FEDERAL REGISTER

Vol. 79 Monday,
No. 91 May 12, 2014

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 416, 440 et al.
Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II; Final Rule

is no requirement that a certain number of transplants be performed during a particular period that is covered in a single SRTR center-specific report. This has resulted in transplant centers being confused about the volume of transplants they are required to perform during any particular period of time covered by the SRTR center-specific reports. We are making changes to clarify the transplant volume and clinical experience requirements.

• *RHC/FQHC definition of physician:* The definition of a "physician" in the RHC/FQHC regulations does not conform to the definition of a "physician" in the Medicare payment regulations. We are revising the regulation to eliminate possible confusion in the provider community by making the definition consistent with that used in the Medicare payment regulations.

Final Provisions that Respond to Stakeholder Concerns: We have identified changes to improve clarity and respond to concerns raised by the public.

• *Hospital governing body:* We are adding a new provision to the "Medical staff" standard of the governing body CoP. This new provision requires a hospital's governing body to directly consult periodically throughout the calendar year or fiscal year with the individual responsible for the organized medical staff of the hospital, or his or her designee. For a multi-hospital system using a single governing body to oversee multiple hospitals within its system, this provision requires the single governing body to consult directly with the individual responsible for the organized medical staff (or his or her designee) of each hospital within its system in addition to the other requirements finalized here. We are also removing the requirement for a medical staff member, or members, to be on a hospital's governing body.

• *Hospital medical staff:* We are retaining the current regulatory provision at § 482.22, but reinterpreting it to allow for either a unique medical staff for each hospital or for a unified and integrated medical staff shared by multiple hospitals within a hospital system. We are adding four new provisions to hold a hospital responsible for showing that it actively addresses its use of a system unified and integrated medical staff model. We are requiring that the medical staff members holding privileges at each separately certified hospital in the system have voted either to participate in a unified and integrated medical staff structure or to opt out of such a structure, and to maintain a hospital-specific separate and distinct medical staff for their respective hospital. We are requiring that the unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified hospital (that is, all medical staff members who hold specific privileges to practice at that hospital) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their hospital. We are requiring that the unified and integrated medical staff is established in a manner that takes into account each hospital's unique circumstances, and any significant differences in patient populations and services offered in each hospital. We are also requiring that the unified and integrated medical staff gives due consideration to the needs and concerns of members of the medical staff, regardless of practice or location, and the hospital has mechanisms in place to assure that issues localized to particular hospitals are duly considered and addressed.

• *Practitioners permitted to order hospital outpatient services:* We are revising the Outpatient services CoP to allow for practitioners who are not on the hospital's medical staff to order hospital outpatient services for their patients when authorized by the medical staff and allowed by State law.

• *Hospital diet terminology:* We are updating terminology related to "diets" and "therapeutic diets" in the CoPs.

• *Request for comment on RHC services:* We sought public comment on potential changes we could make to regulatory or other requirements that could reduce barriers to the provision of telehealth, hospice, or home health services in an RHC. We summarize and respond to these public comments in this final rule.

Technical Corrections: We are making technical corrections to some regulations.

• *Organ Procurement Organizations (OPOs):* We are making some technical corrections to the CoPs for OPOs.

• *Intermediate Care Facilities for Individuals with Intellectually Disabilities (ICFs/IID):* We are making some technical corrections to clarify state survey agency certification survey requirements for ICF/IIDs.

• *Rural Health Clinics (RHCs):* We are correcting a technical error in the regulations by amending § 491.8(a)(6) to conform to section 6213(a)(3) of OBRA '89 (Pub. L. 101–239), which requires that a nurse practitioner (NP), physician assistant (PA), or certified nurse-midwife (CNM) be available to furnish patient care at least 50 percent of the time the RHC operates.

