

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

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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 July 11, 2014, with the exception of amendments to 42 CFR Part 483, which are effective May 12, 2014.

FOR FURTHER INFORMATION CONTACT: Lauren Oviatt, (410) 786-4683. We have also included a subject matter expert under the "Provisions of the Proposed Rule and Analysis and Response to Public Comments" section for each provision set out in this final rule.

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I. Summary and Background

A. Executive Summary of This Final Rule

1. Purpose

In Executive Order 13563, "Improving Regulations and Regulatory Review", the President recognized the importance of a streamlined, effective, and efficient regulatory framework designed to promote economic growth, innovation, job-creation, and competitiveness. To achieve a more robust and effective regulatory framework, the President has 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. This final rule responds directly to the President's instructions in Executive Order 13563 by reducing outmoded or unnecessarily burdensome rules, and thereby

increasing the ability of health care entities to devote resources to providing high quality patient care.

2. Summary of the Major Provisions

This rule reduces regulatory burden on providers and suppliers by modifying, removing, or streamlining current regulations that are excessively burdensome.

- *Radiology services in ambulatory surgical centers:* We are reducing the requirements that Ambulatory Surgical Centers (ASCs) must meet in order to provide radiological services to patients. Our requirements will reflect only those services that ASCs are permitted to 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.

- *Hospital registered dietitian privileges:* We are permitting registered dietitians and other clinically qualified nutrition professionals to be privileged to order patient diets under the hospital conditions of participation (CoPs).

- *Hospital supervision of radiopharmaceutical preparation:* We are revising 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 will no longer be required during the delivery of off-hour nuclear medicine tests. These changes are based on the Society of Nuclear Medicine and Molecular Imaging recommendations on this issue.

- *Hospital reclassification of swing-bed services:* We are revising the requirements by relocating the swing-bed services CoP to Subpart D, to classify swing beds as an optional service. This revision allows an accredited hospital's compliance with "swing bed" requirements to be evaluated by a CMS-approved accrediting organization. This reduces the burden on hospitals by not requiring an additional State survey agency 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. This creates unnecessary paperwork and burden on the transplant program and does not contribute to Federal oversight. We are eliminating this redundant data submission requirement.

- *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. This leads some transplant programs to undergo an onsite survey that may not be necessary to ensure a proper level of federal oversight, and it also does not always provide for the most effective method to target survey resources where they are most needed. In addition, since we are already receiving the data we need to determine if a center is complying with outcome requirements, eliminating this automatic re-approval cycle will not result in any reduction in Federal oversight of the center. It will, however, enable us to more efficiently use our survey resources. In lieu of the automatic 3-year re-approval cycle, we are providing more flexibility in the re-approval cycle to be able to focus survey attention where it is most needed. We are also clarifying the following—(1) the review of mitigating factors process could occur at any time there was non-compliance with the CoPs, and (2) that compliance with the CoPs is a continuous requirement, as already specified in § 488.61(c).

- *Long term care sprinkler deadline extension:* All buildings containing long term care (LTC) facilities were required to have automatic sprinkler systems installed throughout the building by August 13, 2013 (§ 483.70(a)(8)). Based on public feedback, we understand that some facilities were not able to meet the 2013 deadline. In order to maintain access to LTC facilities, and in recognition of financing difficulties faced by some providers, we are allowing LTC facilities the opportunity to apply for a deadline extension, not to exceed 2 years, if certain conditions apply. An additional extension may be granted for up to 1 year, depending on the need and particular circumstances.

- *CAH provision of services:* Critical Access Hospital (CAH) CoPs require that a CAH develop its patient care policies with the advice of “at least one member who is not a member of the CAH staff.” We believe that this provision is no longer necessary and that the original reasons for including this requirement (for example, lack of local resources and in-house expertise) have been effectively addressed. Also, based on our experience with CAHs and input from the provider community, it is a challenge for facilities to comply with this requirement. These challenges include the amount of time it takes to familiarize the non-staff member with the CAH’s operations, high turnover,

and, in many cases, the expense of paying outside personnel.

- *CAH, RHC, and 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. Some providers in extremely remote areas or areas that have geographic barriers have indicated that they find it difficult to comply with the precise biweekly schedule requirement. Many rural populations have limited access to care due to a shortage of health care professionals, especially physicians. Recent improvements in, and expansion of, telemedicine services allow for physicians to provide certain types of care to remote facilities at lower costs. We are revising the CAH and RHC/FQHC regulations to eliminate the requirement that a physician must be onsite at least once in every 2-week period. CAHs and RHCS/FQHCs will continue to be required to have a physician onsite for sufficient periods of time depending on the needs of the facility and its patients.

- *Clinical Laboratory Improvement Amendments Revisions:* This final rule makes a number of clarifications and changes pertaining to CMS regulations governing proficiency testing referrals under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). These changes prevent confusion on the part of laboratories, reduce the risk of noncompliance, and establish policies under which certain proficiency testing (PT) referrals by laboratories may 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 test 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 Distributive testing.

- *Application of the TEST Act:* We are also making a regulatory change, pursuant to the TEST Act, to acknowledge CMS’s ability to substitute alternative sanctions in lieu of the two-year prohibition for the owner or operator when a CLIA certificate is revoked. In the May 2, 2014, **Federal Register** at 79 FR 25436, we published the Medicare Program; 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 final rule with comment period (the “FQHC PPS/CLIA final rule with comment period”), which finalized proposals for implementing the TEST Act.

- *Provisions That Will Remove Obsolete or Duplicative Regulations or Provide Clarifying Information:* We are removing regulations set out in the Code of Federal Regulations (CFR) that have become obsolete and are no longer needed or enforced and clarifying other provisions.

- *Hospital medical staff:* We are clarifying the requirement that a hospital’s medical staff must be composed of doctors of medicine or osteopathy but that it may also include, in accordance with State laws, including scope-of-practice laws, other categories of physicians (as set out at § 482.12(c)) and non-physician practitioners who are determined to be eligible for appointment by the governing body.

- *Transplant centers outcome review:* The transplant center CoPs state that, “[e]xcept for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.” Changes to the transplant center reporting system have made the separate review for lung transplant data obsolete. Therefore, we are removing this language.

- *Transplant center volume and clinical experience requirements:* The transplant center CoPs state that “[t]he required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.” The Scientific Registry for Transplant Recipients (SRTR) provides statistical information about transplant outcomes and transplant programs nationwide. Under the current regulations, however, there

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:		

Issue	Frequency	Estimated savings or benefits (\$ millions)
<ul style="list-style-type: none"> • Reports to CMS& Survey Changes Long Term Care Facilities:	Recurring annually	<1
<ul style="list-style-type: none"> • Sprinkler Deadline Extension Rural Health:	One-time	22
<ul style="list-style-type: none"> • CAH & RHC/FQHC Physician responsibilities CLIA:	Recurring annually	76
<ul style="list-style-type: none"> • CAH Provision of services 	Recurring annually	<1
<ul style="list-style-type: none"> • PT Referral 	Recurring annually	2
Total	679

B. Legislative and Regulatory History

In January 2011, the President issued Executive Order 13563, “Improving Regulation and Regulatory Review.” Section 6 of that order requires agencies to identify rules that may be “outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.” In accordance with the Executive Order, the Secretary of the Department of Health & Human Services (HHS) published on August 22, 2011, a Plan for Retrospective Review of Existing Rules (<http://www.whitehouse.gov/21stcenturygov/actions/21st-century-regulatory-system>). As shown in the plan, the Centers for Medicare & Medicaid Services (CMS) has identified many obsolete and burdensome regulations that could be eliminated or reformed to improve effectiveness or reduce unnecessary reporting requirements and other costs, with a particular focus on freeing up resources that health care providers, health plans, and States could use to improve or enhance patient health and safety. CMS has also examined policies and practices not codified in rules that could be changed or streamlined to achieve better outcomes for patients while reducing burden on providers of care. In addition, CMS has identified non-regulatory changes to increase transparency and to become a better business partner. For example:

- We have automated our review of Health Services Delivery tables, which gives Medicare Advantage (MA) applicants for participation as MA plans immediate feedback on their deficiencies before submitting applications so that they can address them up-front.
- We have changed the timeframes during which a Medicare durable medical equipment (DME) supplier may contact a beneficiary concerning refilling an order from 7 days to 15 days before the beneficiary’s refill date.

- We have streamlined the Skilled Nursing Facility Discharge Assessment through Minimum Data Set (MDS) 3.0 which has been designed to improve the reliability, accuracy, and usefulness of the MDS. The change included the removal of data collections in the MDS that are not relevant to the measurement of quality or used for reimbursement purposes.

As explained in the plan, HHS is committed to the President’s vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework. The objectives are to improve the quality of existing regulations consistent with statutory requirements; streamline procedural solutions for businesses to enter and operate in the marketplace; maximize net benefits (including benefits that are difficult to quantify); and reduce costs and other burdens on businesses to comply with regulations. Consistent with the commitment to periodic review of the regulatory burden on providers and to public participation, HHS will continue to assess its existing significant regulations in accordance with the requirements of Executive Order 13563.

In accordance with these goals, we published two final rules on May 16, 2012. The first rule, titled “Reform of Hospital and Critical Access Hospital Conditions of Participation” (77 FR 29034), finalized updates to the Medicare CoPs and reduces regulatory burden for hospitals and CAHs. The second rule, titled “Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction” (77 FR 29002), addressed burdensome regulatory requirements for a broader range of healthcare providers and suppliers who provide care to Medicare and Medicaid beneficiaries. We proposed a second set of burden-reducing rules on February 7, 2013 (78 FR 9216). This final rule is a continuation of those efforts.

II. Provisions of the Proposed Rule and Analysis and Response to Public Comments

A. Ambulatory Surgical Centers

Section 1832(a)(2)(F)(i) of the Act specifies that Ambulatory Surgical Centers (ASCs) must meet health, safety, and other requirements as specified by the Secretary in regulation in order to participate in Medicare. The Secretary is responsible for ensuring that the Conditions for Coverage (CfCs) and their enforcement protect the health and safety of all individuals treated by ASCs, whether they are Medicare beneficiaries or other patients.

To implement the CfCs, we determine compliance through State survey agencies that conduct onsite inspections of ASC, applying these requirements to the ASCs they survey. ASCs also may be deemed to meet Medicare CfCs if they are accredited by one of the national accrediting organizations that have a CMS-approved Medicare ASC accreditation program.

The ASC CfCs were first published on August 5, 1982 (47 FR 34082), and were subsequently amended several times in the last four years. A final rule published on November 18, 2008 (73 FR 68502), revised four existing health and safety CfCs and created three new health and safety CfCs (42 CFR 416.41 through 416.43 and 416.49 through 416.52); a subsequent final rule amended the Patient rights CfC on October 24, 2011 (76 FR 65886); and most recently a final rule published on May 16, 2012, amended the requirements governing emergency equipment that ASCs must maintain (77 FR 29002).

Section 416.49(b) of Title 42 of the Code of Federal Regulations outlines the radiologic services requirements that ASCs must meet in order to be Medicare-certified. Since ASCs are facilities that operate exclusively to provide a specific range of surgical procedures (see § 416.2), they may provide radiologic services only to the extent that such services are an integral

part of the procedures they perform. Section 416.49(b)(1) states that the ASC must have procedures for obtaining radiological services from a Medicare-approved facility to meet the needs of patients. Section 416.49(b)(2) requires that the ASC's radiologic services must meet the hospital CoPs for radiologic services specified in § 482.26. However, since adopting this rule in 2008, we have learned that some of the hospital CoP requirements are unduly burdensome for ASCs to meet. In particular, the hospital CoP requirement to have a radiologist supervise the provision of radiologic services is unduly burdensome and overly aggressive, as many ASCs are having great difficulty locating a radiologist to supervise the minimal ASC radiologic services provided. The ASC CfCs were first published in 1982 and did not include a radiologist supervision requirement until the 2008 final rule. Moreover, the cost of privileging radiologists as members of an ASC's medical staff and paying radiologists' fees for oversight of radiology studies that are limited to those which are integral to a surgical procedure, with the results applied immediately by the operating physician, is often needlessly burdensome. The ASC governing body, as set out at § 416.41, is responsible for the oversight and accountability for the quality assessment and performance improvement program, and is responsible for ensuring that all policies and services provide quality healthcare in a safe environment. As such, the provision requires that the ASC governing body be responsible for determining if any procedures, now or in the future, require additional review by a radiologist. In addition, the medical staff CfC at § 416.45 requires such governing body be accountable for the medical staff, and to ensure that such staff members are legally and professionally qualified for the positions to which they are appointed and for the performance of the privileges granted. This includes, if applicable, assessing their competency in using imaging as an integral part of the procedures they perform.

In the February 7, 2013, proposed rule, we proposed 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). We also proposed 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 policies must supervise the provision of radiologic services. We stated that we believe these proposed changes to the ASC radiologic services requirements would assure the safety of these services while being less burdensome for Medicare-certified ASC facilities. We requested public comments on whether these proposed changes would allow for appropriate oversight of radiologic procedures conducted in ASCs.

We also noted that there is a technical error in § 416.42(b)(2) of the ASC CfCs and proposed to correct this error. Paragraph (b)(2) references "paragraph (d) of this section" but § 416.42 does not have a paragraph (d). We proposed to correct the error by referencing paragraph (c) of that section instead.

We received fifty-eight timely public comments on our proposed changes to the ASC radiologic services requirements. Commenters included individual clinicians, ASCs, organizations and national associations that represent ASCs, hospitals, healthcare corporations, the nuclear medicine industry, radiologists, and dentists. Overall, the majority of commenters were supportive of the goal of the proposed changes. Summaries of the major issues and our responses are set forth below.

All of the comments, with one exception, expressed strong support for the proposed changes to the oversight of radiologic services in an ASC. Two commenters recommended an alternative supervisory approach for ASC radiologic services, and more than half of the commenters specifically recommended that oversight of radiologic services be directly assigned to the governing body as part of their oversight and operation of the ASC. We did not receive any comments in regards to the technical changes made to § 416.42(b)(2), therefore we are incorporating those changes as proposed in this final rule.

Comment: Two commenters supported the proposal to remove the radiologist supervision requirement in ASCs; however, they suggested that CMS require the supervision rules for ASCs to be the same as those for the Physician Fee Schedule (PFS) and the Hospital Outpatient Prospective Payment System (OPPS). They stated this policy change would allow for radiology studies to be performed under general, direct and personal supervision as defined in § 410.32(b)(3)(i) through (b)(3)(iii).

Response: The regulations referenced at § 410.32(b)(3) are located in the Medicare payment rules at Part 410,

Supplementary Medical Insurance Benefits General Provisions. They are part of § 410.32, which addresses the circumstances under which Medicare will pay for diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests. The diagnostic imaging supervision requirements are, therefore, not applicable to ASCs, since ASCs only furnish radiologic services that are integral to a surgical procedure being performed in the ASC.

Comment: A majority of the commenters that supported our proposal to remove the radiologist supervision requirement of radiological services in ASCs also suggested that responsibility for radiologic services should be that of the governing body. Many commenters noted the importance for each ASC's governing body to have the flexibility to oversee radiologic services in keeping with the facility's policies and state law. Several commenters also stated that replacing the radiologist requirement with an MD/DO supervision requirement would not alleviate any financial or clinical burden, and would continue to be too narrow. For example, several dental facilities submitted comments that stated they would not be able to meet the requirement without significant burden, since their ASCs provide only dental services. These facilities do not have a MD or DO on staff, and would therefore continue to incur a burden to employ an extra staff member only to meet the radiological supervision requirements. ASCs that solely provide podiatry surgical services and employ only podiatrists would experience similar difficulties.

Response: We agree with the suggestion of the commenters that requiring supervision of radiologic services to be provided by an MD or DO would still be too restrictive or burdensome for some ASCs. Accordingly, we are revising our proposed language that would have required a doctor of medicine or osteopathy to supervise the provision of radiologic services, to require the ASC governing body appoint an individual who has appropriate qualifications, in accordance with State law and ASC policies, to provide oversight of the ASC's radiologic services. The appointed individual would be responsible for assuring the ASC's compliance with the provisions of § 482.26(b), (c)(2), and (d)(2). We note that the referenced provisions address requirements related to safety for patients and personnel, such as use of safety precautions (shielding, and appropriate storage, use and disposal of radioactive materials) against radiation

hazards; regular equipment inspection and hazard correction; regular review of radiation workers for the amount of radiation exposure; use of radiologic equipment only by qualified personnel; and maintenance of imaging results or records. The person appointed to oversee radiologic services could be someone already working in the ASC who is qualified in accordance with State law and ASC policies. The ASC's governing body will continue to be required to ensure, through the credentialing and privileging process, that the operating surgeon is competent to perform procedures in the ASC safely when using imaging as an integral part of the surgical procedure.

Comment: One commenter opposed the removal of the radiologist supervision requirement by stating that Independent Diagnostic Treatment Facilities (IDTFs) and ASCs need periodic supervision. In addition, the commenter gave examples, such as equipment repair and radiation badge monitoring, that he or she considered part of the supervision responsibilities of the radiologist.

Response: We understand the importance of oversight of issues related to safety and quality in the provision of radiological services. However, after reviewing all of the comments, we believe we have found a suitable balance for radiologic services oversight in ASCs, since it requires continued oversight, through the privileging process, of the surgeon's skill in using radiologic services during a procedure, and by the governing body of day-to-day operational responsibility for oversight of all the other aspects of the ASC's radiologic services by an individual qualified in accordance with state law and ASC policies.

After consideration of the public comments received and discussed above, we are finalizing our proposed changes to § 416.49(b) with revisions. The revised regulation text at § 416.49(b)(2) in the final rule has been changed from "A doctor of medicine or osteopathy who is qualified by education and experience in accordance with State law and ASC policy must supervise the provision of radiologic services" to "If radiologic services are utilized, the governing body must 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 requirements of this section."

Contact for ASC topics: CAPT Jacqueline Leach, USPHS, (410) 786-4282.

B. Intermediate Care Facilities for Individuals With Intellectual Disabilities

In the May 16, 2012, final rule "Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction," (77 FR 29002) we eliminated the requirement for time-limited agreements for Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs/IID) and replaced it with an open-ended agreement which, consistent with nursing facilities, would remain in effect until the Secretary or a State determined that the ICF/IID no longer met the ICF/IID CoPs. We also added a requirement that a certified ICF/IID would be surveyed, on average, every 12 months with a maximum 15-month survey interval. This requirement provides States with more flexibility relative to the current process. These changes were implemented by revising §§ 442.15, 442.109, and 442.110, and by removing § 442.16.

Section 442.105 describes circumstances for when a state survey agency may provide an annual certification of a facility found out of compliance with standards for ICF/IID's. Since time-limited certification is no longer required for ICF/IID's, this section serves no purpose and is confusing. Therefore, we proposed that this section be deleted. We also proposed to make a corresponding change to § 442.101(d)(3) by removing a reference to § 442.105.

A revision to § 442.110(b) made in the May 16, 2012 final rule extended the time for which a state may certify ICFs/IID with standard level deficiencies. However, the section inadvertently and incorrectly maintains time-limited certification for this sub-set of facilities. This is inconsistent with the revised survey regulation for ICFs/IID put in place in the May 16, 2012 final rule, and will create confusion and barriers to its successful implementation. Therefore, we proposed to delete § 442.110 in its entirety.

We also proposed to delete language in § 442.105 and § 442.110 to make it consistent with the intent of the Burden Reduction I regulatory changes to standardize survey processes of ICFs/IID with those of nursing facilities and other certified providers with open-ended certification periods.

We received one comment on the proposed changes for ICFs/IID, which we discuss here:

Comment: The commenter objected to the complete removal of all provisions found at 42 CFR 442.105 and 442.110. The commenter stated that, "the current rule changes are meant to remove

reference to time limited certifications from the ICF/IID regulations, as well as to eliminate language rendered anachronistic by the move to open ended certification agreements." The commenter further stated that while they appreciate the importance of clarifying the regulation, they believe that § 442.105 and § 442.110 contain valuable instructions for the surveyors that are not specified elsewhere in the regulation.

Specifically, the commenter mentioned that the complete removal of § 442.105 would remove any reference to the language in § 442.101, which states the requirements for obtaining notice of an ICF/IID's certification before a Medicaid agency executes a provider agreement under § 442.12, leaving only the requirement that the facility submit an acceptable plan of correction covering remaining deficiencies (standard level deficiencies). The commenter further stated that they believe this action removes from Federal regulation the specific requirement that facilities must ensure that any deficiencies do not jeopardize the health and safety of residents or limit the facility's capacity to serve them adequately. Absent this provision at § 442.105, the commenter believes that the only regulatory language addressing this need is located at § 442.117. However, the commenter states that the language at § 442.117 is limited to only situations of immediate jeopardy. The commenter recommended that CMS retain all the language of § 442.105 except § 442.105(d) which refers to a prior certification period.

Response: We appreciate the concerns of the commenter that the complete removal of § 442.105 may limit the ability of the State Survey Agencies and CMS to deny certification to a facility whose deficiencies in the aggregate compromise the facility's ability to provide adequate services. However, we believe that § 442.101(d)(1) does provide this ability through the requirement that the ICFs/IID must meet the CoPs for certification. Deficiencies indicating a lack of ability to provide adequate services are cited at a Condition level and the facility cannot be certified or continue certification unless acceptable corrections are made. We believe that the provisions of deleted section § 442.105 are adequately covered by § 442.101(d)(1) and § 442.117. Therefore we are not changing our proposal based on this comment and are removing § 442.105 as proposed.

Comment: The commenter also objected to the complete removal of § 442.110. The commenter stated that § 442.110 requires that a facility's

certification will be automatically cancelled on a specific date unless the State Survey Agency finds that standard level deficiencies have been corrected or sufficient progress toward correction has been made. The commenter feels that allowing a facility's continued certification to be predicated on correcting deficiencies found by the Survey Agency is an important regulatory tool and should be preserved. The commenter recommended that CMS retain § 442.110 and revise it to state that a facility's certification will be automatically cancelled on a specific date unless the State Survey Agency finds that the deficiencies are corrected or sufficient progress has been made and has a new plan for correction that has been accepted.

Response: We agree with the commenter that it is critical to retain the regulatory language which requires that a facility correct cited deficiencies to retain their certification; however, we do not agree that § 442.110 must include a reference to automatic cancellation of certification. In response to this comment, we will retain existing § 442.110 with revisions stating that ICFs/IID may be certified with standard level deficiencies under § 442.101 only if: (1) the survey agency finds that all deficiencies have been satisfactorily corrected; or (2) the survey agency finds that the facility has made substantial progress in correcting the deficiencies and has a new plan of correction that is acceptable.

Contact for ICFs/IID Topics: Martin Kennedy, 410-786-0784.

