



VCU Medical Center

Office of Health Innovation

Proposed Rule: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

Description: This proposed rule would reform Medicare regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, as well as certain regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). In addition to changes and clarifications to selected requirements for providers, the rule addresses stakeholder concerns about governance-related provisions in the most recent changes to the Medicare Conditions of Participation (CoP).

Major Provisions

Radiology services in ambulatory surgical centers: This proposed rule would reduce the requirements Ambulatory Surgical Centers (ASCs) must meet in order to provide radiological services to match those services they actually perform. ASCs are currently subject to the full hospital requirements for radiology services even though they are only permitted to provide limited radiologic services integral to the performance of certain surgical procedures.

- Supervision of radiologic services should be appropriate to the types of procedures conducted by the ASC.
- CMS proposes to remove § 416.49(b)(1) and replace it with the requirement that radiologic services may only be provided when integral to procedures offered by the ASC and must meet the requirements specified in § 482.26(b), (c)(2), and (d)(2).
- CMS also proposes to remove the existing language at § 416.49(b)(2) and replace it with the requirement that an MD/DO who is qualified by education and experience in accordance with State law and ASC policy must supervise the provision of radiologic services.

Hospital registered dietitian privileges: CMS proposes to include qualified dietitians as practitioners who may be privileged to order patient diets under the hospital conditions of participation (CoPs).

- The current Interpretive Guidelines (IGs), which are contained in the State Operations Manual (SOM) for surveyors, states that “[in] accordance with State law and hospital policy, a dietitian may assess a patient’s nutritional needs and provide recommendations or consultations for patients, but the patient’s diet must be prescribed by the practitioner responsible for the patient’s care.”
- CMS believes that registered dietitians are the professionals who are best qualified to assess a patient’s nutritional status and to design and implement a nutritional treatment plan in consultation with the patient’s interdisciplinary care team.
- In order for patients to receive timely nutritional care, the RD must be viewed as an integral member of the hospital interdisciplinary care team, one who, as the team’s clinical nutrition

expert, is responsible for a patient's nutritional diagnosis and treatment in light of the patient's medical diagnosis.

Hospital supervision of radiopharmaceutical preparation: CMS proposes to revise the Nuclear medicine services CoP to remove the modifier "direct" from the in-house preparation supervision requirement. The presence of a pharmacist, MD, or DO would no longer be required during the delivery of off-hour nuclear medicine tests.

- "Direct supervision" means that one of these professionals must be physically present in the hospital and immediately available during the preparation of all radiopharmaceuticals.
- The revision to "supervision" from "direct supervision" would allow for other appropriately trained hospital staff to prepare in-house radiopharmaceuticals under the oversight of a registered pharmacist or doctor of medicine or osteopathy, but it would not require that such oversight be exercised by the physical presence in the hospital at all times of one of these professionals, particularly during off-hours when such a professional would not be routinely present.

Hospital reclassification of swing-bed services: CMS proposes to revise the requirements by relocating the swing-bed CoPs to Subpart D, which would classify swing beds as an optional service. This revision would allow a hospital's compliance with "swing bed" requirements to be evaluated during routine accrediting organization surveys.

- Currently, these requirements are located in Subpart E of Part 482, Requirements for specialty hospitals. As such, the requirements fall outside of those requirements that can be surveyed by an Accreditation Organization (AO), such as TJC, AOA, or DNV, as part of its CMS-approved Medicare hospital accreditation program.
- Moving the swing-bed CoPs to Subpart D would reduce the burden on hospitals by not requiring an additional survey specifically for "swing bed" approval.

Transplant centers reports to CMS: The CoPs require transplant programs to notify CMS of certain changes related to the center's transplant program. The current system for transplant center data analysis, in effect, requires the centers to submit data which CMS routinely receives through other sources. CMS proposes to eliminate this redundant data submission requirement.

- The removal of this requirement would have no impact on the quality of care to transplant recipients, living donors, or potential donors as CMS's identification and follow-up process for programs that do not meet § 482.82 would remain unchanged.

Transplant center re-approval process: The current transplant survey process and regulatory criteria require programs be subject to an automatic onsite review of compliance with key CoPs under a 3-year re-approval cycle under particular conditions. In lieu of the automatic 3-year re-approval cycle, CMS proposes to provide more flexibility in the re-approval cycle to be able to focus survey attention where it is most needed.

- CMS also proposes to:

1. clarify that the review of mitigating factors may occur at any time if there is non-compliance with the CoPs, and
2. remove language stating that a transplant program is approved for three years, which conflicts with language in § 488.61(c) specifying that compliance with the CoPs is a continuous requirement.

Long term care sprinkler waiver: All buildings containing long term care (LTC) facilities are required to have automatic sprinkler systems installed throughout the building by August 13, 2013 (§ 483.70(a)(8)). In order to maintain access to LTC facilities, and in recognition of financing difficulties faced by some providers, we are proposing a provision that would allow LTC facilities the opportunity to apply for a deadline extension, not to exceed 2 years, if all of the following conditions apply:

1. The facility is in the process of replacing its current building, or undergoing major modifications in all unsprinklered living areas and that requires the movement of corridor, room, partition, or structural walls or supports to improve the living conditions for residents, in addition to the installation of a sprinkler system;
2. The facility demonstrates that it has made the necessary financial commitments to complete the building replacement or modification;
3. The facility has submitted construction or modification plans to the State and local authorities that are necessary for approval of the replacement building or modification prior to applying for the deadline extension; and
4. The facility agrees to complete interim steps to improve fire safety of the building while the construction is being completed, as determined by CMS. This could include a fire watch, installation of temporary exits and temporary smoke detection systems, or additional smoke detection systems in the area of construction, increased fire safety inspections, additional training and awareness by staff, and additional fire drills.

CAH provision of services: Critical Access Hospital (CAH) CoPs require that a CAH must develop its patient care policies with the advice of “at least one member who is not a member of the CAH staff.” CMS believes that this provision is no longer necessary and that the original reasons for including this requirement (lack of local resources and in-house expertise) have been effectively addressed.

CAH and RHC/FQHC physician responsibilities: The regulations for CAHs, Rural Health Clinics (RHCs), and Federally Qualified Health Centers (FQHCs), require a physician to be present for sufficient periods of time, at least once in every 2 week period, except in extraordinary circumstances. CMS proposes to revise the CAH and RHC/FQHC regulations to eliminate the requirement that a physician must be onsite at least once in every 2-week period.

- For CAHs, CMS proposes that a doctor of medicine or osteopathy would be present for sufficient periods of time to provide medical direction, consultation and supervision for the services provided in the CAH, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral.

- For RHCs and FQHCs, CMS proposes that physicians would periodically review the clinic or center's patient records, provide medical orders, and provide medical care services to the patients of the clinic or center.
- CMS also proposes to revise the definition of a "physician" in the FQHC/RHC regulations to conform to the definition of a physician in Medicare payment regulations to eliminate possible confusion.