3. Summary of Costs and Benefits

a. Overall Impact

This final rule will create savings and reduce burden in many areas. Several of the changes create measurable monetary savings for providers and suppliers, while others create savings of time and administrative burden. We estimate one-time savings of $22 million for the sprinkler deadline extension in long term care facilities, and annual recurring savings of about $660 million for other provisions in this final rule.

b. Section-by-Section Economic Impact Estimates

The following table summarizes the provisions for which we are able to provide specific estimates for savings or burden reductions (these estimates are uncertain and could be substantially higher or lower, as explained in the regulatory impact analysis section of this rule):

Issue	Frequency	Estimated savings or benefits ($ millions)
Ambulatory Surgical Centers:		
• Radiology Services	Recurring annually	41
Hospitals:		
• Food and dietetic services	Recurring annually	459
• Nuclear medicine services	Recurring annually	77
Transplant Centers:		

opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their hospital;

(3) The unified and integrated medical staff is established in a manner that takes into account each hospital's unique circumstances, and any significant differences in patient populations (such as low income or minority populations, rural populations, etc.) and services offered in each hospital (such as emergency services, psychiatric services, pediatric care, long term acute care, organ transplant services, dialysis, etc.); and

(4) The unified and integrated medical staff gives due consideration to the needs and concerns of members of the medical staff, regardless of practice or location, and the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

Finally, we note that some commenters argued in support of a unified medical staff by pointing to our previous position permitting a single governing body for hospitals within a system. We believe that the CoPs pertaining to the governing body and medical staff are unique in their focus on governance processes. We are taking this opportunity to emphasize that permitting use of a system governing body or medical staff must not be construed as implying that compliance with any other hospital CoPs may also be demonstrated at the system (multi-hospital) level. Each separately participating hospital is required to demonstrate its compliance with all other hospital CoPs in order to participate in Medicare. Although there can be system approaches in many of these areas (such as infection control or quality assessment/performance improvement programs), each individual hospital must demonstrate that it fulfills the applicable CoP requirements.

3. Food and Dietetic Services (§ 482.28)

We proposed to revise the hospital requirements at § 482.28(b), "Food and Dietetic Services," which currently requires that a therapeutic diet must be prescribed only by the practitioner or practitioners responsible for the care of the patient.

The Interpretive Guidelines (IGs) for this requirement, which are contained in the State Operations Manual (SOM) for surveyors, further state 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." State survey agencies have applied this requirement to mean that registered dietitians or other clinically qualified nutrition professionals (RDs) cannot be granted privileges by the hospital to order patient diets (or to order necessary laboratory tests to monitor the effectiveness of dietary plans and orders, or to make subsequent modifications to those diets based on the laboratory tests) since these practitioners have never been considered to be among those in the hospital who are "responsible for the care of the patient." The responsibility for the care of the patient, and the attendant hospital privileges that accompany this responsibility, have traditionally and exclusively been the provenance of the physician, more specifically the MD and DO, and, to a lesser extent, the APRN and PA. Understanding the regulatory language and its interpretation, most hospitals have taken a very conservative approach toward the granting of privileges, especially ordering privileges, to other types of non-physician practitioners, including RDs. Consequently, most hospitals have withheld ordering privileges from RDs absent a clear signal from CMS and the subsequent and necessary changes to the CoPs that would allow them to do so.

After the publication of the October 24, 2011 proposed rule (76 FR 65891) and the May 16, 2012 final rule (77 FR 29034), "Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation," it came to our attention that the regulatory language and the IGs for § 482.28(b) were too restrictive and lacked reasonable flexibility to allow hospitals to extend these specific privileges to RDs in accordance with State laws. We believe that RDs 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. In the February 7, 2013 proposed rule, we provided research evidence that supports the changes we have proposed (78 FR 9222). Without the proposed regulatory changes allowing hospitals to grant appropriate ordering privileges to RDs, hospitals would not be able to effectively realize improved patient outcomes and overall cost savings that we believe would be possible with such changes.