C. Hospitals

1. Governing Body (§ 482.12)

On May 16, 2012, we published a final rule, entitled "Reform of Hospital and Critical Access Hospital Conditions of Participation" (77 FR 29034). In that rule, we finalized changes to the requirements of the "Governing body" CoP, § 482.12, and adopted a policy to allow one governing body to oversee multiple hospitals in a multi-hospital system. Additionally, we added a requirement for a medical staff member, or members, from at least one hospital in the system to be included on the governing body as a means of ensuring communication and coordination between the governing body and the medical staffs of individual hospitals in the system. After publication of the rule, we received considerable feedback that the mandate requiring medical staff representation on the governing body of a hospital could cause unanticipated complications for many hospitals. We recognized that the provision to include

a member of the medical staff on a hospital's governing body creates conflicts for some hospitals, particularly public and not-for-profit hospitals. Issues include, but are not limited to, potential conflicts with some State and local laws that require members of a public hospital's governing body to either be publicly elected or appointed by the State's governor or by some other State or local official(s).

Given the complexity of the issue, and in light of industry feedback, we reviewed this requirement and gathered the relevant background information on the issues raised by stakeholders. After consideration of the issues, we proposed to rescind part of the new requirement and to propose an alternative. Specifically, we proposed to remove the requirement for a medical staff member, or members, to serve on a hospital's governing body and proposed to add a requirement that the hospital's governing body directly consult with the individual responsible for the organized medical staff (or his or her designee). While we believe that it is important that our requirements avoid any unnecessary conflicts for hospitals, we believe that it is essential that the requirements also ensure that the medical staff perspective on quality of care is heard by a hospital's governing body. Therefore, we proposed to add a new provision to the "Medical staff" standard of the Governing body CoP at § 482.12(a)(10). This new provision would require a hospital's governing body to directly consult with the individual responsible for the organized medical staff of the hospital, or his or her designee. At a minimum, this direct consultation would require a discussion of matters related to the quality of medical care provided to patients of the hospital and must occur periodically throughout the fiscal or calendar year. We indicated in the proposed rule that this proposed language reflects our intention to leave some degree of flexibility for a hospital's governing body (or a multi-hospital system's governing body) to determine how often during the year its consultations with the individual responsible for the organized medical staff of the hospital (or his or her designee) would occur, and that we would expect these consultations to occur at least twice during either a fiscal or calendar year. Moreover, we indicated in the proposed rule that we would expect a hospital (or multi-hospital system) governing body to determine the number of consultations needed based on various factors specific to a particular hospital. These factors would include, but are not

limited to, the scope and complexity of hospital services offered, specific patient populations served by a hospital, and any issues of patient safety and quality of care that a hospital's quality assessment and performance improvement program might periodically identify as needing the attention of the governing body in consultation with its medical staff. We also stated that we would expect to see evidence that the governing body is appropriately responsive to any periodic and/or urgent requests from the individual responsible for the organized medical staff of the hospital (or his or her designee) for timely consultation on issues regarding the quality of medical care provided to patients of the hospital.

Additionally, for a multi-hospital system using a single governing body to oversee multiple hospitals within its system, we proposed to require 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 proposed. In the proposed rule, we stated that we believe this proposal represents the best solution for those hospitals that were unintentionally burdened by the requirement finalized in the May 16, 2012, rule, while still addressing the concerns of many stakeholders who responded to the final rule, many of whom firmly stated their belief that medical staff input on a hospital's governing body is essential to the continuing quality of patient care delivered in the hospital.

We received a total of 83 comments from individuals, medical societies, professional societies, hospital associations, and national organizations on this proposal. The comments reflected a mixed response to our proposal, generally divided between the response of physician and physician groups and hospitals and hospital groups. Here we respond to specific comments:

Comment: Commenters generally asked that CMS retain the requirement for a member of the medical staff to be a member of the governing body and felt that physician representation on the governing body was critical to ensure adequate medical staff input into the quality of medical care provided to hospital patients. Some of these commenters felt that any conflict with state or local laws could be resolved without rescinding the provision requiring a medical staff member to be a member of the governing body. One commenter felt the conflict created by the requirement was overstated.

Response: We appreciate the commenters' concerns. However, as discussed in the preamble to the proposed rule, the existing requirement posed unanticipated complications for many hospitals, especially public and government-owned institutions. We believe it is important to avoid such unnecessary conflicts and complications and that our proposal reflects the most efficient option for doing so. We considered deferring to state and local law as suggested, but remained concerned that such deference would not adequately address and resolve the complications and conflicts that we are addressing. We believe our proposal achieves an appropriate balance between the concerns raised by the commenters and the problems and conflicts created by requiring medical staff membership on the governing body.

Comment: A number of commenters expressed support for our proposal to rescind the requirement. One commenter appreciated our acknowledgment of the legal issues created by the existing requirement.

Response: We appreciate the commenters' support of our proposed changes.

Comment: Generally, commenters were supportive of our intent to ensure meaningful communication between the governing body and the medical staff. Several commenters supported the provision as written, with one stating that CMS' alternative proposal will ensure a hospital's governing body hears the medical staff perspective on quality of care while leaving appropriate flexibility in the composition of the hospital's governing body.

Response: We appreciate the commenters' support of our proposed changes.

Comment: We received a number of comments expressing concern that the proposed consultation requirement would be overly burdensome, particularly for multi-hospital systems with a single governing body. One commenter stated that for systems with large numbers of hospitals and a single governing board, requiring separate consultations between each medical staff representative and the entire governing board would prove unworkable. One commenter suggested instead allowing for "a committee structure with representatives throughout the system and at a frequency that is flexible." Other commenters suggested various committee-based options and greater flexibility in achieving the objectives of meaningful communication between the governing body and the medical staff.

Response: Our proposal gives governing bodies flexibility to determine the most effective and efficient way to meet the requirement. We believe it allows sufficient flexibility for hospitals to meet this requirement in a manner appropriate to each organization. As written, this provision does not require separate consultations with each leader of each medical staff and does not exclude the possibility of consulting with multiple medical staff leaders simultaneously using some form of committee structure, so long as the direct consultation occurs periodically throughout the fiscal or calendar year and includes discussion of matters related to the quality of medical care provided to patients of each hospital. Similar to our discussion in the preamble to the May 16, 2012 Final Rule (77 FR 29038), we expect hospital governing bodies, especially a multi-hospital system's single governing body, to carefully consider the unique needs of the patient populations served by its member hospital(s) and their respective medical staffs when determining the number and the type of consultations needed to achieve the necessary communication between the governing body and the medical staff. Furthermore, this proposal does not preclude medical staff membership on the governing body.

Comment: One commenter felt that the proposed provision would not achieve the objective of meaningful communication and several commenters stated that "[w]e do not accept the premise that 'direct consultation,' no matter how frequent or in what form, is an adequate substitution for medical staff representation on a hospital's governing body." One commenter stated that if this proposal is implemented, medical staffs would be unable to comply with § 482.12(a)(5) requiring "that the medical staff is accountable to the governing body for the quality of care provided to patients."

Response: We believe that our proposal will provide for meaningful communication between the governing body and the medical staff while avoiding the complications created by the current requirement. We are confused by the comment that the implementation of this proposed requirement would make it impossible for medical staffs to comply with the current requirement at § 482.12(a)(5) listed above or with § 482.22(b), which requires the medical staff to be "well organized and accountable to the governing body for the quality of the medical care provided to the patients." The finalized requirement merely codifies the requirements applicable to

communications regarding the hospital's quality of patient care, which should be occurring regularly between the governing body and the medical staff. We do not see how the addition of this requirement would make the medical staff *less* accountable to the governing body for the quality of care provided to patients in the hospital. By requiring direct consultation, we believe that the medical staff would be ensured a forum in which its collective voice can be heard regarding patient care. If anything, the requirement holds the governing body accountable to the medical staff for providing that forum through direct consultation.

Comment: Several commenters requested examples of compliance or additional clarification regarding what constitutes "direct consultation."

Response: "Direct consultation" means that the governing body, or a subcommittee thereof, meets with the medical staff leader(s) either face-to-face or via a telecommunications system permitting immediate, synchronous communication.

Comment: One commenter asked if having a member of the medical staff on the governing body would meet the consultation requirement.

Response: As noted earlier, this proposal does not preclude including medical staff on the governing body, as full, non-voting, or ex-officio member(s). However, a hospital would meet the consultation requirement only if the medical staff member serving on the governing body is the same individual responsible for the organization and conduct of the hospital's medical staff, or his or her designee, and only if such membership includes meeting with the board periodically throughout the fiscal or calendar year and discussing matters related to the quality of medical care provided to patients of the hospital. If there were a change in the medical staff leadership and the bylaws governing terms and conditions of governing body membership did not allow for substitution of the new medical staff leader (or his or her designee) on the governing body, then the governing body would be expected to engage in direct consultation with the individual newly responsible for the organization and conduct of the medical staff (or his or her designee). It should be noted that if a hospital chooses to meet the requirement in this manner, there is nothing in the requirements to prohibit the hospital from including other medical staff members on the governing body in addition to the member responsible for the organization and conduct of the medical staff.

After consideration of the comments discussed above, we are finalizing the changes to § 482.12 as proposed.

2. Medical Staff (§ 482.22)

Similar to the issues regarding medical staff representation on the governing body that were discussed in the previous section, we also received a considerable amount of feedback regarding our responses in the May 16, 2012 final rule (77 FR 29061) where we discussed our interpretation of the Medical staff CoP at § 482.22 as requiring that each hospital have its own independent medical staff despite the arguable ambiguity of the regulatory language. After the publication of the May 16, 2012 final rule, it was brought to our attention that, over the years, this apparently ambiguous language might have led some stakeholders to interpret § 482.22 as allowing for separately certified hospitals, as members of a multi-hospital system, to share a unified and integrated medical staff. Therefore, we proposed to amend the introductory paragraph of § 482.22 to require that each hospital must have an organized and individual medical staff, distinct to that individual hospital, which operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients of that individual hospital.

Shortly after publication of the May 2012 final rule, it was also brought to our attention that some of the changes made to the hospital requirements at § 482.22(a), “Medical staff,” were not clear. Our intent in revising the provision was to provide the flexibility that hospitals need under federal law to maximize their medical staff opportunities for all practitioners, but within the regulatory boundaries of their State licensing and scope-of-practice laws. We believe that the greater flexibility for hospitals and medical staffs to enlist the services of non-physician practitioners to carry out the patient care duties for which they are trained and licensed will allow them to meet the needs of their patients most efficiently and effectively.

Section 482.22(a), “Standard: Eligibility and process for appointment to medical staff,” currently requires a hospital’s medical staff to be composed of doctors of medicine or osteopathy. It also allows for a hospital’s medical staff to include other categories of non-physician practitioners determined as eligible for appointment by the governing body, in accordance with State law, including scope-of-practice laws. With the substitution of the term “non-physician practitioners” in the

final rule (which replaced the term “other practitioners”), we might have unintentionally given the impression that the requirements now excluded other types of practitioners previously included among those eligible for appointment to the medical staff. In our guidance prior to the issuance of this final rule, we stated that a medical staff could include “other practitioners” such as doctors of dental surgery or of dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors, as those terms are defined and specified as physicians under section 1861(r) of the Act. Because part of § 482.22(a) states that a hospital’s medical staff must include “doctors of medicine or osteopathy,” other types of physicians, such as those listed above, are inadvertently excluded from the term “medical staff.” Similarly, the new term “non-physician practitioner” therefore might also seem to exclude these other types of physicians simply by its use of the modifier, “non-physician,” since by the definition described at section 1861(r) of the Act, the practitioners are “physicians,” they cannot also be considered to be “non-physicians.” Our intention was not to exclude these types of physicians from the definition described in our regulations. Therefore, we believe it was appropriate to propose revisions to § 482.22(a) to clarify that the medical staff requirements still allow for these types of physicians as well as other types of non-physician practitioners to be eligible for appointment to a hospital’s medical staff.

At § 482.22(a), we proposed to revise the current language to require that a hospital’s medical staff must be composed of physicians and that it may also include, in accordance with State laws, including scope-of-practice laws, other categories of non-physician practitioners determined as eligible for appointment by the governing body. We indicated that the proposed substitution of the current terms, “doctors of medicine or osteopathy,” with the term “physicians,” would be consistent with the statutory language. We also proposed to substitute “must include” with “must be composed of” since we believe that this more accurately reflects the fact that hospital medical staffs are predominantly made up of physicians and would also emphasize the vital positions that physicians hold on these medical staffs. We stated that this proposed regulatory language would require that the medical staff be composed of physicians. Finally, we proposed to retain the language allowing for other types of non-

physician practitioners (such as Advanced Practice Registered Nurses (APRNs), Physician Assistants (PAs), Registered Dietitians (RDs), and Doctors of Pharmacy (PharmDs)) to be included on the medical staff since we continue to believe that these practitioners, even though they are not included in the statutory definition of a physician, nevertheless have equally important roles to play on a medical staff and in the quality of medical care provided to patients in the hospital.

We received over 100 comments on our proposed changes to § 482.22 from individuals, national and State professional organizations, accreditation organizations, individual hospitals and multi-hospital systems, and national and State hospital organizations. Regarding the proposed requirement for a single medical staff for each individual hospital, there was a clear split among commenters with a pronounced difference of opinion on this issue between primarily physicians and their professional organizations on one side and hospitals, multi-hospital systems, an accreditation organization, and hospital organizations on the other. For the most part, physicians and their organizations were supportive of the proposed changes. However, there were some physicians, most clearly those who stated that they had experience with a unified and integrated medical staff for multiple hospitals within a system, who were opposed to our proposed changes. On the other side, hospitals and their organizations, along with accreditation organizations, were opposed to our proposed change to prohibit a unified and integrated medical staff structure for a multi-hospital system made up of separately certified member hospitals.

On the proposed changes to the composition of the medical staff requirements, the comments were mixed though generally supportive of the changes. A number of commenter asked for further clarification of these changes.

Here we respond to specific comments:

Comment: Regarding the proposed changes to the composition of the medical staff, one commenter questioned whether non-physician practitioners and other practitioners (for example, podiatrists, dentists, and oral surgeons) would be granted hospital privileges and be allowed to practice if State law only permitted MDs and DOs to be medical staff members.

Response: The requirement at § 482.22(a) has always allowed hospitals to grant medical staff membership for non-physician practitioners as well as

other practitioners who are not MDs/DOs only if such membership is in accordance with State law. Although our expectation is that all practitioners granted privileges are also members of the medical staff, if State law limits the composition of the medical staff to certain categories of practitioners, there is nothing in the CoPs that prohibits hospitals and their medical staffs from establishing certain practice privileges for those specific categories of practitioners excluded from medical staff membership under State law, or from granting those privileges to individual practitioners in those categories as long as such privileges are recommended by the medical staff, approved by the governing body, and in accordance with State law. However, CMS has always expected a hospital and its medical staff to exercise oversight, such as credentialing and competency review, of those practitioners to whom it grants privileges, just as it would for those practitioners appointed to its medical staff.

Comment: Several commenters expressed concern with our referring to practitioners who are not MDs or DOs as “physicians.” One commenter stated that CMS was trying to undermine the traditional hospital medical staff leadership model composed solely or primarily of MDs and DOs by replacing that model with one composed largely of non-physician practitioners who are hospital employees.

Response: As we stated above, the changes proposed as well as the current requirements do not require hospitals and their medical staffs to appoint practitioners other than MDs and DOs to their medical staffs. The requirement provides hospitals and medical staffs with an option of medical staff appointment for practitioners who are not MDs or DOs, not a requirement. However, in our attempts in the proposed rule to correct the omission of other categories of physicians (as defined in § 1861(r) of the Act and listed at § 482.12(c)(1)) in this requirement, we believe, based on some of the comments received, we might have further confused the issue of the composition of the medical staff. Therefore, we are finalizing a revision to § 482.22(a) in this rule that we believe will adequately present the required part of this provision and that part which is only optional. We are revising the regulatory language to now state that the “medical staff *must* be composed of *doctors of medicine or osteopathy*,” and that in accordance with State law, including scope-of-practice laws, the medical staff “*may also include other categories of physicians (as listed at § 482.12(c)(1))*”

and non-physician practitioners who are determined to be eligible for appointment by the governing body.” [Emphasis added.]

Comment: We received a large number of comments from individual physicians as well as national and State physician organizations that supported our proposed changes to reaffirm and make more explicit the requirement that each hospital to have its own medical staff, specifically those hospitals that are part of a multi-hospital system. These commenters stated they believed that allowing a multi-hospital system to have a unified and integrated medical staff instead of separate medical staffs for each hospital would destroy the concept of medical staff self-governance that is “a basic requirement” for TJC hospital accreditation and which is “mandated by some states.” Additionally, there were some comments from individuals as well as hospital leaders that stated that while they support the proposed requirement overall, they believed that there should be some allowance for hospitals within a system to share medical staff bylaws, rules, and regulations.

Conversely, we also received an equally large number of comments from hospitals, multi-hospital systems, national and State hospital organizations, and individual physicians that rejected these same proposed changes. These commenters offered both anecdotal evidence and preliminary research evidence to support their arguments that unified and integrated medical staffs provide the best means for multi-hospital systems to more efficiently standardize evidence-based “best” practices (for example, innovations that have been proven to reduce healthcare-associated infections (HAIs), hospital-acquired conditions (HACs), and readmissions) across member hospitals. A number of commenters also disputed claims that a unified and integrated medical staff structure for multiple hospitals within a system would undermine medical staff self-governance and pointed out that there is no evidence that the separate-medical-staff-for-each-hospital structure improves the quality of patient care or protects patient safety. A few commenters pointed to several specific benefits that can potentially be derived from a unified and integrated medical staff structure including:

- Increased opportunity to improve peer review processes.
- Improved patient safety through shared credentialing and privileging.
- More efficient sharing of knowledge and innovations among medical staff members.

- Better physician on-call coverage for specialties.
- Consistency with the move toward accountable care organizations and modern care delivery systems.
- More efficient coordination of emergency preparedness and community health planning.

Among the comments supporting unified and integrated medical staffs some stated that they believed that CMS should allow it as an option for hospitals that might not be using such a structure currently. One commenter argued that because the structure of a hospital’s medical staff is commonly defined within medical staff bylaws, which must be approved by both the medical staff and the governing body, a multi-hospital governing body cannot unilaterally force the members of its separate hospital medical staffs to accept a single, unified, and integrated medical staff. This commenter stated that the members of the system’s separate hospital medical staffs had voted many years ago to structure themselves as a unified medical staff because the majority of medical staff members believed that this was the best way for the system and its medical staffs to “achieve our goals for mutual integration.” The commenter further reinforced the idea that this change was not forced upon the separate medical staffs by stating that the medical staff and its members “were, and remain responsible for their self-governance.” The commenter recommended that hospital systems with separately certified hospitals that wish to adopt an integrated medical staff structure should be required to provide for an election or vote on the issue to ensure that the medical staff of each hospital is in agreement. One commenter also noted that unified medical staffs “are self-governing entities that can and do respect the diversity, viewpoints and concerns of medical staff members across the system.” Several commenters in support of unified medical staffs pointed out that many unified medical staffs rely on a system of committees made up of representatives from the various hospitals in a system. These commenters argued that while the unified medical staff model allows for more efficient patient care coordination, the committees and member representatives ensure that hospital-specific concerns are voiced, heard, and addressed by the unified medical staff and the governing body.

Other commenters pointed out the significant burden that would be imposed on hospitals already operating under this structure if CMS were to finalize the proposed requirement. They

pointed to the significant cost of dismantling the unified medical staffs under which many have been operating for several years in many accredited hospitals, in addition to the burden of having to establish new medical staffs at each such member hospital with new bylaws, rules, regulations, and committee structures. A few commenters also asserted that there might be inconsistency in CMS allowing for a single unified structure for a multi-hospital system's governing body (as we did in the May 12, 2012 final rule), but denying the same flexibility for its medical staff structure.

Finally, there were several commenters who stated that they while they disagreed with the proposed clarifications, and believed that a multi-hospital system should be allowed to have a unified and integrated medical staff, they believed that there should be specific parameters limiting how many member hospitals could possibly share a unified medical staff within a system. Commenters suggested establishing a specific number of hospitals or limiting the geographic range by state or metropolitan statistical area.

Response: We appreciate all of the comments received on this issue. After carefully considering all of the arguments for and against allowing a multi-hospital system to use a unified and integrated medical staff structure for its member hospitals, we believe that it is in the best interest of hospitals, medical staff members, and patients to modify our proposed prohibition on the use of a unified and integrated medical staff for a multi-hospital system and its member hospitals so as to enable the medical staff of each hospital to voluntarily integrate itself into a larger system medical staff.

The fact that many hospital systems have been using a unified medical staff model for a number of years, without evidence showing that such a system is detrimental to patients or decreases the quality of care delivered, was a major factor in our decision to allow hospitals and their respective medical staffs the flexibility to decide which medical staff framework works best for their particular situations. The arguments against allowing this flexibility through the CoPs did not provide any evidence that having a single and separate medical staff for each hospital within a system was inherently superior to the unified and integrated model. We weighed this argument against the comments from the physician leaders and members of unified and integrated medical staffs who provided testimony and anecdotal evidence for the benefits of this type of structure. Additionally,

we considered preliminary evidence that appears to show that hospitals using a unified medical staff might be achieving some success in reducing HACs, HAIs, and readmissions, and in improving patient safety and outcomes. One commenter, writing on behalf of a multi-hospital system that the commenter references as the largest in their State, stated that "we believe the concept of a single medical staff has substantially contributed to our success as an integrated delivery system and has accelerated our quality, safety and efficiency performance." The commenter cited the system's achievements, which they believe are a result of this single and integrated medical staff model: Core measures in the top quartile with excellent value-based purchasing scores according to CMS; lower in-hospital mortality rates that are statistically significant, that is, 17 percent lower than expected; lower hospital readmission rates that are statistically significant, that is, 15 percent lower than expected; and the second lowest congestive heart failure readmission rate in the nation, according to published CMS data. We agree that it appears to be evident that a unified system medical staff would usually be better suited to standardizing best practices and implementing quality improvements than would the more fragmented structure of separate medical staffs.

While we do not agree with comments that stated that a unified and integrated medical staff would destroy medical staff self-governance, we appreciate that added flexibility allowing a multi-hospital unified medical staff might conceivably be implemented in a manner that fails to achieve the desired benefits. We also received comments suggesting that if flexibility were permitted, CMS should place parameters or limitations on the use of a unified medical staff. We believe that the specifics should be left up to the medical staffs and governing bodies to determine, but agree that basic parameters are advisable to address the concerns of commenters and ensure due consideration of the unique aspects of each involved hospital (such as requiring that the hospitals have considered the extent to which a medical staff can be shared among its member hospitals as defined in hospital and medical staff policy, by-laws, and protocols).

