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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-33-ALL

DATE: **May 20, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Final Rule - Promoting Program Efficiency, Transparency, and Burden Reduction; Part II - ***Informational Only***

Memorandum Summary

- **Publication of Final Rule:** CMS-3267-F was published on May 12, 2014. In this final rule we implement reforms in Medicare regulations that the Centers for Medicare & Medicaid Services (CMS) has identified as unnecessary, obsolete, or excessively burdensome on health care providers and beneficiaries, as well as certain regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

- **Effective Date:** These regulations are effective on July 11, 2014, with the exception of amendments to:

  - 42 CFR Part 483, related to nursing home sprinklers, which are effective May 12, 2014;
  - 42 CFR Part 485, Subpart F, related to inpatient services in critical access hospitals (CAHs), which were effective October 1, 2013; and
  - 42 CFR Part 491, related to rural health clinic non-physician practitioners, which are effective July 1, 2014.

A. Background

In Executive Order 13563, "Improving Regulations and Regulatory Review", the President directed each executive agency to establish a plan for ongoing retrospective review of existing significant regulations to identify those rules that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive, or that can be modified to be more effective, efficient, flexible, and streamlined.

The final rule "Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II" was published on May 12, 2014 and responds directly to the President's instructions. The publication may be viewed at: http://www.gpo.gov/fdsys/pkg/FR-2014-05-12/pdf/2014-10687.pdf. Listed below are some highlights.

B. Long Term Care Facilities (Automatic Sprinkler Systems): The rule permits a temporary extension of the automatic sprinkler system installation due date under limited circumstances: the facility is constructing a replacement facility, or undergoing major modifications to unsprinklered living areas, or the facility has been unable comply with the original deadline due to a disaster or emergency as indicated by a declaration under section 319 of the Public Health Service Act. CMS may grant an extension of the sprinkler due date for up to two years from the original August 13, 2013 due date. For those facilities granted a temporary extension but that later encounter last minute construction or other unusual circumstances outside the facility's control, the rule provides authority for CMS to consider a final extension up to an additional one year extension of the deadline. As a condition for granting any extension, the rule provides authority for CMS to require additional, interim fire protection safeguards. Additional information concerning the process for requesting an extension may be found in S&C Memorandum 14-29-LSC, accessible at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

C. Clinical Laboratory Improvement Amendments of 1988: The rule makes adjustments to CMS regulations governing actions we take when we find certain violations of proficiency testing requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The changes may prevent confusion on the part of laboratories, reduce the risk of noncompliance, and establish policies under which certain PT referrals by laboratories will not generally be subject to revocation of a CLIA certificate, or a two-year prohibition on laboratory ownership or operation that may be applied to an owner and an operator when a CLIA certificate is revoked.

- *Treatment of proficiency testing samples:* We are adding a clarifying statement that explicitly notes that the requirement to treat proficiency testing (PT) samples in the same manner as patient specimens does not mean that it is acceptable to refer PT samples to another laboratory for testing even if that is the protocol for patient specimens.
- *Intentional referral carve-out:* We are carving out a narrow exception in our long-standing interpretation of what constitutes an "intentional" referral of PT samples. In these instances, the laboratory will be subject to alternate sanctions.
- *New definitions:* To clarify the stipulations of the intentional referral carve-out, we are also adding the following terms, with their definitions, to the regulation: Reflex testing, Confirmatory testing, and repeat PT referral.

NOTE: These CLIA changes related to PT referrals should be read together with another recent rule in which we implemented the "Taking Essential Steps for Testing Act ("TEST Act") (Pub. L. 112-202). That final rule may be accessed at http://www.gpo.gov/fdsys/pkg/FR-2014-05-02/pdf/2014-09908.pdf. The TEST Act rule is explained in S&C Memorandum 14-23-CLIA, which may be accessed at: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

C. Acute Care Services: Unless specifically noted otherwise, changes below are found in the final rule: Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II, adopted May 12, 2014 and effective July 11, 2014.

Sources of other changes are the following rules:

Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation;

Payment Policies Related to Patient Status, adopted August 19, 2013 and effective October 1, 2013; this rule included CAH changes; and

Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral, adopted May 2, 2014 and effective July 1, 2014; this rule included RHC changes.

C.1. ASC Conditions for Coverage, 42 CFR Part 416

- Surgical Services, §416.42

  §416.42(b)(2) corrects a technical error by correctly cross-referencing to §416.42(c) when referencing the regulation that permits exemption from physician supervision of non-physician practitioners who administer anesthesia.

