates the importance of proper medical documentation regardless of form, i.e. written, electronic, or verbal. Accurate medical documentation is critical in ensuring correct coding and reduces the likelihood that claims will be submitted that are medically unnecessary or incorrect. In turn, this will lead to a reduction in denied claims.

<b>Table 1: Medical Records Services Condition of Participation Revisions</b>	
<b>Disclaimer: Revisions only reflect changes in the States Operation Provider Certification Manual.</b>	
<b>State Operations Manual Interpretive Guidelines to Hospitals Prior to Transmittal 37<sup>7</sup></b>	<b>State Operations Manual Interpretive Guidelines to Hospitals Subsequent to Issuance of Transmittal 37<sup>8</sup></b>
<b><i>§482.24 (c)(1)- All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.</i></b>	<i>§482.24 (c)(1)- All patient medical record entries must be legible, complete, dated, timed , and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.</i>

<sup>5</sup> CMS, State Operations Manual, CMS 100-07, Appendix A, Survey Protocol, Regulations and Interpretive Guidelines for Hospitals (Prior to Rev. 37 Issued: 10/17/08)

<sup>6</sup> CMS, Revised Appendix A, "Interpretive Guidelines for Hospitals," [Trans. R37SOMA \(Oct. 17, 2008\)](#).

<sup>7</sup> CMS, State Operations Manual, CMS 100-07, Appendix A, Survey Protocol, Regulations and Interpretive Guidelines for Hospitals (Prior to Rev. 37 Issued: 10/17/08)

<sup>8</sup> CMS, Revised Appendix A, "Interpretive Guidelines for Hospitals," [Trans. R37SOMA \(Oct. 17, 2008\)](#).

<p><b>§482.24(c)(1)(i)- The author of each entry must be identified and must authenticate his or her entry.</b></p>	<p>§482.24(c)(1)(i)- All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner, except as noted in [§482.24(c)(1)(ii)].</p>
<p><b>§482.24(c)(1)(ii)- Authentication may include signatures, written initials or computer entry.</b></p>	<p>§482.24(c)(1)(ii)- For the 5 year period following January 26, 2007, all orders including verbal orders, must be dated, timed, and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to write orders by hospital policy in accordance with State law.</p>
<p><b>§482.24(c)(1)(iii)- Not Applicable</b></p>	<p>§482.24(c)(1)(iii)- All verbal orders must be authenticated based upon Federal and State law. If there is no State law that designates a specific time frame for the authentication of verbal orders, verbal orders must be authenticated within 48 hours.</p>
<p><b>§482.24(c)(2)(i)- Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.</b></p>	<p>§482.24(c)(2)(i)(A)- A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.</p> <p>§482.24(c)(2)(i)(B)- An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.</p>
<p><b>§482.24(c)(2)(v)- Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.</b></p>	<p>§482.24(c)(2)(v)- The language of the CFR remains the same; however, the interpretation of the regulation is in greater detail. More specifically, R37SOMA expands in its description on the minimum elements of an informed consent form as well as clarified a "properly executed informed consent process."<sup>9</sup></p>

<sup>9</sup> CMS, Revised Appendix A, "Interpretive Guidelines for Hospitals," [Trans. R37SOMA \(Oct. 17, 2008\)](#).

## What are the Utilization Review Revisions?

In order to comply with federal regulations, hospitals must develop a Utilization Review Committee who will evaluate the “medical necessity with respect to (1) admissions to their institution (i.e. Medicare claims status review); (2) the duration of care (i.e., continued-stay review); and (3) professional services rendered, such as drugs and biological (i.e. outliers in length of stay or outliers in cost or utilization).”<sup>10</sup> Furthermore, under section 482.30, hospitals are required to develop and implement a utilization review (UR) plan which reviews services rendered by the organization to Medicare and Medicaid beneficiaries. All hospitals are obligated to issue an effective UR plan; however, CMS has permitted two exceptions to the UR plan requirement. More specifically, a hospital is not required to develop and implement a separate UR plan if:

“(1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.

(2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§456.50 through 456.245 of this chapter.”

