



Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 11-04-ALL

DATE: November 26, 2010

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: FY 2011 Inpatient Prospective Payment System (IPPS) Rule Changes Affecting Survey and Certification

Memorandum Summary

- **FY 2011 IPPS Rule Adopted** The final IPPS rule revised several regulations affecting or of interest for survey and certification activities, effective October 1, 2010:
 - **42 CFR 489.13**, governing the determination of the effective date for provider agreement or supplier approval for facilities requiring certification;
 - **42 CFR Part 482, Hospital Conditions of Participation (CoPs)**, governing rehabilitation services and respiratory care services;
 - **42 CFR Part 485, Critical Access Hospital (CAH) CoPs**, i.e., a non-substantive technical correction to the CoPs; and
 - **Medicaid Regulations** governing accreditation of psychiatric hospitals and hospitals with inpatient psychiatric units

Background

The final FY 2011 IPPS rule was published on August 16, 2010 (75 FR 50042) and was effective on October 1, 2010. Several provisions in the rule directly affect areas of survey and certification responsibility. There were also changes in the Medicaid rules that are of interest because of their connection to the Hospital CoPs as well as Centers for Medicare & Medicaid Services (CMS)-approved national hospital accreditation programs.

1. Effective Date of Provider Agreement/Supplier Approval

42 CFR 489.13 governs the determination of the effective date of a Medicare provider agreement or supplier approval for health care facilities that are subject to survey and certification. Facilities subject to survey and certification are those that must comply with Medicare CoPs, long-term care requirements, conditions for coverage (CfC), or conditions for certification (the

term applicable to rural health clinics), depending on the type of facility. (The regulations exempt clinical laboratories, community mental health centers, and federally qualified health centers from its general provisions, establishing alternative requirements for these entities.) Compliance with the applicable conditions or requirements is determined through an onsite survey by the State Survey Agency (SA) or a CMS-approved national accreditation organization (AO). Currently, there are 15 approved accreditation programs offered by seven AOs for the following types of providers or suppliers: hospitals, CAHs, home health agencies (HHAs), hospices, and ambulatory surgical centers (ASCs).

Effective Date May Not be Earlier than the Date When All Federal Requirements are Met

Section 489.13 has been revised to make it clearer that the date of a Medicare provider agreement or supplier approval may not be earlier than the latest date on which all applicable federal requirements have been met, and that such requirements include review and verification of a prospective provider's application to enroll in the Medicare program by CMS's legacy fiscal intermediary (FI), legacy carrier, or Medicare Administrative Contractor (MAC). This clarification was necessary because a September 28, 2009 decision of the Appellate Division of the Departmental Appeals Board (DAB) interpreted §489.13 as not including enrollment application processing among the Federal requirements that must be met. In that case an SA had conducted the initial survey of an applicant on July 6, 2007, prior to receiving the November 21, 2007 notice from the legacy carrier that it was recommending approval of the applicant's enrollment application. The CMS Regional Office (RO) issued a supplier approval effective November 21, 2007, consistent with our traditional interpretation of §489.13. The DAB, however, ruled that the effective date must be July 6, 2007. The DAB agreed with the applicant in this case that the requirement for the Medicare contractor to verify and determine whether an application should be approved is not a requirement for the supplier to meet [under §489.13], but rather a requirement for Medicare contractor action (DAB Decision No. 2271, page 5).

Although SAs and AOs are aware that, in accordance with Section 2003B of the State Operations Manual (SOM), they should not perform a survey of a new facility until the MAC/legacy FI/legacy carrier has provided notice that the information provided on the enrollment application has been verified and enrollment is being recommended, circumstances do occur when the sequence is reversed. Therefore, when the survey occurs prior to the enrollment verification activities, we believe it is essential that the provider agreement or supplier approval date be based on the later date, i.e., the date that the contractor determined that the enrollment application information was complete and verified. In addition to enrollment application verification, there are other Federal requirements not related to a facility's survey, such as provision of required Office for Civil Rights documentation. Accordingly, the revised rule explicitly states in §489.13(b) that:

“Federal requirements include, but are not limited to--

(1) Enrollment requirements established in Part 424, Subpart P, of this chapter. CMS determines, based upon its review and verification of the prospective provider's or supplier's enrollment application, the date on which enrollment requirements have been met;

(2) The requirements identified in §§489.10 and 489.12; and

(3) The applicable Medicare health and safety standards, such as the applicable conditions of participation, the requirements for participation, the conditions for coverage, or the conditions for certification.”