Therefore, we are revising the proposed requirement and finalizing it here by retaining the original and current language of the condition statement, which states that the hospital must have an organized medical staff

that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital. We believe that this will provide more flexibility for each hospital and medical staff to determine the medical staff framework which works best for their situation (for example, whether that decision is for a separate medical staff for each hospital or a unified and integrated medical staff for multiple hospitals with a system). We are also revising this CoP (at § 482.22(b)) to include new provisions that will hold a hospital responsible for showing that it actively addresses its use of a unified and integrated staff model. Under the provisions of this final rule, the unified medical staff would still be composed of medical staff members from each hospital in the system and each member would be eligible to take on a leadership role on the various committees and subcommittees just as he or she would if he or she were part of a separate medical staff. Further, a medical staff and a governing body would still need to work closely together, with the medical staff responsible for the quality of care provided and accountable to the governing body. Neither the governing body nor the medical staff may impose its will unilaterally. They are dependent on each other for the hospital's success. For medical staffs and multi-hospital systems that choose to exercise the flexibility provided by this CoP (to use a unified and integrated medical staff, after determining that such a decision is in accordance with all applicable State and local laws), these new provisions are aimed at ensuring that—

(1) The medical staff members of each separately certified hospital in the system (that is, all medical staff members who hold specific privileges to practice at that hospital) have voted by majority in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure according to provisions included in the medical staff bylaws or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital;

(2) 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;

(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 dietitians, 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 dietitians.” 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 dietitian 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 dietitian 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

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.

We stated that these changes would allow hospitals to establish their own policies on supervision of nuclear medicine personnel and the in-house preparation of radiopharmaceuticals. Absent a requirement for “direct” supervision, we expect most hospitals to follow the Society of Nuclear Medicine and Molecular Imaging recommendations on this issue and to no longer require a registered pharmacist or MD/DO to be on site for direct supervision when radiopharmaceuticals are prepared in-house by staff. We stated that the proposed change would directly reduce the burden of the current direct supervision requirement where it is most needed—in-house preparation of radiopharmaceuticals for after-hours/emergency performance of nuclear medicine diagnostic procedures (for example, coronary artery disease, pulmonary emboli, stroke, and testicular torsion). Given that an estimated 16 million nuclear medicine imaging and therapeutic procedures are performed each year in the United States, we would expect hospitals to achieve significant cost reductions in this area if they take advantage of the proposed change. We welcomed public comments on this proposed change.

We received several comments on our proposed change to § 482.53, primarily from professional organizations, hospitals and hospital systems, and individual nuclear medicine technologists. All commenters were supportive of the proposed change with no commenters opposed.

In accordance with the comments discussed above, we are finalizing the changes to § 482.53(b)(1) as proposed.

5. Outpatient Services (§ 482.54)

We proposed changes to the requirements at § 482.54, “Outpatient services.” Specifically, we proposed to add a new standard at § 482.54(c), entitled “Orders for outpatient services.” We proposed these revisions so that the regulations would codify Interpretive Guideline (IG) changes that we recently made regarding the ordering of outpatient services.

On May 13, 2011, CMS issued memorandum SC–11–28 ([http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter11_28.pdf)

[SCLetter11_28.pdf](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter11_28.pdf)). Among other things, this memorandum included preliminary guidance on who may order hospital rehabilitation (§ 482.56(b)) and respiratory care services (§ 482.57(b)(3)). On November 18, 2011, the final version of the revised IGs for these requirements was released. Subsequently, we received considerable feedback that this guidance, which was intended to expand the categories of practitioners who could order rehabilitation and respiratory care services beyond physicians and stated that all ordering practitioners had to hold medical staff privileges, was actually having the opposite effect and limiting practitioner orders for these services. In the area of outpatient rehabilitation services, in particular, stakeholders informed us that the revised guidance was posing a barrier to care because a substantial percentage of these services are provided in hospital outpatient rehabilitation facilities to patients referred by practitioners who are not on the hospital’s medical staff and who do not hold medical staff privileges. We were advised that, in many cases, the referring practitioners are based in other States to which patients have traveled to receive specialized services. Clearly, these practitioners do not provide care in the patient’s local hospital and are not interested in seeking medical staff privileges merely to refer patients for outpatient services.

It was not our intention to create barriers to care or to limit the ability of practitioners, who are appropriately licensed, acting within their scope of practice, and authorized under hospital policies, to refer patients for outpatient services. We distinguish these outpatient referral cases from cases where a practitioner provides care in the hospital, either to inpatients or outpatients, and must have medical staff privileges to do so. We subsequently issued new guidance on this rule. On February 17, 2012, CMS issued SC–12–17 (http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter12_17.pdf), which clarified that outpatient services may 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.

In light of the above, as indicated in the proposed rule, we believed it would be appropriate to revise § 482.54, the CoP governing outpatient services, which is silent on the issue of who may

order such services, in order to explicitly address this issue. We proposed to revise the requirements to mean that orders for outpatient services may be made by any practitioner who is—

- Responsible for the care of the patient;
- Licensed in the State where he or she provides care to the patient;
- Acting within his or her scope of practice under State law; and
- Authorized in accordance with policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services.

Further, we stated that these proposed requirements would apply to all practitioners who are appointed to the hospital’s medical staff and who have been granted privileges to order the applicable outpatient services; and all practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the hospital for ordering the applicable outpatient services and for referring patients for such services. These requirements would also apply to all hospital services that may be offered on an outpatient basis, including services for which there is regulatory language that, in the absence of the clarifying language we propose herein, would appear to impose more stringent limits as to the practitioners who are permitted to order outpatient services. For example, § 482.53(c)(4) states, “Nuclear medicine services must be ordered only by practitioners whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.” In practice, however, it is not unusual for physicians without medical staff privileges to refer their patients to the hospital for common outpatient nuclear medicine tests, such as myocardial perfusion scans used in conjunction with cardiac stress tests and hepatobiliary scans used in the detection of gallbladder disease. So long as the hospital’s medical staff policies and procedures permit this, we do not believe our regulations should present a barrier. Another example concerns the administration of outpatient chemotherapy. In accordance with § 482.23(c), concerning preparation and administration of drugs, “Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient’s care as specified under § 482.12(c), and accepted standards of practice.” In the absence of the clarification we stated that this language could be confusing, as some hospitals

might read it to preclude providing outpatient chemotherapy on the orders of a practitioner without privileges, which may or may not be desirable to the hospital. We believe that it is more appropriate if the hospital's medical staff and governing body determine what types of outpatient services they are comfortable with providing on the basis of an order (which might commonly also be called a "referral") from a practitioner who does not hold medical staff privileges.

We expect these changes would be primarily neutral in terms of regulatory burden reduction for hospitals. Prior to the November 2011 revisions to the IGs, most, if not all, hospitals were already operating under what was considered standard industry practice with regard to the ordering of, and referral for, outpatient rehabilitation services by practitioners who were not on the hospital's medical staff. Since we moved quickly to clarify our outpatient services ordering policy through communications with stakeholders and further revisions to the IGs, we believe that most hospitals did not make changes to their policies and procedures that would have created burdens for them. We cannot rule out the possibility that some hospitals were deterred by the specific language of other CoPs, such as those governing nuclear medicine or administration of drugs, but we have not received information that would allow us to quantify this. We stated that this proposed change would clearly establish in regulation CMS policy on the ordering and referral of all outpatient services.

We received a total of 35 comments from individuals, medical societies, professional societies, hospital associations and national organizations on this proposal. The comments were generally supportive of our proposal. Here we respond to specific comments:

Comment: Several commenters expressed support for our proposal, but suggested that the language be modified to add language to require that practitioners not appointed to the medical staff be authorized in accordance with both State law and policies adopted by the medical staff.

Response: We appreciate the commenters' support. We also agree with the recommendation and have modified the proposed regulatory language as suggested.

Comment: Several commenters expressed concern regarding both the burden and the practicality of requiring hospitals to obtain information about the current scope of practice for a practitioner in another state and then to determine if the practitioner's ordered

services are within those parameters. These commenters believe that CMS should clarify the proposed requirement that the hospital must check the licensure status of the practitioner in the State where he or she provides care to the patient. They also asked if CMS expected the hospital to set up a credentials file for the non-medical staff practitioner who orders outpatient services, maintain information on his or her State scope of practice, and show that a determination was made that the ability to order the specific outpatient services was within his or her respective State scope of practice.

Response: Hospitals have the flexibility to determine whether or not they will allow a practitioner who is not a member of the medical staff to order outpatient services as well as the ability to establish through medical staff bylaws and hospital policy other parameters for who will and who will not be authorized to order outpatient services. If a hospital is unable or unwilling to verify the respective State scope of practice, licensure, etc., for a practitioner, the hospital is not required to authorize the practitioner to order outpatient services in its facility. If a hospital does allow practitioners not on the hospital's medical staff to order hospital outpatient services, the hospital must be able to demonstrate compliance with the regulatory requirement.

Comment: Several commenters noted that non-hospital providers of similar outpatient services do not have similar requirements and believe that hospitals should not be held to a higher requirement than non-hospital providers of similar services. They believe that requiring a higher standard of hospitals would be an unnecessary burden, increase hospital costs, and provide limited, or no, benefit to patients. Another commenter stated that the hospital CEOs with whom they have spoken believe that hospitals already have better policies than non-hospital providers of the same services that are not subject to the same regulatory requirements.

Response: We are aware that there are other provider types who provide outpatient services and we understand the commenters' concerns about these providers having differing regulatory requirements. These other providers are subject to requirements specific to their particular setting that also include issues such as licensure, scope of practice, and facility policies and procedures. We believe the requirements that we have established in this rule are appropriate to the hospital setting and are necessary to ensure the health and safety of patients

while also ensuring that we do not create unintentional barriers to care or unnecessary limitations on professional practice. We note that this clarification to the CoP for outpatient services creates an option for hospitals and not a requirement. A hospital is required to comply with this requirement only if it chooses to allow practitioners who are not members of the medical staff to order outpatient services.

Comment: Several commenters supported the proposed revisions as written. One commenter stated that they supported the clarifying change as there was prior confusion that membership on the medical staff is required to order outpatient services. Another commenter noted that this change will improve patient access to crucial healthcare services and improve the efficiency and quality of care. They believe that it will prevent needless delays for consumers in accessing the care they need, and that it will promote earlier intervention, which they believe will in turn improve outcomes and reduce costs.

Response: We appreciate the commenters' support for our proposal.

Comment: One commenter believes that this change will "amp up medical spending, often for useless medical imaging and other diagnostic tests."

Response: We disagree. We understand that allowing practitioners who are not a member of the medical staff to order outpatient services has been a standard practice for many years for a majority of hospitals. We have not been presented with any evidence that our clarification will result in any increase in the number and types of outpatient services ordered. We believe that this clarification in policy will prevent the creation of new barriers to care, particularly for patients in rural areas. In addition, CMS has other regulatory mechanisms by which determinations are made as to whether specific outpatient services are medically reasonable and necessary.

Comment: One commenter requested that CMS clarify what constitutes when a practitioner is responsible for the care of the patient asks whether this includes practitioners working under the supervision of, or in collaboration with, the treating physician as well as other practitioners otherwise involved in the care of the patient.

Response: We expect that each hospital medical staff would address which categories of practitioners would be deemed "responsible for care of the patient" in their policies. Such practitioners could include: Any of the practitioners specified under § 482.12(c) who are involved in providing medical care to the patient; any practice partners

of the patient's attending physician who might be covering the physician's patients for a period of time if the physician is not available; any hospitalists, hospital intensivists, and specialty physicians who might have provided care to the patient during a prior hospital stay; any residents/fellows under the preceptorship or supervision of the patient's attending physician or hospitalist, intensivist or specialty physician during a prior hospital stay; and any non-physician practitioners involved in the patient's care.

Comment: One commenter expressed concern about complying with this requirement in teaching hospitals. The commenter requested that CMS clarify that a teaching hospital would not be considered out of compliance with this requirement when they allow interns, residents, and fellows to order outpatient service as part of their training program, in accordance with the hospital's medical staff bylaws, rules, and regulations as well as any other related legal requirements related to with which the hospital must comply.

Response: We do not see a conflict between this requirement and interns, residents, and fellows who are acting in accordance with their respective State's licenses and scope-of-practice laws, and their respective hospital's medical staff bylaws, rules, and regulations.

Comment: One commenter recommends that CMS specify the timeframe and the duration of the verification process for such orders, as they vary in frequency and urgency.

Response: We expect hospitals, when presented with a referral or order for outpatient services from a practitioner who does not have privileges at that hospital and for whom the hospital has not previously verified the practitioner's licensure, etc. to perform such verification before providing the ordered outpatient services to the patient. In accordance with the comments discussed above, we are finalizing the changes to § 482.54 as proposed with two minor revisions. On the recommendation of commenters, we are revising § 482.54(c)(4) by adding the phrase, "State law" so that the provision is now finalized to read, ". . . authorized in accordance with *State law and policies* adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services." Additionally, we are also revising § 482.54(c)(4)(ii) by adding the phrase, "the medical staff" so that this provision is now finalized as applying to all practitioners "not appointed to the medical staff, but who satisfy the above

criteria for authorization by *the medical staff and the hospital* for ordering the applicable outpatient services for their patients." We believe that this additional revision is necessary to clarify that it is a hospital's medical staff that initially recommends authorizing these ordering privileges, after which the governing body, or the hospital, approves them.

6. Special Requirements for Hospital Providers of Long-Term Care Services ("Swing-Beds") (§ 482.66)

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. We believe the requirements at § 482.66 would be more appropriately located under Subpart D of Part 482, optional hospital services, since swing-bed services are optional hospital services for eligible rural hospitals.

Therefore, we proposed to reassign all of the requirements for swing-bed services found currently at § 482.66, Subpart E, to § 482.58, Subpart D. This change would allow compliance with the swing-bed requirements to be evaluated for accredited hospitals during routine AO surveys. As indicated in the proposed rule, by no longer requiring an accredited hospital to undergo a separate survey by a State Survey Agency (SA) to determine continued compliance with the swing-bed requirements in addition to the AO survey for the other CoPs, this proposed change would likely reduce the burden on such a hospital. We welcomed public comments on this proposed change.

We received a total of 8 comments on our proposed changes to § 482.66, primarily from accreditation organizations and hospital organizations. Commenters were supportive of the proposed changes. There were no comments opposed to the proposed changes to § 482.66.

In accordance with the comments discussed above, we are reassigning all of the requirements for swing-bed services found currently at § 482.66, Subpart E, to § 482.58, Subpart D as proposed. We are also making conforming amendments to correct cross-references in §§ 413.24, 413.114, 440.1 and 485.606.

Contact for all hospital topics, CDR Scott Cooper, USPHS, (410) 786-9465.

D. Transplant Centers and Organ Procurement Organizations

1. Reports to CMS (§ 482.74)

On March 30, 2007, we published the "Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Transplants Final Rule" (transplant center final rule, 72 FR 15198). In that rule, we required that transplant centers, among other things, report to CMS any significant changes related to the center's transplant program or changes that could affect its compliance with the CoPs. Among other things, transplant centers must notify us, under § 482.74(a)(2), whenever there is a decrease in the center's number of transplants or survival rates that could result in the center being out of compliance with the clinical experience (number of required transplants) or outcome (survival) requirements at § 482.82.

We routinely receive information about the number of transplants a center performs and survival information from all transplant centers. Transplant centers are required to submit these data to the Organ Procurement and Transplantation Network (OPTN) national database for transplantation. These data are provided to the Scientific Registry of Transplant Recipients (SRTR), which publicly releases outcome (survival) information every six months, after the data have been risk-adjusted. CMS also receives more recent survival information via the Social Security Master Death File. CMS receives clinical experience data and the Social Security Master Death File quarterly, as well as the risk-adjusted outcomes from the SRTR data every six months. Thus, CMS is essentially receiving the same information from the transplant programs individually that we receive routinely from one or more of the resources cited above.

In addition to the above, this notification requirement has also resulted in confusion for the transplant centers. The requirement states that transplant centers should notify CMS when they are out of compliance with a 3-year average of 10 transplants per year. Since the clinical experience standard is based on an average, a transplant center may not know if a given year's volume would be low enough to have the average fall below 10 per year and trigger reporting to CMS, particularly when the number of transplants to be performed in a future year is unknown.

Further, the requirement for notification of outcomes non-compliance is based on the difference

between the observed and the expected outcomes exceeding certain thresholds. However, the expected outcomes are not calculated until at least one year later when the one-year post-transplant tracking period for patient and graft survival is complete. The transplant program would not always know whether a given death or graft failure would put them out of compliance and require notification to CMS. Eliminating this notification requirement will also remove this confusion for the transplant centers.

Thus, the requirement for transplant centers to report a decrease in the center's number of transplants or survival rates when those results could result in the center being out of compliance with the measures in § 482.82 is unnecessary, confusing, and burdensome for transplant centers. Therefore, we proposed to eliminate the requirement at § 482.74(a)(2) that transplant centers notify us. The removal of this requirement would have no impact on the quality of care to transplant recipients, living donors, or potential donors, because our identification and follow-up processes for programs that do not meet § 482.82 remain unchanged.

We received a total of six comments on our proposed change to § 482.74 from health care providers and institutions, as well as from two national associations of transplant professionals. All of the commenters were supportive of the proposed change. We respond to specific comments below:

Comment: Most of the commenters noted that data are already routinely submitted to the OPTN and then these data are provided to the SRTR, which publicly releases outcome (survival) information every six months, after the data have been risk-adjusted. CMS also receives more recent survival information via the Social Security Master Death File. CMS receives clinical experience data and the Social Security Master Death File quarterly, as well as the risk-adjusted outcomes from the SRTR data every six months. Thus, CMS is essentially receiving the same information from the transplant programs individually that we receive routinely from one or more of the resources cited above. The commenters noted that this process is time consuming, labor intensive, and duplicative.

Response: We agree with the commenters. We believe that requiring transplant centers to report these data that are routinely available to CMS is unnecessary, confusing, and burdensome for transplant centers. In

accordance with the comments discussed above, we are finalizing the change to § 482.74(a)(2) as proposed.

2. Transplant Outcome Review (§ 482.80(c) and § 482.82(c))

Sections 482.80(c), approval, and 482.82(c), reapproval, in the transplant center CoPs state that, “[e]xcept for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.” At the time the transplant center final rule was published (March 30, 2007), the adult data cohorts for lung transplants included transplant patients 12 years of age and older. As of June 2010, the adult data cohort includes only those transplant patients that are 18 years of age and older. The age categories for lung transplant patients are now the same as for all of the other transplants reported in the SRTR center-specific reports (*See OPTN/SRTR 2010 Annual Data Report, Rockville, MD: Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation: 2011*). We are reviewing the adult and pediatric outcomes separately for all programs that request Medicare approval to perform both adult and pediatric transplants, including the lung transplant program. This language, “except for lung transplants,” is no longer necessary. Therefore, we proposed to remove the exception language for lung transplants from §§ 482.80(c) and 482.82(c).

We received a total of two comments on our proposed changes to §§ 482.80(c) and 482.82(c) from a health care provider and institution, as well as a national association of transplant professionals. All of the commenters were supportive of the proposed changes. We respond to specific comments below:

Comment: Both of the commenters supported the proposed deletion of the phrase, “except for lung transplants.” One commenter specifically noted that this change clarifies that “adult and pediatric outcomes will be reviewed separately for all [transplant] programs [when they] request Medicare approval to perform both adult and pediatric transplants, including lung transplant programs.”

Response: We agree with the commenters. Since the age cohorts are now the same for all transplant patients, including lung transplants, this language is unnecessary and only causes confusion.

In accordance with the comments discussed above, we are finalizing the

changes to §§ 482.80(c) and 482.82(c) as proposed.

3. Volume and Clinical Experience Requirements (§§ 482.80(c)(2) and 482.82(c)(2))

Regulations at §§ 482.80(c)(2) and 482.82(c)(2) both state “[t]he required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.” We proposed to modify this language to harmonize it with other parts of the current rule. Under the current rule, transplant centers are generally required, with some exceptions, to perform either 10 transplants over a 12-month period for initial approval (§ 482.80(b)) or an average of 10 transplants each year during the approval period (§ 482.82(c)(2)) (preceding reapproval). There is no requirement for a certain number of transplants to be performed during a particular period that would be covered in a single SRTR center-specific report. Thus, this language has resulted in transplant centers being confused about the number of transplants they are required to perform during any particular period of time covered by the SRTR center-specific reports. Therefore, we proposed to remove both §§ 482.80(c)(2) and 482.82(c)(2), and to redesignate the existing paragraph (c)(3) as (c)(2) to clarify the volume and clinical experience requirements.

We received a total of two comments on our proposed changes to §§ 482.80(c)(2) and 482.82(c)(2) from a health care provider and institution, as well as two national associations (writing together) for transplant professionals. All of the commenters were supportive of the proposed changes. We respond to specific comments below:

Comment: Both comments noted that the requirement was confusing and the proposed change would provide clarification. One of the commenters specifically noted that “the SRTR uses a “rolling” time frame and [the current language] is therefore confusing.”

Response: We agree with the commenters that the current language is confusing because there is no requirement for a transplant center to perform a certain number of transplants “during the time frame reported in the most recent SRTR center-specific report.” Removing this language as proposed will eliminate this confusion. In accordance with the comments discussed above, we are finalizing the changes to §§ 482.80(c)(2) and 482.82(c)(2) as proposed.

4. Transplant Center Re-Approval Process

Since the effective date of the CoPs, June 28, 2007, we have completed the initial surveys of all transplant programs that participate or seek participation in Medicare (approximately 845 transplant centers in 245 transplant hospitals), and have started conducting re-approval surveys. The current process and regulatory criteria require, under particular conditions, an automatic onsite review of all CoPs under a 3-year re-approval cycle. We believe that onsite surveys for some of these transplant centers are advisable to promote the health and safety of the patients who receive a transplant in those centers. However, we believe that the time period between recertification surveys should be more flexible, certain current requirements for an onsite survey following evidence of a violation of some CMS requirements may not be necessary, and such regulatory requirements for selecting the facilities that would undergo an onsite survey do not always effectively target survey resources where they are most needed.

We proposed to remove the automatic 3-year re-approval process in favor of a schedule in which each transplant program still has a full onsite recertification survey but the time interval between such surveys for any one program may be longer or shorter than once every three years. In addition, we plan to maintain, via CMS policy, a maximum time interval within which we expect an onsite survey to occur with respect to individual transplant centers. We have a variety of sources we use to generate targeted quality information that can be used to determine the circumstances and frequency under which an onsite survey is best conducted. Examples include previous complaint surveys, prior onsite survey results, issues found during surveys of the broader hospital CoPs, data and information from the Health Resources and Services Administration (HRSA) and the SRTR, notifications of program inactivity, key personnel changes, articles from the press about quality issues, and information submitted by the program through the mitigating factors (MF) process.