The revised Interpretive Guidelines to Hospitals clarify the UR requirement for hospitals that are classified as “deemed to meet all the Medicare conditions of participations.”<sup>11</sup> Hospitals may be deemed to meet all Medicare CoPs by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or other independent accreditation organization if criteria are fulfilled. However, under section 482.30, the UR CoP “is not part of the deemed program for hospitals per 42 CFR 488.5.”<sup>12</sup> Thus, unless the hospital meets the exception at section 482.30(a), all hospitals, accredited or not, are subjected to the UR plan requirements

## How to Comply with the Revisions?

With the New Year approaching compliance officers and billing personnel are in an ideal position to assist their organization in complying with the CoPs. The following chart is an example of a compliance checklist an organization should create when addressing revisions in the State Operations Manual Interpretive Guidelines to Hospitals. Hospitals are encouraged to review the Interpretive Guidelines to Hospitals in detail to ensure that all policies and procedures are updated when applicable.

---

<sup>10</sup> Youngtrom, N. “Strong Utilization Review Committees Can Prevent Inappropriate Hospital Admissions.” [Report on Medicare Compliance](#). 2008:

<sup>11</sup> 42 C.F.R. §488.5(1993).

<sup>12</sup> CMS, Revised Appendix A, “Interpretive Guidelines for Hospitals,” [Trans. R37SOMA \(Oct. 17, 2008\)](#).

## Compliance Checklist for Medical Review and Utilization Review Conditions of Participation

Does your organization conduct regular audits of medical records to ensure that medical records are:

- Legible- clearly written to prevent misread or misinterpretation;
- Complete- orders, progress notes, nursing notes, verbal orders, date, time, and signatures are documented correctly; and
- Authenticate- are the date, time and signatures appropriate as specified by [§482.12\(c\)](#)?

Does your organization have policies and procedures that:

- Ensure that documents are authenticated subsequent to creation?
- Require “prompt authentication of **all** orders?”<sup>13</sup>
- Include a read back and verification process for verbal orders?
- Abide by the Federal or State 48-hour verbal order authentication requirement if applicable?
- Comply with medical history and physical examination criteria as presented in [§482.24\(c\)\(2\)\(i\)\(A\)](#) and [§482.24\(c\)\(2\)\(i\)\(A\)](#)?
- Ensure that only licensed individuals that are authorized “in accordance with State law and hospital policy”<sup>14</sup> administer medical history and physical examinations?
- Specify which services require written patient consents?
- Address the minimum six elements of informed consent forms?

Does your organization’s informed consent form include the following six minimum elements?

- Name of hospital where procedure or treatment will take place.
  - Name of specified procedure or treatment.
  - Name of practitioner responsible in administering the specified procedure or treatment.
  - Statement “that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or patient’s legal representative.”<sup>15</sup>
  - Signature of patient (or patient’s legal representative when appropriate).
  - Date and time of patient’s (or patient’s legal representative when appropriate) signature.
- Does your organization conduct regular audits confirming medical records contain complete informed consent forms when applicable?
  - Does your organization have a procedure implemented to verify written signatures, electronic signatures, written initials and stamps?
  - Does your organization have the appropriate electronic signature security measures “that maintains the integrity of entries and verification of electronic signatures and authorizations?”<sup>16</sup>
  - Does your organization have a utilization review plan for services furnished to Medicare and Medicaid patients? If there lacks a utilization review plan, does the organization have an agreement with the QIO to address utilization review issues?
  - Do the records and reports of the Utilization Review Committee verify that utilization review activities described in the utilization review plan are performed?
  - Does the Utilization Review Committee’ minutes evidence detailed discussion of “review of the medical necessity of admissions, the appropriateness of the setting, the medical necessity of extended stays, and the medical necessity of professional services?”<sup>17</sup>
  - Are all applicable utilization review materials signed and dated?

<sup>13</sup> CMS, Revised Appendix A, “Interpretive Guidelines for Hospitals,” [Trans. R37SOMA \(Oct. 17, 2008\)](#).

<sup>14</sup> Ibid.

<sup>15</sup> Ibid.

<sup>16</sup> Ibid.

<sup>17</sup> Ibid.