DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 416, 440, 442, 482, 483, 485, 486, 488, 491, and 493

[CMS-3267-F]

RIN 0938-AR49

Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule reforms 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). This final rule also increases the ability of health care professionals to devote resources to improving patient care, by eliminating or reducing requirements that impede quality patient care or that divert resources away from providing high quality patient care. We are issuing this rule to achieve regulatory reforms under Executive Order 13563 on improving regulation and regulatory review and the Department's plan for retrospective review of existing rules. This is the latest in a series of rules developed by CMS over the last 5 years to reform existing rules to reduce unnecessary costs and increase flexibility for health care providers.

DATES: These regulations are effective on **[OFR—Insert date 60 days after the date of publication in the Federal Register]**, with the exception of amendments to 42 CFR Part 483, which are effective **[OFR – Insert date of publication in the Federal Register]**.

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)