We also proposed 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 3 years. However, it is expected that compliance with CMS requirements is continuous, as is expected of all Medicare providers and suppliers.

Currently the regulations require that we review each transplant program's data before the end of 36 months after the program's prior approval. The regulations require a review of most other CoPs if we find that there is non-compliance with the requirements at § 482.82(a) for timeliness of data submission to the OPTN, or non-compliance with the requirements at § 482.82(b) for clinical experience, or at § 482.82(c) for patient and graft survival outcomes. An onsite survey for analysis of these data is the most common method of conducting such a review, but we have found that an onsite review for deficiencies in these areas is not always necessary if CMS determines that communication with the program and offsite analysis of information submitted by the hospital will suffice to make a final determination and/or approve a plan of correction. For instance, CMS regulations require that transplant programs submit 95 percent of their OPTN forms within 90 days of their due date. On a quarterly basis, we receive data from the OPTN that provides us with the number of forms due for each program and the number that were submitted within the required timeframe. Based on the 3-year period from mid-2008 through mid-2011, 73 transplant programs had data submission rates below 95 percent and, if due for re-approval, would have required an onsite survey. Of these 73, most (43 programs) had average data-submission rates between 90 and 95 percent. While remedial action is necessary in every case, it does not follow that these 43 programs required an automatic, onsite survey. We proposed that we can take action to address the non-compliance (such as through direct communication with hospital officials and, if necessary, application of remedies already available in law or regulation) while reserving for CMS's discretion the decision of whether or not an onsite survey is necessary or advisable.

We also receive data on a quarterly basis about the number of transplants performed at each center. Because of this data transfer, we are routinely aware of the average number of transplants being performed by or at a given transplant program. There are circumstances where it would not be in the public interest to spend the resources to perform a full onsite transplant center survey solely because the 3-year average volume is low. For example, if a transplant program had performed an average of 9.3 transplant surveys over the prior 3-year period (fewer than the current requirement of

an average of 10 per year), and the most recent year indicated 14 transplants performed, sending a full team to do an onsite survey of all CoPs, for this reason alone, may not make the best use of limited resources for the hospital or for CMS.

Of the approximately 845 total transplant programs, 442 are required to meet clinical experience requirements (that is, volume requirements). Pediatric transplant programs and adult heart/lung and adult pancreas programs do not have to meet clinical experience requirements (§§ 482.80(d) and 482.82(d)). Using clinical experience data from October 1, 2008 through September 30, 2011, 30 transplant programs that were required to meet experience requirements had performed fewer than the required number of 10 transplants per year on average. If due for re-approval, these 30 programs would have required an onsite survey regardless of any other evidence CMS may have had from history, recent program improvements, or the most recent clinical experience.

We monitor and enforce Medicare's requirements for patient and graft survival rates every 6 months based on the most recent report from the SRTR. A program is out of compliance if its observed patient and graft survival is significantly lower than expected to such an extent that it crosses three thresholds set out in the CoPs at § 482.82: The observed minus expected is greater than 3, the observed divided by expected is greater than 1.5, and the one-sided p-value is less than .05 (§ 482.82(c)(3)).

We follow up with these transplant programs through an offsite survey, an onsite complaint survey, or an onsite full re-approval survey. These follow-up activities are conducted by the CMS Regional Office, a federal contractor, or the State Survey Agency (acting on CMS's behalf). The follow-up occurs at the time of non-compliance and does not wait until the re-approval survey occurs. Following the citation of an outcomes deficiency and the establishment of a date for prospective termination from Medicare participation, programs may submit an application for mitigating factors (MF) based on non-compliance with the outcomes CoP. We provide ample time between the citation and the prospectively scheduled Medicare termination date for the program to provide evidence and, via conference call, discussion of the evidence that would support the mitigating factors request. If the MF request is approved, we specify the time period for the MF

approval and remove the prospectively scheduled Medicare termination.

We also proposed to provide at the new § 488.61(c)(3)(v) an example of a set of mitigating factors that we would consider. We have granted a very small number of MF requests on the basis of the categories currently used as examples in the regulation, such as natural disasters (one case) or access to care (one case). However, we have more frequently granted MF requests in cases where the transplant center has implemented substantial program improvements that address root causes of past graft failures and/or patient deaths, has institutionalized those improvements so they may be sustained over time, and has been able to demonstrate recent outcomes data with sufficient volume and with sufficient post-transplant survival periods such that we conclude that the program is in present-day compliance with the outcomes requirements in the regulation, but for the data time lag inherent in the SRTR reports upon which we otherwise rely. CMS has approved an MF request for 35 transplant programs on this basis since the implementation of the regulation in 2007. Additional MF approvals have been made pursuant to dialogue and a binding System Improvement Agreement between CMS and the transplant center that the hospital will engage in a clear regimen of quality improvement and the hospital subsequently demonstrated both substantial completion of that regimen and improved outcomes. We believe that the addition of this example in the body of the regulation will provide better guidance for transplant centers, offer encouragement for the productive application of hospital staff expertise in making program improvements that increase patient and graft survival, and promote government transparency.

We received a total of twelve comments from nine commenters on our proposed changes to § 488.61(c) from health care providers, institutions, and associations, as well as two national associations for transplant professionals and one national accrediting organization. Overall, the majority of commenters were supportive of the proposed changes. We respond to specific comments below:

Comment: Two of the commenters disagreed with our proposal to remove the automatic three-year re-approval process. One commenter, a healthcare professional, stated that the OPTN does not do a good job of monitoring programs that have failed to meet outcome requirements or have otherwise failed to maintain their

programs. The commenter indicated that CMS should realize, after six years of routine surveys, that many of the programs that are not in compliance with the CoPs are unwilling or unable to meet the requirements in the CoPs, even knowing that they would be surveyed. The commenter noted that one of the reasons for the transplant center CoPs was because of the “very public problems” in transplant programs. The commenter also said he thought it was foolish for CMS to abandon its most effective tool, the routine survey.

Response: We disagree with this commenter. Although we agree with the commenter that the onsite survey is an effective tool for ensuring compliance with the transplant center CoPs, we also believe onsite surveys are not necessary for all transplant centers. As discussed above, the current requirement for automatic, onsite surveys for transplant centers based solely on that transplant center’s failure to be in compliance with the data submission, clinical experience, or outcome requirements in § 482.82 is often an inefficient use of CMS’s survey resources. Transplant centers that are not in compliance with these requirements certainly require CMS follow-up; however, we believe that the type of follow-up should be up to CMS’s discretion. Requiring automatic, onsite surveys, regardless of the degree and type of non-compliance, will inevitably result in onsite surveys being conducted at transplant centers when another type of follow-up would have adequately addressed the non-compliance with a more efficient use of CMS’ limited survey resources.

Comment: Another commenter, a national accrediting organization, expressed concern over CMS not conducting on-site surveys unless the results of data analysis warranted such a review. Data gleaned from the SRTR may not be a reliable indicator of the quality of the care being delivered and the commenter did not believe that this should be the sole determinant of whether there should be an on-site survey. The commenter stated that the proposed method by which the data would be collected by CMS raises concern about whether organizations that are found deficient would have the opportunity to amend their practices before they are penalized. Transplant centers that submit unreliable data, which may or may not contain balancing measures to account for the complexities of its individual populations, risk not meeting the CMS threshold for quality care and potential unwarranted penalties. The commenter also noted that, in their experience,

surveying healthcare facilities supports the need for validation of data and documentary evidence with onsite review and that they believe the proposed approach is inconsistent with CMS’ evaluation of quality and safety of other high-risk healthcare programs and services.

Response: We disagree with this commenter. We will continue to conduct onsite surveys of all transplant centers. We are eliminating the 3-year approval period, which previously included a policy that onsite surveys be triggered by the failure of a center to be in compliance with the data submission, clinical experience, or outcome requirements in § 482.61(c). CMS is constantly enforcing the transplant center CoPs through the review of data from the SRTR, offsite surveys, and complaint surveys. In addition, as stated above, we will also be establishing, through CMS subregulatory policy, a maximum time interval within which we expect that each transplant center will have an onsite survey.

Regarding the commenter’s concern about the SRTR data, we are obligated by the OPO CfCs to use SRTR’s data (at § 486.318(a)(2) and (b)(2)). In addition to the SRTR data, we also review data from other sources and other information in determining when to survey OPOs. For example, we may conduct a survey when we receive a complaint from a healthcare provider or the public. We may also decide to conduct a survey after receiving information through another governmental agency or the media.

In regards to the commenter’s concern about transplant centers having the ability to make changes to their programs before being penalized by CMS, we believe that all of the transplant centers monitor their performance on the requirements. In addition, transplant centers are required to have a comprehensive, data-driven quality assessment and performance improvement (QAPI) program that is designed to monitor and evaluate the center’s performance of all transplantation services as set forth in § 482.98. Therefore, transplant centers should be aware of any problems in their programs and be working towards improving their performance.

CMS constantly monitors and enforces the transplant center CoPs through the review of available data, offsite surveys, and complaint surveys. In addition, we are not abandoning the onsite survey process. Our proposal simply allows us to use discretion, based upon our extensive experience with transplant centers, to determine when an onsite survey is necessary and

when another type of follow-up is appropriate. Also, CMS will be establishing via policy a maximum time interval within which an onsite survey must occur.

Comment: One commenter, a healthcare institution, noted that our proposed addition to the examples of mitigating factors CMS would consider in the re-approval of a transplant center in § 488.61(c) should be in set forth in paragraph (c)(4), not paragraph (c)(3).

Response: We agree with the commenter. The examples of the mitigating factors CMS will consider are set forth in § 488.61(c)(4) and the proposed additional example should also be located in that section. Therefore, we will be finalizing our additional example of a mitigating factor as proposed; however, we will be re-designating it so that it is set forth at § 488.61(c)(4)(v).

After consideration of the comments discussed above, we are finalizing the changes to § 488.61(c) as proposed, except for re-designating proposed § 488.61(c)(3)(v) as § 488.61(c)(4)(v).

5. Technical Corrections

On May 31, 2006, we published the Conditions for Coverage for Organ Procurement Organizations (OPOs) Final Rule (OPO final rule 71 FR 30982). We have discovered that there were some technical errors in that rule. Therefore, we proposed to make the following technical corrections:

- Section 486.306 states, in paragraph (a), that “An OPO must make available to CMS documentation verifying that the OPO meets the requirements of paragraphs (b) through (d) of this section . . .” This section only contains paragraphs (a), (b), and (c). We proposed to delete the reference to “(d)” in paragraph (a) and insert “(c)” in its place. This paragraph would then read, “the OPO meets the requirements of paragraphs (b) and (c) of this section . . .”

- Section 486.308(b)(1) reads, in part, “if additional time is needed to select a successor OPO to an OPO that has been de-certified.” We proposed to remove the “to” between the two “OPOs” and replace it with “for” in this sentence. The paragraph would then read, “if additional time is needed to select a successor OPO for an OPO that has been de-certified.”

- Section 486.344(d)(2)(ii) reads, in part, “If the identify of the intended recipient is known. . . .” We intended to say the “identity” of the intended recipient. We proposed to remove the word “identify” and replace it with “identity.” The clause would then read,

“If the identity of the intended recipient is known”

We received one public comment in response to these proposed technical corrections. That commenter supported the corrections as proposed. Therefore, we are finalizing these changes as proposed.

In addition to the comments we received concerning our proposed changes, we also received comments that were extraneous to those changes. Since these comments address issues beyond the scope of this rule, we will not specifically respond to them here. However, we have reviewed these comments and will consider them in any future rulemaking.

Contact for all transplant center and OPO topics: Diane Corning, (410) 786-8486.

E. Long-Term Care Facilities

On August 13, 2008, we published a final rule requiring all buildings containing long term care facilities to have automatic sprinkler systems installed throughout the building (73 FR 47075). The deadline for meeting this requirement was August 13, 2013. The regulation requires that all facilities be in compliance. On August 16, 2013, CMS issued a memorandum to State survey agencies describing enforcement guidelines for this requirement (see Survey & Certification Memorandum SC-13-55, accessible at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-55.pdf>). Life Safety Code (LSC) surveys will continue to occur as part of normally-scheduled annual surveys, or as part of a complaint visit in which LSC deficiencies are noted or referred. LSC surveys that find a facility to be without a complete automatic sprinkler system installed in accordance with *NFPA 101, LSC, 2000 Edition and NFPA 13, Installation of Sprinkler Systems, 1999 edition* will be cited as not in compliance with CMS requirements. Facilities that are cited for not meeting the sprinkler requirement will be required to submit a plan of correction (POC) to correct the deficiency.

The 2008 final rule was based on a CMS analysis of fire safety in nursing homes, and the agency’s conclusion that fire safety protections would clearly be improved by ensuring that all facilities be fully sprinklered within a reasonable period of time. Based on recent public comments and input, we believe that some facilities were not able to meet the August 2013 deadline due to the magnitude of the enterprise they are undertaking (such as large scale

construction of a replacement facility) combined with recent financial and construction constraints. We therefore proposed to allow certain long term care facilities to apply for a temporary deadline extension of the sprinkler system requirement, under very limited circumstances, if they are unable to meet the deadline. Our intent is to establish a rigorous review process for all deadline extension requests. Upon finalization of this rule, CMS will continue to cite facilities that do not meet the requirement, except that CMS may grant extensions of the due date to the relatively small number of facilities that meet the extenuating circumstances set forth below.

We proposed to add a provision at § 483.70(a)(8)(iii) that would allow long term care facilities the opportunity to apply for a deadline extension, not to exceed 2 years, if all of the following conditions apply:

- 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;
- The facility demonstrates that it has made the necessary financial commitments to complete the building replacement or modification;
- 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
- 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.

An extension may be granted for up to 2 years, depending on the need and particular circumstances. We would determine the length of the extension based on the information submitted by the facility.

We also proposed to add a provision at § 483.70(a)(8)(iv) that would allow for a renewal of the deadline extension for an additional period, not to exceed 1 additional year. We proposed that a facility could only apply for a single extension renewal.

We received a total of 13 comments on our proposed sprinkler deadline extension provision from individuals and organizations such as accrediting bodies, patient advocacy groups, health care systems, and LTC facilities. Overall, the majority of commenters were supportive of the proposed changes. Here we respond to specific comments:

Comment: The majority of commenters supported the proposal and thanked us for the opportunity to comment in support of the proposal. Several commenters disagree with our proposal to grant extensions. One commenter expressed that allowing for this extension could compromise the safety of nursing homes patients, as they are continuing to live in facilities that do not have sprinklers in them during the extension period. In addition, one commenter felt that only facilities that are currently unoccupied should be able to apply for this extension to ensure the safety of patients and staff.

Response: We thank the commenters who expressed support for our proposal and agree that this regulation is necessary in order to allow facilities that have run into issues the opportunity to become compliant while also continuing to provide the safest environment possible for all patients and staff.

We understand that the commenters disagree with the proposal to grant extensions in certain circumstances because they feel that facilities have had ample time to come into compliance with the sprinkler requirement. Some facilities will not be able to meet the deadline and will need the extension to allow for the completion of construction. If the facilities are not given an extension it may cause facilities to be closed and will require patients to be moved to other facilities that may be further away and not as easily accessible. An example of unforeseen issues that may have caused a facility to be unable to meet the 2013 deadline may be delayed construction or depleting funds. For example, many providers established financial plans to construct a replacement facility that would comply with the sprinkler requirement, or to effect substantial building modifications that would include fund sprinkler compliance projects. However, following the initial CMS final rule in 2008 that mandated automatic sprinkler systems, a number of such facilities found their financial gains disappear due to the national recession, depleting the project funds, or making it impractical to sell an existing facility where the sale was necessary to fund the replacement

facility. Also, challenges have come from the recent natural disasters such as Hurricane Irene in 2011 and Superstorm Sandy in 2012, causing delays in project starts and creating a backlog of projects.

We also understand the safety concerns of the commenters who disagreed with our proposal. We share their goal of improving safety for all long term care facility residents while continuing to assure resident stability and access to much needed long term care services. We are requiring that, as part of receiving an extension, a facility must implement interim fire safety measures. Interim measures may include the initiation of a fire watch, installation of temporary exits, installation of temporary smoke detection or smoke alarm systems, and increased fire safety training or fire drills for staff or other means to ensure the continued fire safety of the residents of the facility.

Comment: One commenter observed that recent natural disasters, including Hurricane Irene and Superstorm Sandy, have significantly impaired the ability of some nursing homes to meet the August 13, 2013, deadline to achieve full sprinkler status. The commenter observed that recent challenges from Superstorm Sandy in late 2012 caused delays in project starts and a backlog of construction projects and requested that we provide for an additional extension one year beyond what we proposed.

Response: We agree that natural disasters are a valid reason for a delay in compliance with the August 13th deadline. In reviewing the comments, we concluded that the original CMS proposal did not fully accommodate the significant impairments that might result from a major disaster. While section 1135 of the Act allows the Secretary to waive certain requirements in the case of a declared public health emergency, construction delays and financial hardships occasioned by a major disaster may extend far beyond the date of a declared public health emergency. While we still intend that any authority for an extension of the sprinkler deadline be narrowly construed, in this final rule we have added explicit recognition of a major disaster event as a potential basis for an extension of the due date at § 483.70(a)(8)(iii). We do believe that three years is a considerable amount of time in which to complete the construction, even if a facility is impacted by a natural disaster. Therefore, we are finalizing the extension timeframe as proposed.

Comment: Some commenters have seemingly used the public comment process to apply for an extension, while

others explicitly requested an explanation of the process.

Response: We appreciate the opportunity to explain the process for submitting an application. As we proposed, and are finalizing in this rule, a facility must meet the following criteria in order to qualify for an extension:

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 or has had its planned sprinkler installation so impaired by a disaster or emergency, as indicated by a declaration under section 319 of the Public Health Service Act, that CMS finds it would be impractical to meet the sprinkler installation due date.

2. The facility demonstrates that it has made the necessary financial commitments to complete the building replacement or modifications;

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 completed, as determined by CMS. This could include a fire watch, installation of temporary exits and temporary smoke detection systems or additional smoke detection system in the area of construction, increased fire inspections, additional training and awareness by staff, and additional fire drills. CMS may also require that information about these interim steps be posted in the facility in an informational manner accessible to residents and family members.

In order to demonstrate that it meets the above criteria, a facility must submit certain information. The following are examples of information that may need to be submitted by the facility. We intend for this list to be merely illustrative, and note that it does not include all possible information that may be requested by CMS in order to make the final extension decision. This list is subject to change and the process will be described in further detail in subregulatory guidance.

(1) *Organization Information:* The name, address, CCN, contact information, and other data regarding

the nursing home that is requesting the extension.

(2) *Type and Qualifications of Request:* (a) Replacement Facility or (b) Major Modification, or (c) major disaster. A request from the facility for an extension of time to complete the installation of an automatic sprinkler system and the circumstances behind the request for an extension of time, including a description of what the facility is proposing (such as a replacement of the existing facility or major modification of the living area, or reconstruction from a major disaster), and an explanation of the circumstances that prevent timely installation of the sprinklers and that qualify the request for an extension approval under terms of the regulation.

(3) *Timeframe:* The length of time for which the extension is requested.

(4) *Major Modifications:* In the case of the major modification of the living area, a description and/or drawing of the proposed work shall be submitted for review, a listing of all units affected, square footage involved, overall estimated project cost, proposed length of time for the extension, correspondence to the State Licensure Authority concerning the proposed major modifications to the facility and their response to such request, an explanation of the manner in which the modifications will improve the environment for residents, and whether any residents or residents might be negatively affected by the modifications.

(5) *Projected Milestones:* A list of project milestones for completion of the modifications or replacement of the facility will be required to be submitted for review to help in determining the length of the extension time required to complete the work proposed.

(6) *Financial Commitments:* Documentation from financial institutions attesting to the facilities financial capabilities to complete the building replacement or modifications. This could include such things as final loan approvals, final grant approval or other such things that could enable CMS to determine the financial capabilities of the facility to complete the project in a timely manner.

(7) *Construction Documentation:* Documentation concerning the submittal of construction plans and specifications for the replacement of an existing long term care facility or the modification of an existing long term care facility. This information shall include correspondence with State and local plan approval authorities indicating approval or receipt of plans for approval and the date of anticipated plan approval from the approving

authorities. For facilities with partial plan approval or preliminary plan approval a copy of any final approval documentation will also be required to be submitted when received by the facility.

(8) *Interim Fire Safety Improvements:* Suggestions for any enhanced measures that the facility has implemented or could implement to strengthen resident protections against fire hazard during the time period prior to final achievement of full sprinkler status for the facility.

A facility requesting an extension of time must submit the required information to the appropriate CMS Regional Office and State survey agency. CMS Central Office will post the major substance of the requests on an appropriate CMS Web site (such as <http://www.medicare.gov/nursinghomecompare/>), together with contact information for any public input. When the CMS Regional Office is satisfied that the submitted information is complete, it will consult with the State survey agency and make a recommendation to CMS Central Office regarding the request. The CMS Regional Office will also recommend any interim steps to improve fire safety at the requesting facility. CMS Central Office will review the submitted material from the CMS Regional Office, consult with the State fire Marshall and the State Ombudsman program, and make a final determination as to whether or not to grant the requested time extension and what interim fire safety steps will be required in the facility. CMS will notify the requesting facility and State survey agency as to the final determination. While an original deficiency citation is subject to appeal consistent with 42 CFR Part 498, we note that CMS's discretion to grant an extension of the due date is not subject to judicial appeal.

If a further one time only one year extension is requested, further documentation from the facility will be required as to why the first extension requested was not adequate, when completion is anticipated, and what is being done to insure the continued fire safety of any existing building that has not had an automatic fire sprinkler system installed.

Comment: A commenter suggested that we allow a 3 year waiver for facilities purchasing a new building without sprinklers to install sprinklers.

Response: Facilities are free to purchase any building that becomes available, however the newly purchased facility will need to be in compliance before it is able to complete the Medicare process and become a

Medicare approved facility. Therefore, the facility would need to be fully sprinklered before any occupancy.

Comment: A few commenters suggested changes to the criteria that a facility must meet in order to qualify for the extension. One commenter suggested that facilities applying for the extension only be required to show that they are working toward securing the necessary financial commitments. Another commenter suggested that the construction plans must be approved by state and local authorities in order to qualify.