It should be noted, because a few States elect not to use the regulatory term "registered" and choose instead to use the term "licensed" (or no modifying term at all), or because some States also recognize other nutrition professionals with equal or possibly more extensive qualifications, we proposed to use the term "qualified dietitian." In those instances where we have used the most common abbreviation for dietitians, "RD," throughout this preamble, our intention is to include all qualified dietitians and any other clinically qualified nutrition professionals, regardless of the modifying term (or lack thereof), as long as each qualified dietitian or clinically qualified nutrition professional meets the requirements of his or her respective State laws, regulations, or other appropriate professional standards.

In order for patients to have access to the timely nutritional care that can be provided by RDs, a hospital must have the regulatory flexibility either to appoint RDs to the medical staff and grant them specific nutritional ordering privileges or to authorize the ordering privileges without appointment to the medical staff, all through the hospital's appropriate medical staff rules, regulations, and bylaws. In either instance, medical staff oversight of RDs and their ordering privileges would be ensured. Therefore, we proposed revisions to § 482.28(b)(1) and (2) that would require that individual patient nutritional needs be met in accordance with recognized dietary practices. We would make further revisions that would allow for flexibility in this area by requiring that all patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or other clinically qualified nutrition professional as authorized by the medical staff and in accordance with State law. We believe that hospitals that choose to grant these specific ordering privileges to RDs may achieve a higher quality of care for their patients by allowing these professionals to fully and efficiently function as important members of the hospital patient care team in the role for which they were trained. In the proposed rule, we stated that we believe hospitals would realize significant cost savings in many of the areas affected by nutritional care.

We received over 100 comments on our proposed changes to § 482.28 from professional organizations, accreditation organizations, hospitals and hospital systems, and individuals. Overall, the majority of commenters were supportive of the proposed changes, though there were a large number of commenters who were opposed to the exclusive use of the terms "registered dietitian," "qualified dietitian," or "RD" for varied reasons. Here we respond to specific comments:

Comment: As stated above, the majority of commenters were very supportive of the proposed changes with many citing improved patient care, greater efficiency in delivering dietary services, and significant cost savings as benefits that would be realized if the proposed changes were to be finalized. A few commenters provided references (to the same published studies that we cited) that offer evidence of the benefits that might be derived by hospitals if dietitians were granted ordering privileges as well as to guidelines, best practices, professional standards, and recommendations for the ordering of enteral and parenteral nutrition. Other commenters provided detailed information on the recognized training, education, and other qualifications that dietitians and nutrition professionals must meet in order to practice in their respective professions.

Response: We appreciate the commenters' support of our proposed changes as well as the references to the research provided. We agree that these changes will benefit patients as well as the practitioners caring for them, and will allow hospitals to achieve greater efficiency and cost savings in the delivery of food and dietetic services to patients.

We also appreciate the information on the professional standards and guidelines for enteral and parenteral nutrition therapy provided as well that provided on the qualifications for the various dietetics and nutrition professions.

Comment: One commenter, while agreeing with the intent of the proposed changes and many of the statements made in the preamble in support of these changes, did not agree with the use of the term "qualified dietitian" in the regulatory text. The commenter stated that "the terminology 'registered dietitian' or 'RD' is the nationally accepted designation for a professional who has met the minimum educational standards, [and] taken a registration exam complete with mandatory continuing professional education." Similar to this commenter, a few individuals and one professional organization asked for CMS to use the term "registered dietitian" instead of "qualified dietitian," or to clarify that the definition of qualified dietitian used here is consistent with the one currently found under the transplant center process requirements at § 482.94(e), which defines a qualified dietitian as "an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration." However, many of the registered dietitians who commented simply thanked CMS for the proposed changes, stated their support for them, and acknowledged the possible benefits that might be derived from the regulatory changes to § 482.28.