Implications for Revised HHA Initial Certification Process

In the preamble to the final rule, we generally stated that the CMS contractor, i.e., the MAC or legacy FI, should verify that a provider or supplier is in compliance with all enrollment requirements when an enrollment application is submitted, during the period in which the provider or supplier is undergoing the health and safety survey and certification process and before the issuance of a provider agreement or supplier approval and billing privileges (see 75 FR at 50402). A future HHA memo will describe a revised initial enrollment and certification process for HHAs that entails a two-step enrollment application verification process by the CMS contractors. Under this process the MAC/legacy FI will conduct a second verification of the application information after receiving notice from the RO that the HHA has satisfied all survey and certification requirements, and the RO will not issue the HHA a provider agreement until the MAC/legacy FI advises that the HHA continues to meet the enrollment requirements. It is anticipated that the MAC/legacy FI will indicate in such second notice to the RO an enrollment verification date that is the same as the date in its preliminary recommendation which preceded the survey. Thus, for HHAs that continue to meet all enrollment requirements there would be no impact on the effective date of their provider agreement as a result either of the revised regulation or the revised enrollment verification process. However, if a subsequent contractor review (that takes place after the SA or AO survey) identifies noncompliance with any Federal requirements, then enrollment would be denied by the MAC/legacy FI and the applicant would be afforded appeal rights concerning the denial.

Treatment of Deemed Facilities

Section 489.13 has also been revised to ensure that non-accredited and accredited, deemed facilities are treated in the same manner with respect to determination of their Medicare agreement effective date. Accordingly, §489.13(d), containing separate provisions for deemed facilities, is being deleted in its entirety, and provisions governing deemed facilities are integrated into §489.13(b) and (c). In particular, deleted §489.13(d)(2) was a source of ongoing confusion for providers and suppliers. This deleted provision gave CMS the discretion to make the effective date of a provider agreement or supplier approval for a deemed facility retroactive up to 1 year, but as a matter of longstanding policy CMS did not exercise this discretion. The deletion of this provision should eliminate confusion about the availability of retroactive effective dates for accredited, deemed facilities.

2. Revisions to the Hospital CoPs

CMS revised the hospital CoPs relating to rehabilitation services at §482.56 and respiratory care services at §482.57 after receiving public requests for clarification. The questions concerning these CoPs suggested apparent inconsistencies between the two CoPs themselves, as well as between the two CoPs and many State laws regarding which practitioners are allowed to order rehabilitation and respiratory care services in the hospital setting. Rehabilitation services

include, for example, physical therapy, occupational therapy, audiology, and speech-pathology services.

Rehabilitation Services

Many States, under their scope-of-practice laws and other regulations, allow only specific qualified, licensed practitioners (including physicians, nurse practitioners (NPs), and physician assistants (PAs) to order rehabilitation services and respiratory care services. However, the previous standard at §482.56(b) required only that hospital rehabilitation services be ordered by practitioners authorized by the medical staff to do so. This requirement was too ambiguous and did not explicitly acknowledge various State laws that limit the ordering of hospital services (including diagnostic tests, drugs and biologicals, and inpatient treatment modalities) to specific qualified, licensed practitioners who are responsible for the care of the patient.

Accordingly the standard at §482.56(b) has been revised to clarify the types of practitioners who are allowed to order rehabilitation services, i.e., qualified, licensed practitioners who are responsible for the care of the patient and who are acting within the scope of practice under State law. The revised rule also requires that these practitioners must be authorized to order rehabilitation services by the hospital's medical staff, in accordance with both hospital policies and procedures and State laws. The revised rule also requires that all orders for these services be documented in accordance with the requirements at §482.24, the Medical Records CoP.