Response: We would like to thank the commenters for giving us this opportunity to address suggestions and clarify any statements that may have been confusing. Facilities have already been given 5 years to comply with the 2013 deadline. The extensions we proposed were intentionally defined to apply only in circumstances where total facility replacement is being effected or major modification is planned. We consider these plans to be ones that are likely to be most affected by construction delays, market, or funding issues due to the recent national recession. Even in these circumstances, given the 5 year advance notice, current low interest rates, and recent improvement in the real estate markets, we expect that a serious intention to fully install sprinklers would have evidence of the necessary financial commitments. We recognize that financial commitments often have contingencies attached to them (such as a loan that is contingent upon sale of another property), and will take such factors into consideration provided that there are firm commitments in place subject to fulfillment of the pertinent contingencies and other relevant considerations. With regard to the comment regarding approval by local authorities, while we agree that receiving approval of construction plans from state and local authorities is a positive sign that a project is on track to be completed by the end of the extension period, we do not believe that such approval is absolutely necessary at the time that a facility applies for an extension. Therefore, we are finalizing the extension criteria as proposed.

Comment: One commenter suggested various types of alternative sanctions to penalize facilities for being out of compliance with the LTC sprinkler requirement. In addition, they also suggested that facilities should not be allowed to receive a waiver of liability for any fire-related injuries that occur as a result of the facility not being in compliance with the sprinkler requirement.

Response: We are allowing facilities to apply for an extension only in very limited circumstances. If a facility meets the narrow terms of the regulation, and fulfills the terms of any requirements that accompany an approval (such as enhanced procedures for added fire protection during the extension period), then imposition of a penalty would be inconsistent with CMS concurrence that the facility met the terms of the regulation. However, we project that most facilities that were not fully sprinklered, as of the time of publication of the proposed rule, will not meet the terms of this narrowly-construed extension regulation. If such facilities have not achieved full sprinkler status by the sprinkler due date, then they will indeed be subject to sanction. With regard to waivers of liability, CMS does not have authority to waive civil or criminal liability.

Comment: One commenter suggested that before applying for a waiver, facilities should have to notify the state survey agency, state long-term care ombudsman; state fire marshal; local fire marshal; consumer advocacy groups; facility residents, families and other resident representatives; and the public of its intent to request a waiver; the reasons for its request; enhanced procedures it will take to ensure the safety of residents until compliance with the sprinkler requirement is achieved; its time frame for reaching compliance; and an opportunity for those receiving notification to attach comments and recommendations to the request. In addition to submitting comments and recommendations, the state survey agency, state ombudsman, and state fire marshal should be required to sign off on the request and the facility's plans for the interim safety of residents until sprinklers are installed. The commenter suggested that CMS should consider all comments and recommendations when deciding whether to grant the waiver.

Response: We agree with the value of transparency in the process of facilities requesting extensions, as well as the CMS approval or denial process. We therefore plan to engage in a process whereby facilities will make requests to the CMS Regional Office and State survey agency. CMS Central Office will post the major substance of the requests on an appropriate CMS Web site (such as <http://www.medicare.gov/nursinghomecompare/>) together with contact information for any public input. When the CMS Regional Office is satisfied that the submitted information is complete, the staff will consult with the State survey agency and make a recommendation to CMS Central Office

regarding the request. The CMS Regional Office will also approve the suggested recommended interim fire safety steps, or recommend any interim steps to improve fire safety at the requesting facility. CMS Central Office will review the submitted material from the CMS Regional Office, and make a final determination as to whether or not to grant the requested time extension and what interim fire safety steps will be required in the facility. CMS will notify the requesting facility and State survey agency as to the final determination. We remind facilities that a sprinkler deadline extension from CMS would not waive relevant State or local fire safety laws.

Comment: One commenter expressed concern that some facilities might take this required construction as an opportunity to convert facilities to different levels of care, such as skilled nursing and rehabilitation. This could cause a problem if facilities then involuntarily discharge current nursing home residents to make room for skilled nursing or rehabilitation residents.

Response: While we understand that the commenter is concerned about the possibility of this occurring, we are not aware of any facilities that have used the construction associated with installing sprinklers as an opportunity to change the care level of any beds from unskilled to skilled, or to involuntarily discharge residents during the entirety of the phase-in period. Since the vast majority of LTC facilities have already installed sprinkler systems and have not engaged in this practice, we have no basis from which to conclude that the small minority of facilities that would qualify for this extension would suddenly begin doing so. Furthermore, the LTC facility regulations at § 483.12, Admission, Transfer, and Discharge Rights, contain strict requirements that govern the discharge of residents that would effectively curb the use of involuntary discharge practices. The regulations states that, the facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—

- The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;
- The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;
- The safety of individuals in the facility is endangered;
- The health of individuals in the facility would otherwise be endangered;

- The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a nursing facility, the nursing facility may charge a resident only allowable charges under Medicaid; or

- The facility ceases to operate.

Furthermore, the regulation also requires that the long term care facility must notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand at least 30 days before the resident is transferred or discharged. The written notice must include the following:

- The reason for transfer or discharge;
- The effective date of transfer or discharge;
- The location to which the resident is transferred or discharged;
- A statement that the resident has the right to appeal the action to the State;
- The name, address and telephone number of the State long term care ombudsman;
- For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and
- For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.

Appendix PP of the CMS State Operations Manual (http://cms.hhs.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltc.pdf) further directs LTC facility surveyors to closely review the clinical records of discharged residents to determine the reasons for transfer/discharge. Surveyors are also directed to communicate with the ombudsman and ask if there were any complaints regarding transfer and/or discharge, as well as the results of any ombudsman investigations. We believe that this comprehensive package of regulations and survey enforcement procedures provides an appropriate level of protection to assure that residents are not involuntarily discharged for reasons related to the installation of sprinklers in LTC facilities.

Comment: One commenter suggested public notification of noncompliance. The commenter suggested public notice in two different forms—by posting a notice in the facility and also by a special notification posted on *Nursing Home Compare*.

Response: We appreciate the commenter's suggestion. It is important to note that a facility receiving a deadline extension would not be considered non-compliant. If the facility has applied for an extension, and the extension has been granted, the facility would be considered compliant for the duration of the facility's approved time period. Therefore there would be no need to post a public notification of noncompliance.

Comment: One commenter suggested specific interim staffing requirements and monitoring efforts is required for each facility that is granted an extension. The commenter suggested that CMS impose the following requirements:

1. Hard-wired smoke alarms that automatically alert all sections of the facility and notify local fire departments and other emergency responders. These hard-wired smoke detectors should be placed in all resident rooms, public areas, laundry rooms, kitchens, basements, attics, and utility closets where combustible materials may be stored.

2. Enhanced staffing to ensure that the facility and all units within the facility are adequately staffed on all shifts.

3. Strict state survey agency monitoring to ensure that all staff on all shifts, including temporary staff, are sufficiently trained in Life Safety Code requirements and oriented to the facility and facility emergency procedures.

4. Enhanced state surveys, including Life Safety Code inspections, during the waiver period to ensure the facility complies with all interim safety requirements, including staffing levels.

5. Immediate jeopardy citations and appropriate remedies for failure to be in compliance with interim Life Safety Code requirements.

Response: We agree that each of these could be an appropriate temporary fire safety measure; however we do not agree that all of these measures are necessary in every single facility. We believe that the best way to address interim fire safety measures is to customize them to each facility. Therefore, we are finalizing the regulation text that the facility must agree to complete interim steps to improve fire safety, as determined by CMS, as proposed. We will take the commenter's recommendations into

consideration as we consider the unique aspects of each extension request.

After consideration of the comments discussed above, we are finalizing the proposed changes to § 483.70(a)(8)(iii) and (iv) with the minor modifications discussed above.

Contact for long term care sprinkler topics: Kristin Shifflett, (410) 786-4133.

F. Rural Health and Primary Care

We received a total of 60 comments on our proposed regulatory changes for Critical Access Hospitals (CAHs), Rural Health Clinics (RHCs), and Federally Qualified Health Centers (FQHCs). The comments came from national and state professional associations, state medical associations, health care systems, individual and group practitioners and consumer advocacy organizations. Overall, the majority of commenters were supportive of the proposed changes. There were also some specific dissenting comments, and other comments that suggested further changes. We respond to these comments here.

1. CAH Provision of Services (§ 485.635(a))

The current CoPs at § 485.635(a)(2) require CAHs to develop their policies and procedures with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff. Currently, at least one member of the professional group must be a non-CAH staff member. We proposed to remove the requirement that a CAH must develop its patient care policies with the advice of a non-CAH staff member, thereby allowing CAHs flexibility in their approach to developing their patient care policies and procedures. Specifically, we proposed to remove the provision at the end of § 485.635(a)(2) that states, “. . . at least one member is not a member of the CAH staff.”

Comment: All of the commenters on our proposed change to § 485.635(a)(2) agreed with removing the requirement that a CAH must develop its patient care policies with the advice of a non-CAH staff member. Several commenters stated that CAHs typically engage in network arrangements with other non-CAH hospitals and that those arrangements provide a mechanism for review and assistance with the development of appropriate patient care policies.

Response: We are pleased to have received favorable comments regarding the elimination of this requirement.

After consideration of the comments discussed above, we are finalizing the changes to § 485.635(a)(2) as proposed.

2. CAH and RHC/FQHC Physician Responsibilities (§§ 485.631(b)(1)(v), 485.631(b)(2), and 491.8(b)(2))

The current requirements for CAHs, RHCs, and FQHCs specify that a physician must be present in the CAH, RHC, or FQHC for sufficient periods of time at least once in every 2-week period, to provide medical direction, medical care services, consultation, and supervision of other clinical staff. The regulation further requires a physician to be available through telecommunication for consultation, assistance with medical emergencies, or patient referral. Sections 1861(aa)(2)(B) and 1820(c)(2)(B)(iv) of the Act require supervision and oversight of services furnished by physician assistants and nurse practitioners in a CAH, RHC, and FQHC but they do not prescribe the frequency of the physician visits nor do they require onsite supervision. We proposed to revise the CAH regulations at § 485.631(b)(2) and the RHC/FQHC regulations at § 491.8(b)(2) to eliminate the requirement that a physician must be onsite at least once in every 2-week period (except in extraordinary circumstances) to provide medical care services, medical direction, consultation, and supervision. For CAHs, we proposed that a doctor of medicine or osteopathy would be required to be present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the CAH, and be available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. For RHCs and FQHCs, we proposed that physicians would be required to 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.

In the course of reviewing public comments, we determined that the administrative burden on physicians and facilities could be further reduced by making an additional similar change to § 485.631(b)(1)(v). These requirements set out a similar 2-week minimum interval for physicians to review and sign a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants, according to the policies of the CAH and according to the State's current standards of practice. Accordingly, as discussed in further detail below and after consideration of

the public comments received, we will similarly revise § 485.631(b)(1)(v) to require that a sample of outpatient records be reviewed “periodically.” We believe that removing the specified 2-week requirements at §§ 485.631(b)(1)(v) and 485.631(b)(2), and at § 491.8(b)(2), will provide CAHs, RHCs, and FQHCs with the flexibility to manage patient care activities in such a way as to maximize staff time to provide patient access to quality care in rural and remote areas.

Finally, we note that for most outpatient therapeutic CAH services provided to Medicare beneficiaries, a physician or appropriate non-physician practitioner is still required to furnish direct supervision and be immediately available to furnish assistance and direction for the duration of the service, in accordance with 42 CFR 410.27(a)(1). We continue to believe this is an appropriate standard for Medicare payment under section 1861(s)(2)(B) of the Act, which requires these services to be furnished incident to a physician’s services and applies to CAHs if the context otherwise requires under section 1861(e) of the Act (see 77 FR 68426). Unlike sections 1861(aa)(2)(B) and 1820(c)(2)(B)(iv) of the Act, our regulation at 42 CFR 410.27(a)(1) does not necessarily require a physician to furnish the required supervision if a non-physician practitioner listed in 42 CFR 410.27(g) (a clinical psychologist, licensed clinical social worker, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife) is qualified to supervise the service (see the Medicare Benefit Policy Manual (Pub. 100–02) Ch. 6 Sec. 20.5.2). The payment provisions in section 1861(s)(2)(B) of the Act and 42 CFR 410.27 are not enforced via the survey and certification process and are not evaluated as part of the assessment of compliance with the CAH CoPs.

Comment: The majority of commenters supported the proposed change to eliminate the “2-week” requirement, under §§ 485.631(b)(2) and 491.8(b)(2), that a physician must be physically present once in a two-week period to provide medical direction, medical care services, consultation and supervision of other clinical staff in either the CAH, RHC, or FQHC.

Many commenters stated that the increased use of telecommunications and telemedicine, and the use of non-physician practitioners under physician oversight, allow rural facilities the flexibility to schedule physician on-site services to better match the needs and requirements of the community they serve. One commenter suggested that, because of these technological advances,

the current requirements do not improve the quality of care.

Comments from a large consumer group were particularly supportive of the proposal because they believe it would improve consumers’ access to care in remote and underserved areas where there may be a shortage of physicians. Similarly, commenters from the rural provider community remarked that the current requirement is unnecessarily restrictive and that revising it will benefit patients by allowing practitioners and health care providers and suppliers greater flexibility. They stated that providers in remote areas may find it difficult to comply with a biweekly schedule. One commenter remarked that physically travelling to outlying clinics twice each month is not an efficient use of a physician’s time, and that it was a significant part of that commenter’s decision not to apply for RHC status for one of its remote clinics.

One commenter stated that States now have scope of practice laws for non-physician practitioners such as a physician assistant (PA) or a nurse practitioner (NP). These State laws specify the extent to which a PA or NP can practice independently or under remote supervision. The commenter also stated that, in a number of states, the existing RHC requirement for physician on-site availability has the practical effect of superseding state law and the regulations create an added cost to the RHC.

Response: We appreciate the comments supporting this proposed change. With the development of technology that facilitates telemedicine, a physician should have the flexibility to use a variety of ways and timeframes to provide medical direction, consultation, supervision, and medical care services, including being on-site at the facility.

The rule will allow for increased use of team-based care while still requiring the physician to be on-site, as appropriate, to ensure the delivery of quality care. Importantly, the proposed regulation would not preclude a State or a rural provider from establishing requirements for physician supervision of non-physician practitioners that are more stringent. As we stated in the proposed rule, for those CAHs that offer a range of complex services and have more than one physician on staff, a visit just once every 2 weeks could be inadequate. It is our experience that such facilities have policies and procedures in place to ensure quality provision and oversight of the services they provide.

We note that CAHs, RHCs, and FQHCs are still required to have a physician who provides medical direction and is involved in the development of the policies and procedures, provides consultation, and supervises other clinical staff. The proposed change should provide RHCs and FQHCs with the flexibility to optimize their physician on-site time to effectively meet the needs of their patients.

Comment: Several commenters requested that CMS provide additional guidance in the final rule regarding what expectations CMS has for an MD and DO’s presence, given the diversity of CAHs affected. The commenters stated that CAHs differ greatly in terms of the size of the populations served and in the range and extent of services offered. One commenter stated that we should consider whether removal of the bi-weekly presence is appropriate in all cases. A commenter noted that, for some CAHs, the presence of an MD or DO may in fact be required more frequently than every two weeks. Additionally, some commenters remarked that telecommunication may not always be an appropriate mechanism for delivering care, such as in the provision of surgical services when a physician’s physical presence would be required.

Some commenters asked CMS to clarify and further explain the meaning of “sufficient periods of time,” but others disagreed with the proposal entirely, stating that requiring a doctor to be present for “sufficient periods of time” is inadequate for ensuring appropriate supervision of medical care provided by non-physician practitioners.

Response: We appreciate the commenters’ remarks and requests for additional guidance. We expect the policies for medical oversight and supervision at each facility to reflect the requirements of applicable State law as well as the scope of services furnished.

We believe that specifying a precise timeframe for a physician to visit the CAH, RHC, or FQHC, and provide the general oversight required under sections 1861(aa)(2)(B) and 1820(c)(2)(B)(iv) of the Act would not guarantee better health care. With the development of technology such as telemedicine, we believe a CAH, RHC, or FQHC should have the flexibility to use a variety of ways and timeframes for physician(s) to provide the necessary medical direction and oversight. For example, a physician supervising a RHC or FQHC might visit the facility more frequently than biweekly during peak seasons for certain illnesses and make less frequent visits during other times of

the year. For CAHs that offer a range of complex services, have more than one physician on staff, and have busy emergency departments and/or extensive outpatient services, a visit by a physician only once every 2 weeks could be grossly inadequate. On the other hand, a bi-weekly on-site visit may be unduly burdensome to a small CAH in a remote rural area that offers very limited services and has a low patient volume.

We note that § 485.635(a) requires a CAH and § 491.9(b) requires the RHC or FQHC to furnish health care services in accordance with appropriate written policies consistent with applicable State law. Thus, we would not expect these facilities to offer any services without adequate staffing to provide those services, including staffing or supervision by physicians as applicable. We expect each facility to evaluate its services and adjust its physician schedule accordingly, as an appropriate physician schedule would reflect the volume and nature of services offered. The amount of time spent at the CAH or RHC by the physician to provide general oversight as well as patient care will be evaluated at the time of a survey for compliance with the CoPs (CAHs) or CfCs (RHCs). FQHCs are only required to attest to their compliance to the Medicare requirements but may be surveyed in response to a complaint. We do not envision developing specific formulas for minimum amounts of time a physician is required to be present at these facilities. Rather, we would identify for further evaluation cases where we find significant disproportion between the volume of services offered and the amount of time a physician is present.

Comment: A few commenters suggested that more review and analysis is necessary before revising or eliminating this requirement, stating that patient safety should be carefully considered.

Response: We agree with the commenters that patient safety considerations are vitally important. CMS continuously analyzes patient safety issues, and we have been working steadily to reduce unnecessary regulatory burden on providers so that resources can be freed up for providing quality health care. As evidenced by the Hospital and CAH final rule issued on May 16, 2012 (77 FR 29034), we have been introducing changes only after careful review of the feedback we receive from the provider community and other stakeholders. Patient safety is paramount, and we are mindful of the financial and labor constraints impacting health care delivery in remote

and rural settings. We will continue to review all regulatory matters from a patient safety and quality of care perspective.

Comment: Several commenters stated that, instead of revising the on-site review requirements to make them more flexible, quality care could be better ensured if CMS would work with stakeholder groups on the development of programs to support the few primary care physicians in rural and frontier areas and to recruit primary care physicians.

Response: We are mindful of the difficulties inherent in attracting physicians to practice in rural settings. CMS is engaged in a multi-pronged strategy to improve and expand the delivery of quality health care services. We routinely work with stakeholder groups to maximize access to quality health care services and maximize the ability of physicians to practice in rural settings. We note that The Department of Health and Human Services has established a number of different programs, such as the National Health Service Corps (NHSC), to train and recruit health care practitioners, including physicians, to provide services in rural and underserved areas. More than 40,000 primary care medical, dental, and mental and behavioral health professionals have served in the NHSC since its inception.

In addition, we recognize the tremendous opportunity to improve and deliver quality health care that is presented by telemedicine technologies and the services these technologies support. As appropriate, we encourage the use of such technologies to provide flexibility in the delivery of health care and to increase patient access to care. We also recognize that non-physician practitioners will increasingly be relied upon to assist with the delivery of essential medical services.

Comment: Another commenter asked which entities would be authorized to determine whether facilities are in compliance.

Response: The authority to determine whether or not facilities are in compliance remains with CMS, which utilizes results of surveys conducted by State survey agencies or those accrediting organizations which have Medicare CAH or RHC accreditation programs approved by CMS under Part 488.

Comment: Several commenters remarked that while the proposed rule introduces welcome changes to § 485.631(b)(2), the rule did not propose to modify the very similar requirements at § 485.631(b)(1)(v) that address physician review of outpatient records.

If left unchanged, these requirements for the bi-weekly physician review of outpatient records would appear to be in conflict with the original proposal. Commenters stated that, as proposed, the new rules would create a dual standard that would be confusing and would contribute to the administrative burden for rural healthcare facilities and CAHs. One commenter specifically requested clarification of existing requirements at § 485.631(b)(1)(vi), which are related to the proposed regulation but were not addressed in the proposed rule. The requirements at § 485.631(b)(1)(vi) state that a doctor of medicine or osteopathy is not required to review and sign outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants where State law does not require record reviews or co-signatures, or both, by a collaborating physician.

The commenter suggested clarification was needed in either the regulatory text or in the State Operations Manual at Appendix W regarding this issue. The commenter stated that some jurisdictions are struggling with the interpretation and applicability of this CoP standard. The commenter suggested that, where there are no affirmative statements in State law explicitly requiring such record reviews, none should be required. The commenter stated that some States that do not have explicit record review requirements are in fact requiring them because of their confusion about the current CoP standard.

Response: We agree with the commenters that continuing to require a bi-weekly schedule for physicians to review and sign a sample of outpatient records of patients cared for by non-physician practitioners, as set forth at § 485.631(b)(1)(v), does not fully align with our initial, more limited, proposal. We believe the changes suggested by the commenters are appropriate and in keeping with the burden reducing goals of our initial proposal to eliminate the prescriptive 2-week physician on site visit requirement at § 485.631(b)(2).

We also appreciate the commenter's remarks about the confusion at § 485.631(b)(1)(vi) regarding a physician's responsibility to review outpatient records. Section § 485.631(b)(1)(vi) states that a physician "is not required to review and sign outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants where State law does not require record reviews or co-signatures, or both, by a collaborating physician." Section 485.631(b)(vi) was

intended to mean that, if the applicable State law does not require a record review or co-signature, or both, by a collaborating physician, then CMS would not require the periodic record review described at § 485.631(b)(v).

Because we recognize that there has been confusion about the interaction of the current requirements of § 486.631(b)(v) and (vi), we are revising the regulatory language at § 485.631(b)(1) to address these concerns. We believe the changes suggested by the commenters are appropriate and in keeping with the burden reducing goals of our initial proposal to eliminate the 2-week physician on site visit requirement at § 485.631(b)(2). We agree with the commenters and have removed the language requiring biweekly outpatient record review.

Specifically, we will delete § 485.631(b)(1)(vi) and will revise the regulatory language at § 485.631(b)(1)(v) to state that a Medical Doctor (MD) or Doctor of Osteopathy (DO) must “periodically” review and sign a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants only to the extent required under State law where State law requires record reviews or co-signatures, or both, by a collaborating physician. If the applicable State law does not require a record review or co-signature, or both, by a collaborating physician, then CMS does not require such periodic record review.

We note that there is no regulatory requirement for the review of records to be performed onsite and in person. Thus, if the CAH has electronic medical records that can be accessed and digitally signed by the MD or DO, this method of review is acceptable.