- Laboratory and Radiologic Services, §416.49

  §416.49(b) was revised to:
  - Make explicit that radiologic services may only be provided in an ASC when integral to procedures offered by the ASC.
  - Require an ASC providing radiologic services to comply with only the following provisions of the hospital Condition of Participation for radiologic services: §482.26(b) (Safety for patients and personnel), (c)(2) (Personnel who may use radiologic equipment) and (d)(2) (Maintenance of records of radiologic services). Certain hospital requirements (related to mandatory provision of radiologic services, supervision of such services by a radiologist, and practitioner signing of radiologic reports) no longer apply to ASCs.
  - Require the ASC's governing body to appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring that all radiologic services are provided in accordance with the cross-referenced Hospital requirements.

C.2. Hospital Conditions of Participation, 42 CFR Part 482

- Governing Body, §482.12

  - §482.12 was revised to remove the requirement that the hospital's governing body must include a member or members of the medical staff, in favor of required consultation (described below).

- §482.12(a) was revised to add a new requirement at §482.12(a)(10) for the governing body to consult directly with the individual responsible for the organization and conduct of the hospital's medical staff, or his/her designee. The consultation is required to be periodic throughout the year and to include discussion of matters related to the quality of medical care provided to the hospital's patients. For a multi-hospital system using a single governing body, there must be consultation directly with the individual (or designee) responsible for the medical staff in each hospital within its system.

- Medical Staff, §482.22

  - §482.22(a) was revised to indicate that the medical staff must include MDs or DOs, but may also include other categories of physicians listed at §482.12(c)(1), as well non-physician practitioners. A prior rule change inadvertently omitted the reference to other categories of physicians.
  - §482.22(b) was revised to add new §482.22(b)(4), which permits a hospital which is part of a hospital system consisting of multiple separately certified hospitals to have a unified, integrated medical staff for its member hospitals, in accordance with State law. Each separately certified hospital in a system using a unified, integrated medical staff must demonstrate that:
    - The medical staff members holding privileges at each separately certified hospital have voted by majority, in accordance with medical staff bylaws, to accept a unified, integrated medical staff, or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital;
    - The unified, integrated medical staff has bylaws, rules and requirements describing its processes for self-governance, appointment, credentialing, privileging, oversight, peer review policies and due process rights guarantees. Members of the medical staff at each separately certified hospital must be advised of their right to opt out after a majority vote to maintain a separate and distinct medical staff for their hospitals;
    - The unified, integrated medical staff is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and
    - The unified, integrated medical staff establishes and implements policies and procedures to ensure the needs and concerns expressed by members at each separately certified hospital are given due consideration, and that there are mechanisms to ensure that issues localized to particular hospitals are duly considered and addressed.

- Food and dietetic services, §482.28

  §482.28 (b)(1) and (2) were revised to permit a qualified dietitian or qualified nutrition professional to order diets if authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals. This includes therapeutic diet ordering. This means that ordering of diets is no longer restricted to practitioners responsible for the care of the patient.

- Nuclear Medicine Services, §482.53

  §482.53(b)(1) was revised to remove the requirement for "direct" supervision of in-house preparation of radiopharmaceuticals is by an appropriately trained registered pharmacist or MD/DO. This means it is no longer required that a supervising physician or pharmacist must always be present when radiopharmaceuticals are being prepared.

- Outpatient Services, §482.54

  A new standard at §482.54(c) was added to the hospital Outpatient Services CoP which codifies current SOM Interpretive Guidelines regarding the ordering of outpatient services. Outpatient services can be ordered by any practitioner responsible for the care of the patient, who is licensed and acting within his or her scope of practice in the State where he or she provides care to the patient, and who has been authorized by the medical staff and approved by the governing body to order specific outpatient services. This new standard applies to members of the medical staff who have been granted privileges to order outpatient services as well as practitioners not on the medical staff but who are authorized to order outpatient services and refer patients for outpatient services by meeting the criteria listed.

- Swing-Bed Services, §482.58

  The regulation governing swing bed services was moved from Subpart E, concerning Specialty Hospitals, to Subpart D, concerning Optional Hospital Services. This means that CMS-approved Medicare hospital accreditation programs will now have to develop and implement standards for swing-bed services, and that separate State surveys of swing-bed services will not be required in deemed status hospitals, once CMS has approved the revised accrediting organization standards.