Respiratory Care Services

In contrast to the rehabilitation services situation, the previous rule governing respiratory care services at §482.57(b)(3), which explicitly stated that these services “must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy,” was too narrow. Many States, under their scope-of-practice laws and other regulations, allow qualified, licensed practitioners (including NPs and PAs) to order respiratory care services. While doctors of medicine or doctors of osteopathy had the option under the prior rule of delegating this task to NPs and PAs, this delegation requires physicians to countersign all orders by NPs or PAs for respiratory care services. CMS found no evidence that supports a different, and possibly higher, standard for ordering respiratory care services as compared to rehabilitation and other hospital services. CMS also concluded that requiring physician countersignature of orders written by qualified, licensed NPs and PAs for hospital rehabilitation and respiratory care services was burdensome and also runs counter to the policy of many States in their NP and PA State regulations and scope-of-practice laws.

Accordingly, CMS revised the existing requirements at §482.57 to allow qualified, licensed practitioners as well as physicians, to order respiratory care services as long as such privileges are authorized by the medical staff and are in accordance with both hospital policies and procedures and State laws. As is required under the CoPs for all patient orders, the ordering practitioner must also be an individual who is responsible for the care of the patient. The revised rule also requires that all orders for these services be documented in accordance with the requirements at §482.24, Medical records.

3. Revisions to the CAH CoP Rules

In the FY 2010 IPPS rule revisions were made to add a provision, §485.610(b)(4), that permits continued participation of CAHs located in areas no longer rural, up to September 30, 2011. (See S&C-10-10-CAH, December 31, 2009) The FY 2011 IPPS rule revision adds a conforming reference to this subsection at §485.610. This is a technical change that requires no action or changes on the part of SAs or ROs.

4. Medicaid Rule Revisions – Inpatient Psychiatric Services

Medicaid coverage of inpatient psychiatric services provided to individuals under the age of 21, when initially authorized under the Social Security Act in 1972, was limited to psychiatric hospitals accredited by The Joint Commission (TJC). In 1984, Congress eliminated the requirement for such hospitals to be accredited exclusively by The Joint Commission (section 2340(b) of Pub. L. 98-369). Through subsequent statutory and regulatory amendments, Medicaid coverage of inpatient psychiatric services provided to individuals under the age of 21 was also authorized for inpatient psychiatric programs within hospitals that are not psychiatric hospitals. Accreditation by TJC has remained a Federal regulatory requirement for psychiatric hospitals and inpatient psychiatric programs within hospitals. Several psychiatric hospitals and hospitals with inpatient psychiatric programs contacted CMS to request relief from The Joint Commission accreditation requirement. In addition, TJC has previously expressed concern with this mandate, as its policy is for facilities to seek accreditation voluntarily.

In response to these concerns the revised Medicaid rules in Parts 440 and 441 remove the requirement related to Medicaid coverage of inpatient psychiatric services provided to individuals under age 21 that psychiatric hospitals and hospitals with inpatient psychiatric programs (i.e., a hospital that is not a psychiatric hospital but which has an inpatient psychiatric unit) obtain accreditation from TJC. Under the revised rule:

- Psychiatric hospitals have the choice of undergoing a CMS survey to determine whether the hospital meets the requirements to participate in Medicare as a psychiatric hospital under 42 CFR 482.60 or of obtaining accreditation from a national AO whose psychiatric hospital accreditation program has been approved by CMS, i.e., the AOs approved for Medicare deeming purposes.
- Inpatient psychiatric programs in hospitals (i.e., psychiatric units in hospitals that are not psychiatric hospitals) have the choice of undergoing a CMS survey to determine whether the hospital meets the requirements to participate in Medicare as a hospital under 42 CFR Part 482, or of obtaining accreditation from a national AO whose hospital accreditation program has been approved by CMS. Currently there are three CMS-approved hospital accreditation programs, offered by the American Osteopathic Association, Det Norske Veritas Healthcare, and The Joint Commission. Although there are at present no CMS-approved AO psychiatric hospital programs, we anticipate that that may change over the next year.

Questions concerning this memorandum may be addressed to David Eddinger, at david.eddinger@cms.hhs.gov.