Comment: One commenter requested clarification of the term “outpatient,” as used in § 485.631(b)(1)(v). The commenter wondered whether the term “outpatient” referred only to hospital-based outpatient services such as the Emergency Department.

Response: We interpret the term “outpatient,” for the purposes of the CoPs, to mean all patients receiving CAH services other than those who have been admitted as an inpatient on the basis of an inpatient admission order. It would include patients receiving observation services, emergency department services, same-day surgery services, and any other form of ambulatory care services.

Comment: One commenter suggested that, in addition to modifying the 2-week onsite requirement, that CMS should include a provision that would

explicitly state the necessity of ensuring immediate availability of a physician with relevant training and expertise, whereby “immediate availability” would include contact by electronic or telephonic means, without delay, and interruptible. The contacted physician and means of communication should be such that it is possible for the physician to furnish appropriate assistance and direction throughout the performance of the procedure and inform the patient of provisions for post-procedural care, and such shall be contained in the standardized procedure or protocol.

Response: The CAH conditions of participation provide a regulatory structure that we believe promotes and facilitates the availability of health care professionals, including availability using electronic communications, to provide care to rural communities. We note that the requirements at § 485.618, Condition of Participation—Emergency Services, provides for immediate physician access in the event emergency care is needed. In particular, § 485.618(e) requires a CAH to have established procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

Comment: One commenter supported the proposal but urged CMS to make it clear that only the frequency requirement would change; the role of the medical director would stay the same for a CAH, RHC, or FQHC.

Response: We agree with the commenter’s assessment and would like to emphasize that the role of the medical director of the CAH, RHC, or FQHC remains unchanged by our proposal. We are amending the regulations with respect to the prescribed frequency of a physician’s on-site presence at a CAH, RHC, or FQHC.

In accordance with the comments discussed above, we are finalizing the changes to §§ 485.631(b)(2) and 491.8(b)(2), as proposed. We are also revising § 485.631(b)(1)(v) to require that a sample of outpatient records be periodically reviewed.

3. RHC/FQHC Definitions: Physician (§ 491.2)

We proposed to revise the definition of “physician” at § 491.2 to more closely conform with the definition of “physician” that appears under the rules governing payment and Medicare agreements with RHCs and FQHCs in

Part 405 at § 405.2401(b). We proposed to revise the definition to include (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the function is performed; and (2) within limitations as to the specific services furnished, a doctor of dental surgery or of dental medicine, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor (see section 1861(r) of the Act for specific limitations). Our proposal also specified that a physician meet the requirements of sections 1861(r), 1861(aa)(2)(B), and 1861(aa)(3)(B) of the Act.

We received a total of 40 comments on our proposed changes to § 491.2 from accrediting bodies, consumer advocacy organizations, individuals, and national health care provider organizations. Overall, the majority of commenters disagreed with the proposed changes. Here we respond to specific comments.

Comment: An overwhelming majority of commenters stated that they did not want to see an expansion of the definition of a physician beyond an MD or DO; these comments appeared to be rooted in a concern for patient safety and for proper legal oversight. They expressed the concern that changing the definition would create a conflict in §§ 491.7(a)(1) and 491.8 regarding physician responsibilities and the duties in performing oversight for an RHC/FQHC and providing medical care services. Many commenters apparently interpreted the proposed change as allowing a chiropractor, optometrist, or dentist to supervise nurse practitioners and physician assistants. For example, one commenter stated that they were not aware of any State that would permit a PA to be supervised by anyone other than a medical doctor (MD) or an osteopathic doctor (DO).

The commenters expressed concern that by altering the definition of a physician, CMS would be extending the scope of practice for certain non-physician practitioners in RHCs and FQHCs, as well as eliminating the requirement for medical direction and oversight by MDs and DOs in these facilities.

Commenters noted that, unlike the training for a dentist, optometrist, podiatrist, or a chiropractor, the broad curriculum for MDs and DOs trains medical students on all organ systems, including the important aspects of preventive, acute, chronic, continuing, rehabilitative, and end-of-life care.

Some commenters also expressed concern that other practitioners with significantly less training than MDs and DOs are promoting themselves as “physicians,” resulting in confusion

among patients. They stated that extending the definition would exacerbate this problem because the public currently finds it difficult to differentiate among various professionals and that allowing para-professionals to use the word “physician” would only complicate the issue.

A few commenters requested that we revise the definition to have it exactly conform to the definition in 42 CFR 405.2401 to specifically include residents. Another commenter stated that nurse practitioners should be included in the definition of “physicians” or listed with physicians as a qualified provider wherever the terms “physician” or “physician services” are used.

Conversely, several commenters agreed with expanding the definition. One commenter was unclear as to what impact the definition change would have on the cost of services in the RHC or the ability of an RHC to provide services in compliance with applicable state law.

Response: Our proposal did not—and was not intended to—change or remove the statutory supervision requirements at sections 1861(aa)(2)(B) and (aa)(3) of the Act. Rather, our intent was to clarify that other categories of physicians are permitted to practice in RHCs and FQHCs to the extent allowed by the Act and by the law of the applicable state. The Act requires a non-physician directed clinic to have an arrangement with one or more physicians (an MD or DO as described in 1861(r)) under which provision is made for an MD or DO to provide periodic reviews of services furnished by physician assistants and nurse practitioners, and to prepare medical orders to care and treat patients. Also the MD or DO must be available for consultation, patient referrals, and for advice and assistance in the management of medical emergencies.

As pointed out by a commenter, we also are not aware of any state that would allow anyone other than an MD or DO to supervise non-physician practitioners (NPPs). We stated in the proposed definition change that, within limitations as to the specific services furnished, the definition of a physician (as provided in section 1861(r)) would also include a doctor of dental surgery or of dental medicine, a doctor of optometry, podiatry, or chiropractic. However, as we reviewed the public comments regarding the proposed revision and considered the wide range of comments, it became apparent to us that most commenters had either misinterpreted or not fully understood

the proposed revision. Also, making this conforming change will not impact the cost of services in the RHC or the ability of an RHC to provide services in compliance with applicable state law. With respect to the comment to include residents in the list of physicians, we do not believe that we need to specifically list residents because they are already captured under the category of physicians.

We believe that most of the commenters misinterpreted the proposed definition because we referred to the oversight functions of a doctor of medicine or osteopathy (MD/DO) by providing only the statutory citations without further discussion and that it was not apparent to the commenters that we were not instead proposing to change the oversight roles of an MD or DO. Therefore, we are clarifying our proposed definition of a physician in this final rule by stating the specific functions of a doctor of medicine or osteopathy required in the statute (sections 1861(aa)(2)(B) and (aa)(3) of the Act). We will change the definition as follows: “Physician means the following: (1) As it pertains to the supervision, collaboration, and oversight requirements of sections 1861(aa)(2)(B) and (aa)(3) of the Act, a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and (2) Within limitations as to the specific services furnished, a doctor of dental surgery or of dental medicine, a doctor of optometry, a doctor of podiatry or surgical chiropridy or a chiropractor (see section 1861(r) of the Act for specific limitations).”

4. Technical Correction

We proposed to correct 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 an NP, PA, or certified nurse-midwife (CNM) be available to furnish patient care at least 50 percent of the time the RHC operates.

Comment: The few comments that we received on this proposed correction agreed with making the technical change in the regulation to conform to the statute which requires an NP, PA, or certified nurse-midwife (CNM) to be available to furnish patient care at least 50 percent of the time the RHC operates.

Response: We appreciate the comments on this proposed change and will finalize it as proposed.

5. Comments Beyond the Scope of This Rulemaking

Comment: One commenter recommended that CMS revise rules for physician supervision of outpatient therapies in CAHs to recognize the unique patient access issues and physician and nurse shortages in remote, rural areas.

Other commenters recommended that CMS should eliminate requirements for physician supervision of nurse practitioners and other Advanced Practice Registered Nurses (APRNs). The commenters requested an explanation into why review of non-physician practitioners was necessary. One commenter explained that, in his particular state, advanced practice nurses are allowed to practice independently, and physician assistants can practice with the appropriate physician supervision. The commenter wondered why medical record review was required in CAHs, RHCs, and FQHCs. The commenter stressed that in his state, non-physician practitioners can even set up their own clinics with the right supervision, all without any medical records review.

Some commenters stated that in many cases, Medicare coverage rules arbitrarily determine which “physician” services are restricted to doctors of medicine and osteopathy only and which are permissible for nurse practitioners and other APRNs to provide. Commenters also recommended that nurse practitioners should be included in the definition of “physician” or listed with physicians as a qualified provider wherever the terms “physician” or “physician services” are used.

Some commenters favoring the proposal described their support for what they described as “the agency’s recognition of the ability of nurse practitioners and other staff to provide critical medical services to patients without the supervision of physicians.” Some commenters expressed the view that licensed advanced nurse practitioners, if licensed to practice independently in their state, could more realistically and effectively fulfill this obligation within a time frame mutually agreed upon in accordance with the clinic’s needs.

One commenter stated most RHCs are unable to participate in electronic health record incentives. The commenter urges CMS to support passage of the Rural Health Clinic Fairness Act of 2013 (H.R. 986), a bill introduced in the U.S. House of Representatives on March 6, 2013.

Several commenters stated that the list of medication classes in Part 491 may be overly specific and outdated. They suggested that we require the medical staff to review and agree upon a list of emergency supplies appropriate to the particular practice.

One commenter recommended that CMS re-evaluate the laboratory requirements to determine whether the six tests required to be available in the RHC are relevant and appropriate.

Response: We appreciate these comments and, while they are beyond the scope of this rule, we will consider these suggestions for future rulemaking.

Contacts for rural health and primary care CoP/CfC issues: Mary Collins, (410) 786-3189.

G. Solicitation of Comment on Reducing Barriers to Services in Rural Health Clinics (RHCs)

We requested comments on potential changes we could make to regulatory or other requirements to reduce barriers to telehealth, home health, hospice, or other services provided by RHCs. We requested that commenters include an explanation of why the service is needed, the barriers to providing the service, and possible solutions that comply with our legislative authority and the need for administrative accountability. We did not propose any policy changes for RHCs in these areas.

We received a total of 23 comments from national and state professional associations, state medical societies and associations, individual and group practitioners, health care systems, and consumer advocacy organizations. Commenters were appreciative of CMS's efforts to eliminate unnecessary, obsolete, and excessively burdensome regulations, and provided many thoughtful comments and suggestions to remove barriers to telehealth, home health, hospice, and other services provided by both RHCs and Federally Qualified Health Centers (FQHCs).

1. Telehealth

In the proposed rule, we stated that RHCs that are located in rural Health Professional Shortage Areas (HPSAs), or in counties outside of Metropolitan Statistical Areas (MSA), are authorized by law to be telehealth originating sites (the location of an eligible Medicare beneficiary at the time the service is furnished via a telecommunications system). We also stated that the statute authorizes physicians, nurse practitioners, physician assistants, certified nurse midwives, clinical nurse specialists, clinical psychologists, clinical social workers, and registered dietitians or nutrition professionals to

be distant site providers (practitioners furnishing covered telehealth services), and that the statute does not include RHCs as distant site providers. FQHCs are also statutorily authorized to be telehealth originating site providers, and are also not included in the statutorily authorized list of distant site providers of telehealth.

We noted that RHC practitioners may be eligible to furnish and bill for telehealth distant site services when they are not working as an RHC practitioner at the RHC, but they cannot furnish and bill for telehealth services while working as an RHC practitioner because RHCs are not authorized distant site providers. Also, these practitioners cannot bill Medicare Part B while they are working for a Medicare RHC since Medicare is paying the RHC through the Medicare RHC cost report an all-inclusive rate per visit that includes all direct and indirect costs, such as the practitioner's services, space to provide those services, support staff services, related supplies, records costs, and other services. To allow separate Medicare Part B physician fee schedule payments to a practitioner while that practitioner is working for the RHC would result in duplicate Medicare payment for the telehealth service; once through the Medicare RHC cost report and again through the Medicare Part B physician fee schedule payment. This would also apply to FQHCs.

Due to the lack of resources in many rural areas for health services, especially mental health services, and the potential for telehealth to increase access to care, we asked for comments on ways to allow RHC practitioners to furnish distant site telehealth services in compliance with our statutory authority and without resulting in duplicate payment or increased cost reporting and compliance burdens.

Comment: A commenter asked for a statutory citation that identifies any service site as an authorized distant site provider of telehealth services. The commenter stated that the statute does not limit distant site providers to specific locations, and that the statute does not limit payment for telehealth services to providers billing under the Medicare physician fee schedule. The commenter suggested that Medicare establish a new revenue code and pay RHCs the all-inclusive rate for distant site telehealth services if the service qualifies and is furnished by an authorized telehealth provider.

Response: The statutory provisions related to telehealth are located in section 1834(m) of the Act. The Act lists specific sites that may serve as originating sites for telehealth, and

includes RHCs and FQHCs. The Act defines "distant site" as "the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system." It then defines "physician" as having "the meaning of that term in section 1861(r), and defines "practitioner" as having the meaning given that term in section 1842(b)(18)(C)." Since neither the definition of "physician" nor the definition of "practitioner" includes RHCs or FQHCs, we do not believe that RHCs or FQHCs are authorized under the statute to be distant site providers of telehealth services. Establishing a new revenue code would not alleviate the requirement for a service to be statutorily authorized in order to receive payment.

Comment: Several commenters expressed their support of appropriate uses of telehealth and telemedicine services if policies are in place to assure quality of care. The commenters stated that the expansion of telehealth services should be based on analysis and evidence that shows improved access and outcomes without lowering quality of care or resulting in a two tiered system of care. They emphasized the role and responsibility of physicians in assuring quality of care and supervising non-physician practitioners and technicians furnishing telehealth services. The commenters recommended that we work with stakeholders to implement policies to ensure that physicians remain part of a patient's medical team and the technology is used to enhance the delivery of medical care.

Response: We thank the commenters for their support of using technology to enhance access to health care and their emphasis on maintaining quality of care.

Comment: A commenter suggested that RHCs bill an encounter code for a specialist or LCSW visit if the telemedicine visit is provided by the RHC, and that the RHC would pay the specialist or the LCSW.

Response: We assume that this commenter is suggesting that the RHC be allowed to carve out the telehealth service from the RHC cost report and allow specialists and LCSWs to bill an encounter on the physician fee schedule. While we appreciate the comment, telehealth is a Medicare Part B service, and RHCs and FQHCs cannot bill for Part B services that are part of the RHC or FQHC benefit during RHC or FQHC hours of operation.

Comment: A commenter expressed support for RHCs to provide distant site telehealth services for primary health

care and specialty consultation, and recommended that CMS issue regulations to allow RHCs to provide and adequately bill for distant site telehealth services.

Response: We thank the commenter for their support of RHCs and the use of telehealth services. Since RHCs are not statutorily authorized to be distant site providers of telehealth services, we are unable to issue regulations that would allow RHCs to provide and bill for distant site telehealth services.

Comment: A commenter suggested that we modify the definition of a visit at 42 CFR 405.2463 to remove the face-to-face requirement that could prohibit telehealth sessions from qualifying as a visit in RHCs and FQHCs, and revise the regulations defining “incident to” services (42 CFR 405.2413, 405.2415, and 405.2452) to include telehealth services. The commenter also suggested that we modify our policies to allow billing of two visits if a telehealth visit occurs on the same day as another office visit.

Response: The commenter correctly notes that for RHCs and FQHCs to be reimbursed under the all-inclusive rate, there must be a face to face encounter between the RHC or FQHC practitioner and the patient, and that this requirement would need to be modified in order for RHCs and FQHCs to be able to bill for a telehealth visit. However, since RHCs and FQHCs are not statutorily authorized to serve as distant site providers of telehealth services, we do not believe that revising the face to face requirement for telehealth services in RHCs and FQHCs would enable RHCs and FQHCs to bill for an RHC or FQHC visit that is provided via telecommunications.

The commenter also suggested that we revise the regulations defining “incident to” services so that telehealth services could be included in the definition of “incident to” services. “Incident to” services are included as costs on the cost report and are not separately billable as an RHC or FQHC visit. We will consider the commenter’s suggestion as a possible topic for future rulemaking.

Comment: A commenter proposed that we recognize RHCs as clinician sites for the provision of telehealth services and suggested two options for RHCs to be reimbursed for these services. The first option would be to allow RHCs to be paid under Part A and have reasonable costs for the telehealth equipment and connectivity defined as allowed charges. The second option would be to allow Medicare telehealth costs to be offset by Medicare Part B payment, up to 100 percent of costs, and

treat allowed telehealth costs in excess of payment as allowable RHC costs.

Response: As previously discussed, RHCs and FQHCs are not statutorily authorized to furnish distant site telehealth services, and therefore cannot bill this as an RHC or FQHC visit. RHCs and FQHCs also cannot bill Part B for a RHC or FQHC covered service while operating as an RHC or FQHC, as that would result in duplicate payments. However, we intend to explore whether some costs associated with telehealth services provided “incident to” an RHC or FQHC visit could be considered allowable costs.

Comment: A commenter stated that telehealth services are critically important in rural areas and Medicare should more broadly include and reimburse for telehealth services in the RHC program.

Response: We agree that telehealth services are important in rural areas and will continue to consider ways we could more broadly include and reimburse for telehealth services, especially in rural areas.

Comment: A commenter suggested that we consider eliminating the HPSA/non-MSA geographical requirements for patients receiving telehealth services; eliminate separate billing procedures for telemedicine; reimburse for telehealth services furnished by physical, respiratory, occupational, and speech therapists, licensed professional counselors and therapists, and social workers; increase reimbursement for the originating telemedicine sites; and provide reimbursement for store and forward applications. The commenter also made several recommendations regarding the credentialing and privileging of telehealth providers and facilities.

Response: Carrying out these recommendations would require statutory changes. Therefore we are unable to act on these suggestions.

2. Hospice

In the proposed rule, we stated that the hospice statute (section 1861(dd) of the Act) authorizes physicians and NPs to be attending physicians for Medicare beneficiaries that elect the Medicare hospice benefit, and that because RHCs are not statutorily authorized to be hospice providers, RHCs can only treat hospice beneficiaries for medical conditions not related to their terminal illness. FQHCs are also not statutorily authorized to be attending physicians for hospice and also can only treat hospice beneficiaries for medical conditions not related to their terminal illness.

We noted that RHC practitioners may be eligible to furnish and bill for hospice services when they are not working as an RHC practitioner at the RHC, but they cannot furnish and bill for hospice services while working as an RHC practitioner because RHCs are not authorized hospice providers. Also, these practitioners cannot bill Medicare Part B while they are working at a RHC since Medicare is paying the RHC an all-inclusive rate per visit that includes all direct and indirect costs, such as the practitioner’s services, space to provide those services, support staff services, related supplies, records costs, and other services. To allow separate Medicare Part B physician fee schedule payments to a practitioner while that practitioner is working for the RHC would result in duplicate Medicare payment for the hospice services; once through the Medicare RHC all-inclusive rate and again through the Medicare Part B payment. We inadvertently omitted FQHCs from this discussion in the proposed rule, and note that this applies to them as well.

We acknowledged that in some rural areas, the RHC may be the only source of health care in the community, and there may be no other providers available during RHC hours to provide services that are related to the beneficiaries’ terminal illness. This also applies to FQHCs. We specifically asked for comments on ways to allow RHC practitioners to furnish hospice services in compliance with our statutory authority and in a way that will not result in duplicate payment or increased cost reporting and compliance burdens, especially in areas with limited hospice providers.

Comment: Several commenters noted that some RHCs and FQHCs are reluctant to refer their patients to hospice care, and some beneficiaries may be reluctant to elect the hospice benefit, because they might no longer be able to receive care from their RHC or FQHC provider, and that this is especially problematic in rural areas where there may not be other available providers.

Response: We understand this concern and are interested in identifying and removing barriers to hospice care, especially in rural communities.

Comment: A commenter suggested that RHCs be allowed to provide hospice services and that reimbursement for hospice services provided by the RHC be treated as if that service had been provided in the RHC face-to-face encounter with the RHC provider.

Response: We thank the commenter for the suggestion, but RHC practitioners are not authorized to be hospice attending physicians, and reimbursing RHCs for hospice care would result in duplicate payment because the hospice is already being paid for these services.

Comment: Some commenters suggested that we allow RHC practitioners, or the RHC, to bill Part B for attending physician services furnished during RHC hours of operation, and carve this out of the RHC cost report, since they are non-RHC services.

Response: The RHC cannot bill Part B for hospice services, as RHCs are not hospice providers. However, we will consider for future rulemaking whether there may be limited situations where RHC and FQHC practitioners may be allowed to furnish certain items and services comprising hospice-related care during RHC or FQHC hours of operation and carve out all costs associated with the provision of the care.

Comment: Some commenters stated that attending physician visits are similar to most other physician visits that are billed under CPT evaluation and management codes. The commenters suggested that physicians or NPs that are employed by RHCs serve as a hospice patient's attending physician, and the RHC could bill for physician services using CPT codes, as they do with other physician services, so that the physician did not have to enroll in Part B.

Response: We appreciate the suggestion, but RHCs and FQHCs cannot bill Part B for physician services unless they terminate their RHC or FQHC certification and enroll as a Medicare Part B provider or supplier.

Comment: Some commenters stated that because PAs always work with physicians, and in some rural areas they may be the only practitioner on site, they should be authorized to provide hospice services.

Response: PAs are important members of the health care team and we understand that a PA may be the only provider immediately available in a rural area. However, authorizing PAs to provide hospice care would require a statutory change.

Comment: A commenter stated that the language in the proposed rule indicates that CMS is contemplating ways that RHCs could become qualified hospice providers, and that RHCs acting as a hospice organization should be required to meet the same conditions of participation, rules, and standards as all other Medicare-certified hospices.

Response: It was not our intent to indicate that we are contemplating ways

for RHCs to become qualified hospice providers.

Comment: A commenter suggested that in order to ensure that RHC practitioners are appropriately paid for services related to a hospice patient's terminal diagnosis without duplication and without a special hospice "carve out", CMS could unbundle a portion of practitioner visits and payments that currently represent services provided for a hospice patient's terminal condition and then analyze the data to estimate an appropriate "add-on" that RHCs could be reimbursed for attending physician services on a per-capita basis. The commenter also suggested that CMS consider establishing a revenue code for services provided to hospice beneficiaries, collect data about those services on the cost report, modify cost reporting principals to make these services an allowable cost, and then account for them in the updates to the payment formula for RHCs.

Response: We appreciate these suggestions; however, they would require statutory changes.

3. Home Health

In the proposed rule, we stated that RHCs that are located in areas with a shortage of home health agencies are authorized to provide nursing care furnished by a registered nurse or a licensed practical nurse to a homebound individual, and that the care must be provided under a written treatment plan that is established and periodically reviewed by a physician, NP, or PA. We also noted that there are relatively few RHCs that provide this service, and we sought comments on whether there is a need for home health services in communities served by RHCs, if there are barriers to providing these services, and if so, what are some possible strategies to reduce or eliminate the barriers.