C3. Critical Access Hospitals (CAHs), 42 CFR Part 485, Subpart F

- Designation and Certification of CAHs, §485.606

  The cross-reference to hospital swing bed services found in this CAH regulation was revised to reflect the renumbering of the hospital regulation. This CAH regulation prohibits a State from denying CAH designation to an otherwise eligible hospital solely because the hospital provides swing bed services. The revision has no substantive effect on the current CAH requirement.

- Number of Beds and Length of Stay, §485.620

  The provision at §485.620(a) was revised to remove an outdated reference to a January 1, 2004 effective date, after which a CAH may not maintain more than 25 inpatient beds that may be used to provide either inpatient or swing-bed services. *This change was effective October 1, 2013.* The revision has no substantive effect on the current CAH requirement.

- Staffing and Staff Responsibilities, §485.631

  - §485.631(b)(1)(v) & (vi) were revised to:

    - Address confusion about the prior rule's requirements concerning physician review of outpatient records by deleting §485.631(b)(1)(vi) and incorporating its provisions into §485.631(b)(1)(v). The revised requirement calls for a CAH MD or DO to periodically review a sample of outpatient records of patients cared for by non-physician practitioners, but only to the extent required under State law where State law requires such record reviews and/or co-signatures. The requirement is not substantively different from the current CAH requirement, but is stated more clearly.
    - Remove the requirement for those reviews which are required under State law to take place at least every two weeks.
  - §485.631(b)(2) was revised to remove the requirement that an MD or DO must be present in the CAH at least once every two weeks. CAH MDs/DOs are now required to be present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the CAH. This revision recognizes that many of the MD/DO required functions may be performed remotely via electronic means, and that the time required to be on-site will vary from CAH to CAH, depending on the volume and type of services they offer.

- Provision of Services, §485.635

  - §485.635(a)(2) was revised to remove the requirement for the CAH's patient care policies to be developed with the advice of at least one individual who is not a member of the CAH's professional healthcare staff.
  - §485.635(a)(3)(vii) was revised to remove language that could have been misunderstood as making it appear optional for a CAH to provide acute inpatient services. *This change was effective October 1, 2013.*
  - §485.635(b)(1) was revised to add a new, explicit requirement at §485.635(b)(1)(ii) for CAHs to furnish acute care inpatient services. After regulation changes adopted in 2012 removed language referring to "direct" services a CAH must provide, as opposed to services a CAH may provide under arrangement, the language remaining could have been misinterpreted to suggest that a CAH must only provide outpatient services. *This change was effective October 1, 2013.*
  - §485.635(c) was revised to remove inpatient hospital care as a service that may be provided under arrangement, to avoid creating the misperception that CAHs are not required to furnish inpatient services. *This change was effective October 1, 2013.*

C.4. Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs), 42 CFR Part 491

- Definitions, §491.2

  The definition of a "physician" has been revised to include a doctor of dental surgery or dental medicine, a doctor of podiatry or surgical chiropody, or a chiropractor, within the

limitations of services these types of physicians are permitted to offer under Section 1861(r) of the Social Security Act. However, it continues to be the case that only MDs or DOs may fulfill the requirements for supervision, collaboration and oversight of non-physician practitioners in an RHC or FQHC.

- Staffing and Staff Responsibilities, §491.8

  - §491.8(a)(3) was revised to permit an RHC to have a nurse practitioner or physician assistant provide services under contract to the RHC, so long as the RHC has at least one employee who is a nurse practitioner or physician assistant. *This change is effective July 1, 2014.*
  - §491.8(a)(6) was revised to require for RHCs that a nurse practitioner, physician assistant, or certified nurse-midwife is available to furnish patient care services at least 50% of the time the RHC operates. This aligns the regulatory language with the current statutory requirement. Note that since the statutory provision was self-implementing, CMS has enforced the 50% standard even prior to this regulation change. (See S&C 09-14)
  - §491.8(b) has been revised to delete the requirement formerly at §491.8(b)(2) for a physician to be present in the RHC or FQHC at least once every two weeks. This recognizes that many of the physician's required functions may be performed remotely via electronic means, but does not remove the requirement that a practitioner, whether a physician or non-physician practitioner, must be present at all times the RHC or FQHC operates. Provisions formerly at §491.8(b)(1)(i) – (iii) have been renumbered to be §491.8(b)(1) – (3), but are otherwise the same.

The final rule, CMS-3267-F, was published on May 12, 2014. The publication can be viewed at: http://www.gpo.gov/fdsys/pkg/FR-2014-05-12/pdf/2014-10687.pdf.

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/s/

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cc: Survey and Certification Regional Office Management