Effective Date: October 1, 2010. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/
Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management

Attachment

Text of Revised Regulations Effective October 1, 2010

Hospital CoP Revisions

Section 482.56 is amended by revising paragraph (b) to read as follows:

§482.56 Condition of participation: Rehabilitation services.

* * * * *

(b) Standard: Delivery of services. Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.

(1) All rehabilitation services orders must be documented in the patient's medical record in accordance with the requirements at §482.24.

(2) The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of §409.17 of this chapter.

Section 482.57 is amended by revising paragraph (b)(3) and by adding paragraph (b)(4) to read as follows:

§482.57 Condition of participation: Respiratory care services.

* * * * *

(b) * * *

(3) Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.

(4) All respiratory care services orders must be documented in the patient's medical record in accordance with the requirements at §482.24.

CAH CoP Rule Revision

Section 485.610 is amended by revising the introductory text of paragraph (b) to read as follows:

§485.610 Condition of participation: Status and location.

* * * * *

(b) Standard: Location in a rural area or treatment as rural. The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section or the requirements of either (b)(3) or (b)(4) of this section.

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Effective Date Rule

Sections 489.1 and 489.13 are revised to read as follows:

§489.1 Statutory basis.

(a) This part implements section 1866 of the Social Security Act (the Act). Section 1866 of the Act specifies the terms of provider agreements, the grounds for terminating a provider agreement, the circumstances under which payment for new admissions may be denied, and the circumstances under which payment may be withheld for failure to make timely utilization review. The sections of the Act specified in paragraphs (a)(1) through (a)(4) of this section are also pertinent.

(1) Section 1861 of the Act defines the services covered under Medicare and the providers that may be reimbursed for furnishing those services.

(2) Section 1864 of the Act provides for the use of State survey agencies to ascertain whether certain entities meet the conditions of participation.

(3) Section 1865(a)(1) of the Act provides that an entity accredited by a national accreditation body found by the Secretary to satisfy the Medicare conditions of participation, conditions for coverage, or conditions of certification or requirements for participation shall be treated as meeting those requirements. Section 1865(a)(2) of the Act requires the Secretary to consider when making such a finding, among other things, the national accreditation body's accreditation requirements and survey procedures.

(4) Section 1871 of the Act authorizes the Secretary to prescribe regulations for the administration of the Medicare program.

(b) Although section 1866 of the Act speaks only to providers and provider agreements, the effective date rules in this part are made applicable also to the approval of suppliers that meet the requirements specified in §489.13.

(c) Section 1861(o)(7) of the Act requires each HHA to provide CMS with a surety bond.

§489.13 Effective date of agreement or approval.

(a) Applicability—(1) General rule. Except as provided in paragraph (a)(2) of this section, this section applies to Medicare provider agreements with, and supplier approval of, entities that, as a basis for participation in Medicare are subject to a determination by CMS on the basis of--

(i) A survey conducted by the State survey agency or CMS surveyors; or

(ii) In lieu of such State survey agency or CMS conducted survey, accreditation by an accreditation organization whose program has CMS approval in accordance with section 1865 of the Act at the time of the accreditation survey and accreditation decision.

(2) Exceptions. (i) For an agreement with a community mental health center (CMHC) or a federally qualified health center (FQHC), the effective date is the date on which CMS accepts a signed agreement which assures that the CMHC or FQHC meets all Federal requirements.

(ii) A Medicare supplier approval of a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under Part 493 of this chapter, and only for the specialty and subspecialty tests it is authorized to perform.

(b) All health and safety standards are met on the date of survey. The agreement or approval is effective on the date the State agency, CMS, or the CMS contractor survey (including the Life Safety Code survey, if applicable) is completed, or on the effective date of the accreditation decision, as applicable, if on that date the provider or supplier meets all applicable Federal requirements as set forth in this chapter. (If the agreement or approval is time-limited, the new agreement or approval is effective on the day following the expiration of the current agreement or approval.) However, the effective date of the agreement or approval may not be earlier than the latest of the dates on which CMS determines that each applicable Federal requirement is met. Federal requirements include, but are not limited to--

(1) Enrollment requirements established in Part 424, Subpart P, of this chapter. CMS determines, based upon its review and verification of the prospective provider's or supplier's enrollment application, the date on which enrollment requirements have been met;

(2) The requirements identified in §§489.10 and 489.12; and

(3) The applicable Medicare health and safety standards, such as the applicable conditions of participation, the requirements for participation, the conditions for coverage, or the conditions for certification.