Comment: A commenter stated that NPs are a key component in the re-engineering of health care and vital to a coordinated care model, and requested that they be allowed to order and certify patients in need of home health care services.

Response: We agree that NPs are important team members in the provision of coordinated care. However, sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act mandate that only a physician is permitted to certify or recertify a patient as eligible to receive Medicare home health services.

Comment: A commenter stated that one of the difficulties RHCs face in providing home health services is that there is a lack of definition on what

constitutes a home health service area or a home health service shortage area.

Response: We thank the commenter for identifying this issue. Unlike primary care, dental, or mental health shortage areas, there is currently no federal determination of home health shortage areas.

Comment: A commenter suggested that home health providers and home health patient stakeholder communities should determine what constitutes a home health shortage area.

Response: We agree that input from the community could be very beneficial in informing these determinations and encourage community input to the extent possible when considering home health services.

Comment: A commenter suggested that CMS broaden the physician types eligible to establish and review home health plans of care to include optometrists, and suggests that by allowing more physician types to order appropriate home health services, barriers to care will be removed.

Response: Section 1861(r) of the Act defines a physician as a doctor of optometry for purposes of "outpatient physical therapy services" as described at 1861(p) of the Act and "medical or other health services" as described at section 1861(s) of the Act. Section 1861(s) of the further describes "medical or other health services" as things such as physician services (general), psychologist services, and nurse-midwife services. Home health services are not included the "medical or other health services" section of the Act; rather, home health requirements are described in sections 1861(m) and (o) of the Act. Therefore, while we appreciate the comment, a doctor of optometry is not recognized by the Act as being eligible to perform home health services.

Comment: A commenter noted that 42 CFR 405.2416(b) includes personal care services that are covered under Medicare as services that can be provided by RHCs and FQHCs as part of visiting nurse services and recommended that our manuals clarify that this is included in addition to skilled nursing services.

Response: We thank the commenter for noting that this is an allowable service and we will review the manuals to determine whether any revisions are needed.

4. Other Services

In the proposed rule, we stated that we would welcome comments on other barriers to providing RHC services and asked for suggestions for removing those barriers.

Comment: Several commenters requested that we remove the restrictions on contracting with non-physician practitioners in RHCs, and expand our definition of “employ” to include independent contractors.

Response: The proposed rule titled, “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” (CMS-1443-P), published September 23, 2013 (78 CFR 58386), proposed to allow RHCs to contract with non-physician practitioners, consistent with statutory requirements that require at least one NP or PA be employed by the RHC (section 1861 of the Act). The ability to contract with NPs, PAs, CNMs, CP, and CSWs will provide RHCs with additional flexibility with respect to recruiting and retaining non-physician practitioners. Until this proposal is finalized, RHCs can contract with physicians while nonphysicians must be employees of the RHC.

Comment: Several commenters noted that FQHCs can bill Diabetes Self-Management Training (DSMT) as an FQHC visit, and requested that RHCs also be able to bill for DSMT visits.

Response: The commenters are correct that DSMT is a billable visit in an FQHC but not in an RHC. Section 5114 of the Deficit Reduction Act of 2005 amended the Act [1861(aa)(3)] to include DSMT and Medical Nutrition Therapy (MNT) on the list of covered services for FQHCs when these services are furnished by a certified provider who meets the regulatory requirements. It did not add DSMT and MNT to the list of covered services for RHCs. Coverage by RHCs would require a statutory change.

Comment: A commenter requested that we allow health care services to be performed in an RHC when an RHC practitioner is not present, and noted that services such as phlebotomy can be provided by licensed practitioners in unsupervised locations such as a patient home.

Response: The RHC Conditions for Certification, at 42 CFR 491.8(a)(6), currently require that a physician, NP, PA, CNM, clinical social worker, or clinical psychologist be available to furnish patient care services at all times the clinic or center operates. Additionally, the Medicare payment rate assumes that a practitioner is on-site at all times the RHC or FQHC is operating, and includes all the costs associated with the service (for example, practitioner compensation, overhead,

equipment). Therefore, changing this policy could have an impact on the RHC’s or FQHC’s payment rate, as the costs of operating the RHC or FQHC would increase at a time when billable visits were not occurring.

Comment: One commenter encouraged CMS to use its regulatory proposals and payment policy updates as an opportunity to remove remaining regulatory and payment barriers that are reducing consumer access to timely and efficient care and limiting health professionals from practicing to the full extent of their state practice licenses.

Response: When barriers are identified, we will take steps to remove those barriers whenever possible. As the commenter did not specify any particular barriers, we cannot provide a more specific response.

Comment: One commenter suggested that CMS allow physician assistant owned clinics to obtain a National Provider Identifier (NPI) number for purposes of billing Medicare for services.

Response: We appreciate the comment, but Section 1842(b)(6)(C) of the Act prohibits PAs from enrolling in and being paid directly for Part B services. Therefore, Medicare Part B payment can only be made to a PA’s employer (unless the employer is a PA or a group of PAs), and a PA may not directly bill Medicare Part B for Medicare-covered services.

5. Comments Outside the Scope

We received several comments outside the scope of this solicitation for comments. We appreciate and will consider the commenters’ suggestions, but we will not address the comments here.

Contact for RHC & FQHC Comments: Corinne Axelrod, 410-786-5620.

H. Clinical Laboratory Improvement Amendments of 1988 (CLIA)

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. 100-578. The purpose of CLIA is to ensure the accuracy and reliability of laboratory test results for all Americans. Under this authority, which was codified at 42 U.S.C. 263a, the Secretary issued regulations implementing CLIA on February 28, 1992 at 42 CFR Part 493 (57 FR 7002). The regulations specify the standards and specific conditions that must be met to achieve and maintain CLIA certification. CLIA certification is required for all laboratories, including but not limited to those that participate in Medicare and Medicaid, which test human specimens for the purpose of

providing information for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of health, of human beings.

Among other things, the regulations require laboratories conducting moderate or high-complexity testing to enroll in an approved proficiency testing (PT) program that covers all of the specialties and sub-specialties for which the laboratory is certified. There are currently 229,815 CLIA-certified laboratories. Of these laboratories, 35,084 are required to enroll in an HHS-approved PT program and are subject to all PT regulations.

Congress emphasized the importance of PT when it drafted the CLIA legislation. For example, in discussing their motivation in enacting CLIA, the Committee on Energy and Commerce noted that it “focused particularly on proficiency testing because it is considered one of the best measures of laboratory performance” and that proficiency testing “is arguably the most important measure, since it reviews actual test results rather than merely gauging the potential for good results.” (H.R. Rep. No. 100-899, at 15 (1988)) The Committee surmised that, left to their own devices, some laboratories would be inclined to treat PT samples differently than their patient specimens, as they would know that the laboratory would be judged on its performance in analyzing those samples. For example, such laboratories might be expected to perform repeated tests on the PT sample, use more highly qualified personnel than are routinely used for such testing, or send the samples out to another laboratory for analysis. As such practices would undermine the purpose of PT, the Committee noted that the CLIA statute was drafted to bar laboratories from such practices, and to impose significant penalties on those who elect to violate those bars (H.R. Rep. No. 100-899, at 16 and 24 (1988)).

We proposed to make a number of clarifications and changes to the regulations governing PT under CLIA. PT is a valuable tool the laboratory can use to verify the accuracy and reliability of its testing. During PT, an HHS-approved PT program sends samples to be tested by a laboratory on a scheduled basis. After testing the PT samples, the laboratory reports its results back to the PT program for scoring. Review and analysis of PT reports by the laboratory director will alert the director to areas of testing that are not performing as expected and may also indicate subtle shifts or trends that, over time, could affect patient results. As there is no on-site, external proctor for PT testing in a laboratory, the testing relies in large part

on an honor system. The PT program places heavy reliance on each laboratory and laboratory director to self-police their analysis of PT samples to ensure that the testing is performed in accordance with the CLIA requirements. For each PT event, laboratories are required to attest that PT samples are tested in the same manner as patient specimens are tested. PT samples are to be assessed by integrating them into the laboratory's routine patient workload, and the testing itself is to be conducted by the personnel who routinely perform such testing, using the laboratory's routine methods. The laboratory is barred from engaging in inter-laboratory communication pertaining to results prior to the PT program's event cut-off date and must not send the PT samples or any portion of the PT samples to another laboratory for testing, even if it would normally send a patient specimen to another laboratory for testing.

One type of laboratory testing is "reflex testing." By reflex testing, we mean confirmatory or additional laboratory testing that is automatically requested by a laboratory under its standard operating procedures for patient specimens when the laboratory's findings indicate test results that are abnormal, are outside a predetermined range, or meet other pre-established criteria for additional testing. For patient specimen testing, reflex testing may be legitimately performed by the same laboratory that performed the initial testing or may be performed by referral of the patient specimen for testing at a laboratory operating under a different CLIA certificate. For PT, reflex testing is prohibited unless it is performed by the same laboratory that performed the initial testing, is included in that laboratory's standard operating procedure, and the results are reported as part of the proficiency testing program.

Another type of laboratory testing is "confirmatory testing." By confirmatory testing, we mean testing performed by a second analytical procedure that could be used to substantiate or bring into question the result of an initial laboratory test. For patient specimen testing, confirmatory testing may legitimately be performed by the same laboratory that performs the initial test or by a second laboratory operating under a different CLIA certificate than the laboratory performing the initial testing. For PT, confirmatory testing is prohibited unless it is performed by the same laboratory that performed the initial test, is included in that laboratory's standard operating procedure, and the results are reported

as part of the proficiency testing program.

Any laboratory that intentionally refers its PT samples to another laboratory for analysis risks having its certification revoked for at least one year, in which case, any owner or operator of the laboratory risks being prohibited from owning or operating another laboratory for two years (42 CFR 493.1840(a)(8), (b)). The phrase "intentionally referred" has not been defined by the statute or regulations, but we have consistently interpreted this phrase from the onset of the program to mean general intent, as in intention to act. Whether or not acts are authorized or even known by the laboratory's management, a laboratory is responsible for the acts of its employees. Among other things, laboratories need to have procedures in place and train employees on those procedures to prevent staff from forwarding PT samples to other laboratories even in instances in which they would normally forward a patient specimen for testing.

PT samples are not to be referred to another laboratory under any circumstances. However, despite the issuance of considerable guidance and the near-universal inclusion of instructions in laboratory operations manuals, there continue to be cases where PT samples are forwarded to another laboratory for analysis. Laboratory staff are either not being made aware that the prohibition applies even in instances where they would normally forward a patient specimen for additional testing, or, due to failures in training or the lack of clarity of laboratory operating manuals, they fail to abide by the laboratory's written policies prohibiting the referral of PT samples to another laboratory.

For example, some laboratories have indicated that they have been confused by the requirement at § 493.801(b) that laboratories test PT samples in the same manner as patient specimens. If their standard operating procedure is for some types of patient specimens to be sent to another laboratory for reflex or confirmatory testing, they have erroneously believed that there would be a basis for also referring a PT sample. Furthermore, they have strenuously argued that their mistaken interpretation was innocent, and that we should find an improper, but not intentional, referral of a PT sample in those instances.

We disagree with any assertions that such referrals are "improper" but not "intentional" under our long-standing interpretation of "intentional". As noted above, we have consistently interpreted "intentional" to mean general intent, as

in intention to act, and expansive case law has supported this interpretation. That said, we recognize that, in cases of a PT referral involving reflex or confirmatory testing under standard operating procedures, the revocation of a CLIA certificate, combined with the resulting potential prohibition on the owner and operator to own or operate a laboratory for 2 years, may create access issues for patients in need of laboratory services. We also note that laboratory testing protocols have changed over time, and reflex or confirmatory testing has become more prevalent, resulting in an increased risk of PT referral.

We are mindful that all healthcare beneficiaries depend on a functioning PT program conducted in accordance with the regulations and statute to ensure that laboratories provide accurate and reliable test results; however, we recognize that human error can and does occur. For these reasons, we proposed a narrowly crafted exception from the long-standing interpretation of "intentional" to allow for the imposition of alternative sanctions when there is a single instance of PT referral related to reflex, confirmatory, or, as discussed below, distributive testing. Laboratories are obligated to provide staff with clear standard operating procedures and effective training for all current and newly hired employees, and must ensure continued compliance with those procedures to prevent PT referral. Repeat PT referrals, even if related to reflex, confirmatory, or distributive testing, would be considered "intentional" and may be subject to the sanctions of revocation and ban against the owner and operator. A PT referral is a prohibited act and will always involve consequences.

In addition to the already extensive campaign to highlight the bar on PT referrals, we have considered what more we could do to further ensure laboratory awareness of this prohibition. We therefore proposed to make two changes to the CLIA regulations relevant to PT referral. The first proposed change was the addition of a statement to § 493.801(b) to explicitly note that the requirement to test 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 standard operating procedure for patient specimens. This means that, in instances where the laboratory's patient testing standard operating procedures would normally require reflex or confirmatory testing at another laboratory, the laboratory should test the PT sample as they would a patient specimen up until the point

they would typically refer a patient specimen to a second laboratory for any form of further testing. A PT sample must never be sent to another laboratory under any circumstances.

The second proposed change was to establish a narrow exception to our long-standing interpretation of what constitutes an “intentional” referral. We noted, however, that for all other instances in which a PT sample is referred, the standard for “intentional” would continue to be a general intent to act—that is, to send a PT sample to another laboratory for analysis. For the narrow exception to this general rule, we proposed that when CMS determines that a PT sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, confirmatory, or distributive testing, then we would consider the referral to be improper and subject to alternative sanctions in accordance with § 493.1804(c), but not intentional, provided that, if the specimen were a patient specimen, the referral would have been in full conformance with written, legally accurate, and adequate standard operating procedures for the laboratory’s testing of patient specimens, and the PT referral is not a repeat PT referral. Alternative sanctions may include any combination of civil money penalties, directed plan of correction (such as required remedial training of staff), temporary suspension of Medicare or Medicaid payments, or other sanctions specified in accordance with regulation.

By “full conformance” with the laboratory’s written, legally accurate and adequate standard operating procedures we mean that the procedures adequately describe what is to be done, and that what is to be done is in conformance with applicable laws (such as the ban on referring PT samples to another laboratory for analysis). Furthermore, we mean that the referral policy does not afford any discretion to staff as to whether a patient specimen would be forwarded or not. For example, standard operating procedures do not allow for selectivity on the part of the laboratory staff. Rather, they require the application of pre-established criteria that result in a mandate to forward a patient specimen to another laboratory for further analysis. For example, if standard laboratory protocols dictate that all specimens showing HIV-positive test results be sent to a second laboratory for confirmatory testing, but we find that the individual referred only 1 of the 2 positive HIV PT samples, we would consider the referral to be not in conformance with the laboratory’s own

standard operating procedure. In this instance, the laboratory may be subject to the sanctions of revocation and ban against the owner and operator as opposed to alternative sanctions.

By providing that the referral is not a repeat PT referral, we mean that the referral is not a repeat PT referral as defined by § 493.2, as recently amended by the FQHC PPS/CLIA final rule with comment period, published in the May 2, 2014, **Federal Register** at 79 FR 25436. Specifically, there has not been an instance of identified PT referral in the two survey cycles prior to the time of the PT referral in question. Two survey cycles generally equates to a four-year period on average. This is not a precise calendar time period but is carefully recorded as a matter of actual and documented survey event dates. Both CMS and accrediting organizations perform initial surveys at least 3 months but no later than 12 months from the effective date of CLIA certification. Subsequent routine recertification surveys are performed biennially. A survey cycle means the time between an initial survey and recertification survey or the time between a recertification survey and the next recertification survey, and is approximately two years. The time interval from the effective date of the CLIA certificate until the initial certification is also included as part of the initial certification survey cycle. Complaint and validation surveys are performed on a non-routine basis, and are considered to be separate from survey cycles for the purpose of determining the timeframe for two survey cycles.

In other words, a referral would not be considered “intentional” if the CMS investigation reveals PT samples were sent to another laboratory for reflex, confirmatory, or distributive testing, the referral is not a repeat PT referral, and the referral occurred while acting in full conformance with the laboratory’s written, legally accurate and adequate standard operating procedure. The key to this exception is the expectation that laboratories will ensure that improper referrals are addressed and eliminated, or we will find that future referrals are intentional. The exception is meant to be a one-time exception to a finding of an intentional referral by virtue of a general intent to forward a PT sample to another laboratory. Upon learning that the laboratory’s training materials, training, or staff capabilities are inadequate to ensure compliance with the PT referral requirements, we expect the laboratory to correct the problems, and will treat subsequent referrals as “intentional” in keeping with our long-standing practices. We believe that it is

reasonable to expect laboratories to maintain a heightened vigilance for this time-frame to ensure that they do not have any repeated difficulties. We requested public comments on these proposed changes.

When we were in the final steps of preparing our proposed rule for publication, Congress enacted the “Taking Essential Steps for Testing Act of 2012” (Pub. L. 112–202, the “TEST Act”), on December 4, 2012. The TEST Act amended section 353 of the Public Health Service Act to provide the Secretary with discretion as to which sanctions she would apply to cases of intentional PT referrals. We therefore proposed to change the “will” to “may” in the second sentence of § 493.801(b)(4) to ensure conformance with the TEST Act, but we noted that other aspects of implementing the TEST Act would be addressed in additional rulemaking. Accordingly, in the May 2, 2014, **Federal Register** at 79 FR 25436, we published the FQHC PPS/CLIA final rule with comment period, which finalized additional proposals for implementing the TEST Act. We invited comment on the proposed change to § 493.801(b)(4) and on any suggestions or concerns the public may have regarding implementation of the TEST Act.

We received a total of 17 comments on our proposed changes to the CLIA regulations discussed above. The comments came from a variety of sources, including laboratory accreditation organizations, laboratory professional organizations, medical societies, and health care systems. Overall, the commenters were supportive of the proposed changes. They expressed appreciation for the proposed changes to the regulations and for efforts to provide additional clarity around the requirement for laboratories to test PT samples in the same manner as patient specimens. Commenters applauded CMS’ efforts to enable more flexibility in the application of penalties and corrective actions under specific circumstances. No commenters opposed the changes. We respond to specific comments below:

Comment: We received one comment that described a laboratory process called “distributive testing.” The commenter described “distributive testing” as a situation in which one laboratory may perform “pre-electrophoretic testing” for protein electrophoresis (a method used by laboratories to separate molecules according to their size and electrical charge) and a portion of the specimen is sent to a second laboratory, with a different CLIA certificate, to perform the

actual electrophoresis. Similarly, serum protein electrophoresis requires a total protein result as well as the electrophoretic results to calculate the percentage of each serum protein components in the five major fractions. The lab performing the electrophoresis may not have the instrument required to measure total protein and typically might send the patient specimen to another lab for this result to be later used in the calculation.

The commenter asks if PT referrals that occur during such distributive testing are included in the exception established in this change.

Response: The situation described by the commenter does not conform to the definition of “reflex” or “confirmatory” testing as described in the proposed definitions. In this scenario, the electrophoresis testing is not performed because pre-electrophoretic test results are abnormal, outside a predetermined range, or used to substantiate the result of an initial laboratory test. Unlike reflex and confirmatory testing which are conditional options based upon the initial test results, distributive testing is understood to be standard practice for all patient specimens associated with a specific test. However, we agree with the commenter that there are sufficient similarities between distributive testing and reflex and confirmatory testing, that it would be appropriate to include distributive testing in the narrow exception we proposed.

We have therefore added a definition of distributive testing at § 493.2 to mean laboratory testing performed on the same specimen, or an aliquot (portion) of it, that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test. When such testing occurs at multiple locations with different CLIA certificates, it is considered distributive testing. We have added the term “distributive testing” to § 493.801(b) and § 493.801(b)(4) so that distributive testing is treated in the same manner as reflex or confirmatory testing.

Comment: One commenter requested clarification of the term “first offense” and asks if a second offense would be charged only if the exact same circumstances caused a second improper referral.

Response: While we did not use the term “first offense” in the proposed rule, it is important to note that the narrow exception is intended to be a *one-time* exception to a finding of intentional referral. Any instance of PT referral occurring within two survey

cycles subsequent to an incident that meets the criteria described in the narrowly crafted exception, whether or not the referral involves reflex, distributive, or confirmatory testing, will be treated as “intentional” and may result in the revocation of the CLIA certificate and the two-year prohibition from owning and operating a laboratory against the owner and operator.

Comment: One commenter asked how CMS will handle increased automation incidents of PT referral.

Response: Incidents of PT referral that are related to an automated laboratory process and rule-based laboratory computer systems have generally been associated with reflex or confirmatory testing. In these cases, alternative sanctions would be applied if the circumstances meet the defined criteria in the exception to the determination of “intentional” PT referral and the incident is not a repeat PT referral as discussed above. If the “automatic incident of PT referral” is not a direct result of the laboratory’s standard operating procedure for reflex or confirmatory testing or distributive testing, the laboratory would not meet the criteria for this exception.

Comment: One commenter expressed concern about the sanctions against the director of a laboratory found to have referred a PT sample. The commenter believes if a laboratory’s PT referral meets the criteria in the exception, then the laboratory director should be allowed to continue directorship of the laboratory without receiving any alternative sanctions.

Response: Revocation of the CLIA certificate is a principal sanction. In the narrowly carved out exception, alternative sanctions are applied in lieu of the revocation of the CLIA certificate. Alternative sanctions may include a directed plan of correction, civil money penalty, state onsite monitoring, or suspension of Medicare payments. Alternative sanctions are enforcement actions taken against the laboratory and not an individual such as the laboratory director. Because the CLIA certificate would not be revoked as the result of a single instance of PT referral meeting the criteria in the narrowly crafted exception, the laboratory’s owner and operator would not be subject to the two-year prohibition from owning and operating a laboratory as a direct result of this incident.

Comment: One commenter asked how CMS will ensure Regional Offices and State Surveyors are consistent in the application of these changes and the associated enforcement.

Response: CMS will continue the current process that requires all

suspected PT referral cases be forwarded to central office for review by a team of experts. The team will continue to thoroughly review every case to determine whether the facts support a determination of PT referral and also if the facts in the case meet the criteria described in this exception. Written guidance and training will be provided to the Regional Offices and State Agencies.

Comment: We received several comments that urged CMS to broaden the proposed exception to take in account honest mistakes made by individuals and other situations that should be eligible for more lenient enforcement.

Response: Because each case of PT referral is unique, every situation cannot be anticipated and discretely defined. The narrow exception created in this rule recognizes that mistakes do occur and we are finalizing the exception as proposed with the sole addition of distributive testing. See also our response to the next comment.