Conversely, one commenter, who included the names of 2,480 individuals who had signed on in support of the comment, stated that they cannot support "Medicare rules that create a monopoly for RDs at the expense of often better-qualified nutrition professionals." Similarly, various comments from "nutritionists," "nutrition professionals," "certified clinical nutritionists," and "certified nutrition specialists" argued that the rule would not serve patients since it excludes non-registered dietitians and other nutrition professionals and that the changes would create a practice monopoly for registered dietitians in hospitals. These commenters expressed the opinion that advanced degree nutrition professionals possess more extensive education and training backgrounds in nutrition than do registered dietitians. One commenter stated that they believe the professional organization representing registered dietitians is attempting to "exclude other nutritional specialists," while many other commenters simply urged CMS to be "forward-looking by incorporating the most flexible, inclusive language to increase the qualified nutrition workforce rather than narrowing it to one private credential, essentially creating a monopoly."

Response: Our use of the term "registered dietitian," in the proposed regulatory language, along with our use of this term and the terms "qualified dietitian" and "RD" in the preamble, was not meant to be exclusive of other nutrition professionals qualified to practice in the hospital setting. We agree with commenters that the regulatory language for § 482.28 should be inclusive of all qualified nutrition professionals. We do not agree with commenters who requested that we use the term "registered dietitian" or define "qualified dietitian" as an individual specifically registered with the Commission on Dietetic Registration. We agree that a more flexible approach would be the best way to ensure that patients benefit from the improved quality of care that these professionals can bring to hospital food and dietetic services. Additionally, we believe that it is best left to individual States to determine the regulatory processes by which these professions are governed and that hospitals, through their medical staff privileging processes, should be allowed the flexibility to determine the credentials and qualifications for dietitians and nutrition professionals, in accordance with their respective State laws if and when they choose to grant ordering privileges to these professionals. Therefore, we are revising our proposed regulatory language in this final rule to now require that all patient diets, "including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian *or qualified nutrition professional* as authorized by the medical staff and in accordance with *State law governing dietitians and nutrition professionals.*" [Emphasis added.]

Comment: A few commenters suggested that the term, "therapeutic diets," be clarified in the requirements as including both enteral and parenteral nutrition support because the commenters are concerned that the term might be interpreted as not including these nutrition modalities.

Response: While we understand the commenter's concerns, we believe that we have made it very clear in the preamble to this rule as well as in the preamble to the proposed rule that we consider all patient diets to be therapeutic in nature, regardless of the modality used to support the nutritional needs of the patient, and that the term would most certainly include enteral and parenteral nutrition support. Further, we believe that our extensive discussion of the research evidence supporting ordering privileges for RDs in both the proposed rule's preamble and its regulatory impact section leaves very little room for misinterpretation of this term since much of our discussion centered on the RD's role and expertise in ordering parenteral nutrition for patients.

Comment: Several commenters supported the proposed change and requested that CMS apply this revision to the Medicare requirements for long-term care facilities and other healthcare facilities in which RDs and nutrition professionals play a role.

Response: We appreciate the commenters' support and suggestions,

but the recommendations are outside the scope of this rule. However, we will keep the suggestion to extend the proposed revisions to the requirements for other providers and suppliers in consideration if we pursue future rulemaking in these areas.

Comment: One commenter noted that while these proposed changes address the nutritional aspects of diet management, they do not address "diet texture modification, which may be recommended by speech-language pathologists for patients with significant swallowing problems." The commenter further states that since speech-language pathologists "are the professionals who typically assess individuals with swallowing disorders . . . they, like dieticians, should have the authority to order diets that reflect changes based on their expert recommendations."

Response: While we agree with the commenter that speech-language pathologists may be the professionals best qualified to make recommendations for patients with swallowing disorders, we do not believe that § 482.28 is the appropriate place for such a change. Additionally, we believe that the recent changes to the medical staff CoP (§ 482.22) with regard to non-physician practitioners allow hospitals to determine if specific categories of practitioners, along with individual practitioners within those categories, should be granted certain privileges within the hospital, including ordering privileges. The changes finalized here for § 482.28 in no way prohibit hospitals from granting specific ordering privileges to speech-language pathologists, or to other non-physician practitioners, as long as those privileges are in accordance with State laws and regulations, including scope-of-practice laws.