(c) All health and safety standards are not met on the date of survey. If, on the date the survey is completed, the provider or supplier has failed to meet any one of the applicable health and safety standards, the following rules apply for determining the effective date of the provider agreement or supplier approval, assuming that no other Federal requirements remain to be satisfied. However, if other Federal requirements remain to be satisfied, notwithstanding the provisions of paragraphs (c)(1) through (c)(3) of this section, the effective date of the agreement or approval may not be earlier than the latest of the dates on which CMS determines that each applicable Federal requirement is met.

(1) For an agreement with an SNF, the effective date is the date on which—

(i) The SNF is in substantial compliance (as defined in §488.301 of this chapter) with the requirements for participation; and

(ii) CMS or the State survey agency receives from the SNF, if applicable, an approvable waiver request.

(2) For an agreement with, or an approval of, any other provider or supplier, (except those specified in paragraph (a)(2) of this section), the effective date is the earlier of the following:

(i) The date on which the provider or supplier meets all applicable conditions of participation, conditions for coverage, or conditions for certification; or, if applicable, the date of a CMS-approved accreditation organization program's positive accreditation decision, issued after the accreditation organization has determined that the provider or supplier meets all applicable conditions.

(ii) The date on which a provider or supplier is found to meet all conditions of participation, conditions for coverage, or conditions for certification, but has lower-level deficiencies, and--

(A) CMS or the State survey agency receives an acceptable plan of correction for the lower-level deficiencies (the date of receipt is the effective date regardless of when the plan of correction is approved); or, if applicable, a CMS-approved accreditation organization program issues a positive accreditation decision after it receives an acceptable plan of correction for the lower-level deficiencies; or

(B) CMS receives an approvable waiver request (the date of receipt is the effective date regardless of when CMS approves the waiver request).

(3) For an agreement with any other provider or an approval of any other supplier (except those specified in paragraph (a)(2) of this section) that is found to meet all conditions of participation, conditions for coverage, or conditions for certification, but has lower-level deficiencies and has submitted both an approvable plan of correction/positive accreditation decision and an approvable waiver request, the effective date is the later of the dates that result when calculated in accordance with paragraph (c)(2)(ii)(A) or (c)(2)(ii)(B) of this section.

Medicaid Rule Revisions – Inpatient Psychiatric Services

Section 440.160 is amended by revising paragraph (b)(1) to read as follows:

PART 440—SERVICES: GENERAL PROVISIONS

§440.160 Inpatient psychiatric services for individuals under age 21.

* * * * *

(b) * * *

(1) A psychiatric hospital that undergoes a State survey to determine whether the hospital meets the requirements for participation in Medicare as a psychiatric hospital as specified in §482.60 of this chapter, or is accredited by a national organization whose psychiatric hospital accrediting program has been approved by CMS; or a hospital with an inpatient psychiatric program that undergoes a State survey to determine whether the hospital meets the requirements for participation in Medicare as a hospital, as specified in Part 482 of this chapter, or is accredited by a national accrediting organization whose hospital accrediting program has been approved by CMS.

* * * * *

Section 441.151 is amended by revising paragraph (a)(2)(i) to read as follows:

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

§441.151 General requirements.

(a) * * *

(2) * * *

(i) A psychiatric hospital that undergoes a State survey to determine whether the hospital meets the requirements for participation in Medicare as a psychiatric hospital as specified in §482.60 of this chapter, or is accredited by a national organization whose psychiatric hospital accrediting program has been approved by CMS; or a hospital with an inpatient psychiatric program that undergoes a State survey to determine whether the hospital meets the requirements for participation in Medicare as a hospital, as specified in Part 482 of this chapter, or is accredited by a national accrediting organization whose hospital accrediting program has been approved by CMS.

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