Comment: Several commenters disagreed with CMS' assertion in the proposed rule that dietitians are the professionals best qualified to assess a patient's nutritional status and to design and implement a nutritional treatment plan. These commenters also disagreed with our statement in the proposed rule that "physicians often lack the training and educational background to manage the sometimes complex nutritional needs of patients with the same degree of efficiency and skill as registered dieticians." These commenters further stated that they believe that "in some cases, such as post-abdominal surgery care, the physician is best suited to determine patient diet." They urged CMS to clarify in the final rule that "in some cases, per medical staff directive, the dietician must defer to or consult with the physician responsible for the care of the patient." The same commenters did agree with "CMS' deference to the authorization of the medical staff at § 482.28" and stated that they believe that "the medical staff should be the arbiter of policies regarding when a dietician is qualified to order patient diets in the hospital."

Response: We agree with the commenters that there are some cases where the dietitian or nutrition professional must defer to, or consult with, the practitioner responsible for the care of the patient, often the practitioner who admitted the patient. We further agree that the medical staff should determine which specific practitioners, including dietitians and nutrition professionals, are qualified for which specific privileges. However, we must point out that this requirement does not require hospitals and medical staff to grant or authorize specific privileges to specific practitioners, but only allows them the flexibility to do so if they choose, and only if State law allows for it.

Comment: Another commenter asked for clarification on whether the proposed requirement only provides a hospital with the option of credentialing and privileging a dietitian.

Response: The requirement, including the revisions we are finalizing here, does not require hospitals to credential and privilege dietitians as a condition of participation, but, as previously stated, allows for it as an option if consistent with State law.

Comment: A few commenters stated that they were concerned about ordering diets for critically ill patients or making specific patients "NPO." They further state that they would feel comfortable ordering diets only if there was a "'diet order per dietitian' order from the doctor."

Response: As we have stated, the requirement does not require dietitians and nutrition professionals to order diets, but only allows for it as an option if consistent with State law and if a hospital chooses to grant such privileges after considering the recommendations of its medical staff. An individual dietitian or nutrition professional would then need to apply for these ordering privileges.

Comment: A few commenters asked for clarification on laboratory ordering privileges for dietitians as part of the proposed requirement. The commenters cited conflicts with the Medicare payment requirements as well as EHR incentives if dietitians were authorized to order lab and other diagnostic services.

Response: As proposed, and as finalized here, the regulatory language did not include privileges for ordering lab or other diagnostic services by dietitians or nutrition professionals. However, the preamble to this section of the proposed rule did include a discussion of such privileges in the context of some of the research cited. Such privileges for dietitians and nutrition professionals are not required or specifically allowed by this requirement, but are instead an option left to hospitals and their medical staffs to determine in consideration of relevant State law as well as any other requirements and/or incentives that CMS or other insurers might have.

In accordance with the comments discussed above, we are finalizing the proposed changes to § 482.28 with the revisions to the regulatory language as noted above.

4. Nuclear Medicine Services (§ 482.53)

The current requirement at § 482.53(b)(1) requires that the in-house preparation of radiopharmaceuticals be performed by, or under the direct supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy. Direct supervision means that one of these professionals must be physically present in the hospital and immediately available during the preparation of all radiopharmaceuticals. Hospitals have reported to us that this requirement is extremely burdensome when the presence of a pharmacist or physician is required for the provision of off-hour nuclear medicine tests that require only minimal in-house preparation of radiopharmaceuticals. Information from stakeholders regarding this issue has revealed that minimal in-house preparation is required for most radiopharmaceuticals. Many are batch-prepared by the manufacturer for hospital use as a way of reducing radiation exposure of hospital personnel, ensuring that on-site hospital preparation of radiopharmaceuticals generally requires only a few final steps, if any.

We proposed to revise the current requirement at § 482.53(b)(1) by removing the term "direct." We stated that, if finalized, the revised requirement would require that in-house preparation of radiopharmaceuticals be performed by, or under the supervision of, an appropriately trained registered pharmacist or doctor of medicine or osteopathy. We also stated that 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