Comment: We received one comment that urged CMS to fully implement the TEST Act now rather than engaging in multiple rulemakings on same topic. The commenter noted that this rule does take some steps toward the use of discretion in PT referral cases, but expresses concern that the changes are too limited.

Response: We proposed a change in the regulations that would acknowledge the Secretary’s discretion under the TEST Act, and we invited comments on this proposal as well as any suggestions or concerns about the additional rulemaking that would be needed to implement the TEST Act. The TEST Act provides the Secretary with the ability to achieve a better correlation between the nature and extent of intentional PT referral and the type and scope of sanctions or corrective actions that are imposed. We agree with the commenter that we should implement the TEST Act as soon as possible. We believe that the TEST Act will allow for policies that are in the best interests of patients, as well as promote efficiency and effectiveness in corrective action by laboratories. We are therefore finalizing the proposal to change “will” to “may” in the second sentence of § 493.801(b)(4) to ensure that this section is in compliance with the TEST Act. In the May 2, 2014, **Federal Register** at 79 FR 25436, we published the FQHC PPS final rule, which finalized additional proposals for implementing the TEST Act.

Comment: Two commenters stated that waived laboratories should be exempt from penalties associated with

PT referral since they are not required by law to participate in PT.

Response: While this comment is outside the scope of this rule, we would like to emphasize that the CLIA statute (42 U.S.C. 263a) states that laboratories holding a certificate of waiver are only exempt from subsections (f) and (g) of the statute. All other subsections apply, including the prohibition against PT referral and the statutory consequences established in subsection (i). Therefore, the statutory requirements under subsection (i) do apply to waived laboratories. Furthermore, subsection (i) of the CLIA statute refers to “any laboratory” that the Secretary determines has intentionally referred its proficiency testing samples. For these reasons, waived laboratories are not exempt from the ban against the referral of PT samples and the penalties required when PT referral has been substantiated.

We also note that we received other comments outside the scope of this rulemaking that we will not address here. We thank the commenters for their input and suggestions.

After consideration of the comments discussed above, we are finalizing the definitions for “confirmatory testing” and “reflex testing” and the changes to § 493.801(b) introductory text and § 493.801(b)(4) as proposed. Also, in accordance with the comments above, we are finalizing a definition for “distributive testing” and adding references to distributive testing to § 493.801(b) and § 493.801(b)(4).

Contact for CLIA issues: Melissa Singer, (410) 786-0365.

III. Collection of Information Requirements

This final rule does not impose any new information collection, recordkeeping, or third-party disclosure requirements. However, this final rule creates certain savings related to information collection, recordkeeping or third-party disclosure requirements. While we detail all of the estimated savings of this final rule in the regulatory impact analysis, the following paragraph provides a brief summary of the estimated savings associated with the currently approved information collection request (ICR).

This final rule would reduce the reporting requirements for transplant centers and organ procurement organizations. As stated later in the regulatory impact analysis, we are eliminating the reporting requirement at 42 CFR 482.74(a)(2). The requirement is redundant as it is a duplication of data submission under the Paperwork Reduction Act. The same information is

currently being collected by the Health Services and Resources Administration (HRSA) under OMB control number 0915-0157. After the requisite notice and comment periods, we will submit a revision of the currently approved ICR for OMB review and approval.

IV. Waiver of Delayed Effective Date for Revisions to 42 CFR Part 483

We ordinarily provide a 60-day delay in the effective date of the provisions of a major rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d)), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3)), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in effective date if the Secretary finds, for good cause, that such delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued under 5 U.S.C. 553(d)(3) and 5 U.S.C. 808(2).

The Secretary finds that good cause exists to make certain regulatory provisions effective upon publication in the **Federal Register**. Specifically, changes to 42 CFR Part 483 in this final rule are effective immediately upon publication. We believe it is in the public interest to make the LTC facility sprinkler extension provision immediately effective. Absent such timely action, a number of nursing homes will be unable to apply for, and obtain, an extension of the due date to achieve full sprinkler status before mandatory sanctions take effect, despite their taking action to build a replacement facility or undertake major modifications that may qualify the facility for an extension of time under this final rule. Instead, such facilities will be terminated from Medicare participation and their residents will face relocation, or the nursing home will suffer mandatory imposition of a denial of payment for new admission. Section 1819(h)(2)(D) of the Act requires a denial of payment for new admissions for a facility that has been found to be out of compliance with CMS requirements if the facility has not achieved substantial compliance within three months, and Medicare termination must be effected within six months pursuant to section 1819(h)(2)(C).

Without an immediate effective date of this rule, these sanctions will take effect for a number of otherwise qualifying facilities that have been cited for noncompliance, and their residents will experience the effects (including relocation from facilities whose Medicare participation will have been

terminated). While publication of the notice of proposed rulemaking for this regulation occurred on February 7, 2013, well in advance of the August 13, 2013 effective date of the sprinkler requirement, it has not been possible to issue a final rule until now. As more time has elapsed, more otherwise qualifying facilities have been cited for noncompliance and will soon face mandatory sanctions.

We also note that this rule provides discretionary authority for CMS to require that a facility implement additional, interim fire safety measures as a condition for receiving an extension. Interim measures may include, for example, the initiation of a fire watch, installation of temporary exits, installation of temporary smoke detection or smoke alarm systems, and increased fire safety training or fire drills for staff or other means to ensure the continued fire safety of the residents of the facility. We believe that an immediate effective date for all changes in this rule affecting Part 483 is in the best interest of nursing home residents and the public in general. For these reasons, we believe that a delay in the effective date of this provision is contrary to the public interest, and are making the provision effective upon publication.

V. Regulatory Impact Analysis

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly,

we have prepared a Regulatory Impact Analysis (RIA) that, to the best of our ability, presents the costs and benefits of the rulemaking.

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. HHS will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a “major rule” as defined by 5 U.S.C. 804(2). This rule will be effective as specified in the **DATES** section of this final rule, 60 days after

date of publication in the **Federal Register**.

A. Statement of Need

In Executive Order 13563, the President recognized the importance of a streamlined, effective, efficient regulatory framework designed to promote economic growth, innovation, job creation, and competitiveness. To achieve a more robust and effective regulatory framework, the President has 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. This final rule continues our direct response to the President’s instructions in Executive Order 13563 by reducing outmoded or unnecessarily burdensome rules, and thereby increasing the ability of health

care entities to devote resources to providing high quality patient care.

B. Overall Impact

This final rule creates ongoing cost savings to providers and suppliers in many areas. Other changes clarify existing policy and relieve some administrative burdens. We have identified other kinds of savings that providers and patients will realize throughout this preamble. The cost-reducing savings that we were able to estimate are summarized in the table that follows. We requested public comments on all of our burden assumptions and estimates. As discussed later in this regulatory impact analysis, substantial uncertainty surrounds these estimates and we especially solicited comments on either our estimates of likely savings or the specific regulatory changes that drive these estimates. In the table that follows we present our best estimate of likely savings; we later address the uncertainty that surrounds these estimates.

TABLE 1—SECTION-BY-SECTION ECONOMIC IMPACT ESTIMATES *

Issue	Frequency	Number of affected entities	Likely savings or benefits (\$ millions)
Ambulatory Surgical Centers:			
• Radiology Services	Recurring Annually	2,544	41
Hospitals:			
• Food and dietetic services	Recurring Annually	4,900	459
• Nuclear medicine services	Recurring Annually		77
Transplant Centers:			
• Reports to CMS & Survey Changes	Recurring Annually	60	<1
Long Term Care Facilities:			
• Sprinkler Deadline Extension	One-time	125	22
Rural Health:			
• CAH & RHC/FQHC Physician responsibilities	Recurring Annually	9,311	76
• CAH Provision of services	Recurring Annually	665	<1
CLIA:			
• PT Referral	Recurring Annually	3	^a 2
Total	\$679

* This table includes entries only for those reforms that we believe would have a measurable economic effect and for which we were able to prepare estimates.

^a\$2 million represents an upper bound on net societal savings because some portion of the estimated effect may consist of transfers from temporarily-banned lab directors to hospitals or laboratories.

As discussed later in this analysis, our estimates are substantially unchanged from the proposed rule in all but three respects. First, since the proposed rule was issued, the Department has created a working group to review current regulatory impact analysis practices and standards on a Department-wide basis. One area of concern to the working group was improving the accuracy and standardizing a wide variety of methods and calculations currently used to estimate regulatory burdens or savings that involve staff time of regulated entities. The tentative conclusion of the

working group is that estimates of time cost can reasonably use salary data collected for many occupations by the Bureau of Labor Statistics (BLS) of the Department of Labor, but that the hourly wage or salary cost of employees should be doubled to include both fringe benefits (for example, health insurance and retirement) and overhead costs (rent, utilities, and other support costs) in an estimate of total costs or savings. In the proposed rule we had used a factor of approximately 50 percent. Accordingly, we are now adjusting all our estimates of employee time costs to

use a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs also vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the wage or salary cost to estimate total cost is a reasonably accurate estimation method. Second, we have also updated wage and salary costs from 2012 to 2014 dollars. Both these changes increase our burden reduction savings estimates. Third, we are using

considerably more conservative estimates of likely hospital responses and subsequent savings in dietary management and oversight. Our primary estimate is now 75 percent of hospitals adopting these changes and we allow for the possibility that the overall response could be as low as 15 percent. We have also reduced our estimates of the time savings involved. These changes reduce our burden reduction savings estimates.

C. Anticipated Effects

1. Effects on Ambulatory Surgical Centers

The potential cost savings from the reduced ASC radiology services requirements are discussed in the preamble section of this rule addressing those reforms. We have calculated the savings based on the elimination of ASC requirements that are inappropriate and unnecessary in the ASC setting, primarily because some of the requirements are intended for inpatient hospital patients, which would not be applicable in the outpatient ASC setting. We estimate that assuming the average cost for affected facilities to meet the radiology services requirements would have been \$16,000 annually ($\$4,000 \times 4$ quarters), the total savings will be \$40.7 million ($\$16,000 \times 2544$ ASCs).

The assumption for this estimate is based on using ASC facilities across the country that provide orthopedic or pain management procedures, which are the facilities most likely to require a radiologist on staff. We reached out to the Ambulatory Surgery Center Association for assistance on the average cost and usage of radiologists in ASCs across the United States. Based on a survey of ASCs and depending on the market, location of the ASC and frequency of the visits, we utilized a \$4,000 average cost per quarter that ASCs are paying for radiologist fees. In addition, we considered the total number of ASCs affected by the current radiology services requirements at an average 48 percent, or 2,544 ASCs, based on current data and the total number of Medicare certified ASCs (5,300 as of December 2011).

We received the following public comments on our estimated benefits to ASCs:

Comment: Several commenters agreed with our assertion that the proposed regulatory change would create savings for ASCs. Commenters agreed that the existing requirements are overly burdensome and unnecessary and that the changes would create savings in the costs of employing a radiologist.

Response: We agree that the existing requirements are overly burdensome

and unnecessary and we thank the commenters for their support of these changes.

Comment: Several commenters also stated that the revisions will reduce the substantial administrative burden of finding a radiologist. One commenter stated that it is “very difficult to find a radiologist that is willing to assume the responsibility for the ASC. It is also difficult to get a radiologist here in a timely fashion to review our program at the intervals required. This has added both staff time and cost to the Center that has not added value to our patient care.” Another commenter stated that “eliminating the need for a radiologist would help us divert those same financial and labor resources towards more relevant and meaningful projects—such as infection control and patient safety.” Yet another commenter stated that ASCs have reported great difficulty finding radiologists willing to be part of their medical staff, as the intra-operative imaging used at ASCs does not require the specialized knowledge and skill of a radiologist,” and that “many ASCs do not regularly make use of any radiology, but nonetheless must face the burden of appointing a radiologist to their medical staff because on rare occasions they have the need for imaging in conjunction with a procedure.”

Response: We understand and agree with the comment. Since the final rule eliminates the requirement for this unnecessary supervision, these difficulties will disappear. We have not attempted to estimate these administrative savings, absent any data, but they could well be substantial.

Comment: Some commenters stated that, in addition to relieving burden on ASCs, it will also reduce burden for the radiologist who otherwise has no other contact or interaction with the ASC.

Response: We appreciate the comment, which confirms the key point that the existing requirement simply wastes resources. That said, it would double-count savings to estimate a burden reduction for radiologists equal to the burden reduction for ASCs. Radiologists will continue to obtain assignments commensurate with their skills and will continue to be paid for work they perform. The time they currently waste on useless work will become productive in other settings, but there is no reason to think that their amount of paid work will change. The obvious “real” savings from the useless work avoided should be counted only once, and we have described them as accruing to ASCs, the payers. Again, we think that there are benefits, in this case to radiologists who prefer real work to

“make-work”, that we are unable to measure.

Comment: One commenter expressed concern about the new proposal to have an MD/DO who is qualified with appropriate education and training to oversee the radiologic services. The commenter questioned whether additional education requirements might also limit those physicians who would be willing to serve in this capacity, and whether this additional layer could potentially create added costs and be burdensome. The commenter believes that, ultimately, the ASC governing body should have this accountability.

Response: We believe that we have addressed the commenter’s concerns by changing the proposed provision in this final rule to require the governing body be responsible for appointing an individual that is qualified in accordance with State law and ASC policy. We have specifically not included qualification requirements and as stated in the preamble, the appointed individual may be someone already working in the ASC that is qualified to perform the required duties. This change was discussed above in section II.A. of this preamble. In practice, we believe that ASCs already utilize such persons. Accordingly, we have not changed our cost estimates.

Comment: One commenter believes that we have incorrectly identified savings as transfers. The commenter stated that the RIA “suggests that what are clearly reductions in regulatory mandates might actually be “transfers” that do not reduce costs. This is incorrect.” The commenter went on to say “it is not reasonable to assume that eliminating any of those unnecessary costs—costs that exist only because created by previous regulatory mandate—is somehow a transfer of money with no “real” economic effect.” Finally, the commenter said that if we continue to make this argument we “should produce hard evidence from either the economic literature or previous economic analyses from agencies either imposing or eliminating regulatory cost burdens that such burdens are properly labeled transfers, and demonstrate a methodology for calculating how much of such cost burden is a mere transfer and not either an increase or reduction in real economic costs.”

Response: We were concerned about how the elimination of these costs should be presented, given that some of the work done by supervising radiologists in ASCs is redundant, and therefore not useful, but—according to anecdotal evidence—still prevents the

radiologists from using their time for other valuable activities (such as self-directed activities). If the information we have about radiologists' time use is accurate, there is no question that these benefits are correctly categorized as savings. If the information we have is not entirely accurate, the benefits should be categorized as a combination of societal savings and transfers from radiologists to ASCs.

We agree with the commenter that elimination of these requirements is a reduction in "real" regulatory costs and not simply a change in "transfer" payments, as these terms are used by regulatory economists, and have amended the analysis accordingly. We are aware of no evidence suggesting anything to the contrary, either from the economic literature or from prior rulemakings. That said, the point we were trying to make was that productive work would be substituted for unnecessary work (see response to preceding comment). As we believe that the evidence upon which we base our impact analysis is sound, we are categorizing these benefits as savings.

2. Effects on Intermediate Care Facilities for Individuals Who Are Intellectually Disabled

Because we are finalizing only technical corrections to descriptive terminology, we do not estimate any costs or savings for ICFs/IID based on this final rule.

3. Effects on Hospitals

There are about 4,900 hospitals that are certified by Medicare and/or Medicaid. We use these figures to estimate the potential impacts of this final rule. We use the following average hourly costs for registered dietitians, advanced practice registered nurses, physician assistants, pharmacists, and physicians respectively: \$57, \$92, \$93, \$116, and \$192 (BLS Wage Data by Area and Occupation at <http://www.bls.gov/bls/blswage.htm>, adjusted upward by 5 percent to inflate—on a projected basis—to 2014 dollars and by a further 100 percent to include fringe benefits and overhead costs).

Ordering Privileges for Registered Dietitians (RDs) (Food and Dietetic Services § 482.28)

We are revising the hospital requirements at 42 CFR 482.28 (b), "Food and dietetic services," which currently requires that therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients. Specifically, we are revising § 482.28(b)(1) and (2) that would change the CMS requirements to

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 qualified nutrition professional as authorized by the medical staff and in accordance with State law. With these changes to the current requirements, a hospital will have the regulatory flexibility either to appoint RDs to the medical staff and grant them specific dietary ordering privileges (including the capacity to order specific laboratory tests to monitor nutritional interventions and then modify those interventions as needed) or to authorize the ordering privileges without appointment to the medical staff, all done through the hospital's medical staff and its rules, regulations, and bylaws. In either instance, medical staff oversight of RDs and their ordering privileges will be ensured.

As we discussed previously in this rule, a 2010 retrospective cohort study¹ of 1,965 patients at an academic medical center looked at the influence of RDs with ordering privileges on appropriate parenteral nutrition (PN) usage and showed a reduction in medically inappropriate PN usage, which translated to an approximately \$135,233 annual savings to the hospital after RDs were granted ordering privileges; included in this savings estimate were solution, materials and pharmacy labor costs specifically related to PN. In order to estimate the reduced costs that our changes to § 482.28 might bring to hospitals, we based our calculations on this study and its finding of \$135,233 savings for a single hospital that granted ordering privileges to RDs. The study presented its figures in 2003 dollars, and to adjust to a comparable figure in 2014 dollars we used the increase in the Gross Domestic Product deflator over this period. Since that index will be up about 25 percent, our savings estimate, rounded, is \$169,000. We note that Peterson et al.'s cost reduction estimate includes only PN solution and pharmacy labor costs, not the savings estimates due to the time needed to administer PN by nurses, time saved by supervising physicians, or many other categories of potential savings. There may, of course, be some minor cost increasing changes, but we know of none that would be consequential (for example, the marginal cost of a day or two eating a regular hospital diet rather than parenteral feeding would at most

be a few dollars per patient, and likely close to zero). Importantly, the Peterson et al study found that inappropriate use of PN decreased only to 27 percent of patients when using nutrition support teams. Other studies have found greater reduction.² We use the Peterson et al estimates of dietary changes and add some, but not all, of the other likely savings to our overall estimate of savings.

We estimate that possibly 5 percent (that is, 245) of all hospitals are out of compliance with the CoPs and already granting RDs ordering privileges through appointment to the medical staff or other mechanisms and have already realized these savings. Additionally, an October 2008 study³ surveyed 1,500 clinical nutrition managers in acute healthcare facilities nationwide in an attempt to describe the level of RD independent prescriptive authority and to explore the barriers to obtaining that authority. The authors of the study reference current CMS policy, stating that: ". . . independent prescriptive authority via clinical privileges would not be a CMS-accepted pathway for RDs to write orders." This mention of the CMS requirements leads us to believe that our requirements (included in the survey response "regulatory agencies") might present a significant barrier to RDs obtaining dietary ordering privileges. Indeed, the results of the survey indicate that roughly 15 percent of the respondents cited "regulatory agencies" as a barrier to obtaining independent prescriptive authority (or dietary ordering privileges as we refer to it in this rule). However, several limitations inherent in this study lead us to question how heavily we should rely on it for the purposes of estimating how many hospitals will take advantage of this allowance under the CoPs. The survey only looked at the perceptions of clinical nutrition managers regarding barriers to RD ordering privileges and did not survey hospital administrators or governing body members on the reasons why hospitals were unable to grant these privileges to RDs at this time. We believe that such a study, had it been performed, would have been much more meaningful and reliable for our

² See, for example, the achievements noted in the Ochoa and colleagues estimates, and the Trujillo and colleagues estimates, as cited in the Peterson et al study (page 1708). These studies found that with decisions made by a nutrition support team, inappropriate PN use could be reduced to as low as 15 percent. Other cited studies have found even greater effects.

³ Weil, Sharon D., Linda Lafferty, Kathryn S. Keim, Diane Sowa and Rebecca Dowling. Registered Dietitian Prescriptive Practices in Hospitals. J AM Diet Assoc. 2008; 108; 1688–1692.

¹ Peterson SJ, Chen Y, Sullivan CA, et al. Assessing the influence of registered dietician order-writing privileges on parenteral nutrition use. J AM Diet Assoc. 2010; 110; 1702–1711.

purposes in estimating how many hospitals would possibly implement the granting of ordering privileges to RDs. The authors of the study also state that “. . . the limitations of this study must be considered and a major limitation was the small response rate (23.4 percent). . .” (or only 351 respondents from the 1,500 clinical nutrition managers surveyed).

As a result of our concerns as to the validity of this study, we specifically discussed this issue with the American Hospital Association (AHA) and the Federation of American Hospitals (FAH), who both assured us that most hospitals will be eager to implement this change and will begin the process of granting the privileges to dietitians upon publication of the rule. Input from all stakeholders has been overwhelmingly, if not universally, supportive. Not one public comment identified any regulatory impediment, other than the hospital CoPs, to change and the comments were overwhelmingly supportive of the policy. Consequently, we believe this survey's results to be flawed or erroneous, and largely irrelevant at this point in time. However, we have decided to use its conclusions as the lower bound of possible hospital policy and practice changes based on this final rule. Therefore, based on this study, it is possible that as few as 15 percent of hospitals (or only 735 hospitals) would take advantage of these changes to revise hospital policy and realize the estimated savings.

Additionally, because there is still some degree of uncertainty involved in estimating how many hospitals will immediately take advantage of this allowance under the CoPs versus how many will elect to gradually phase in such changes to RD ordering privileges, we have chosen to present a primary estimate (based on our experience with hospitals and our discussions with stakeholders) in which 3,675 hospitals (or 75 percent) elect to make these changes, though we believe that an upper bound estimate of nearly 95 percent of hospitals might ultimately implement these changes at some point in the future. Because 75 percent is our primary estimate, we are presenting only those savings estimates and numbers here and not those for the 15-percent lower bound estimate and the 95-percent upper bound estimate. (Our Accounting Table, however, does allow for a wide range of possible lower and upper bound savings, some of which could include both upward and downward changes partially offsetting each other.) Our extensive experience with hospitals, hospital organizations,

and RD professional organizations leads us to believe that by finalizing this change here, a significant number of hospitals will move to grant RDs ordering privileges. We also based our savings estimates on the following assumptions:

- The Peterson, et al., study was conducted at a 613-bed tertiary academic medical center; hospitals smaller than the one studied will have lower PN usage due to lower patient censuses and will thus have lower net savings;
- We adjusted the net savings relative to average bed size for hospitals of 164 beds (from AHA Hospital Statistics), meaning that average annual savings will be \$36,513 per hospital using the 2003 figure, but \$45,641 after adjusting for inflation; and
- The savings are based on the impact that RD ordering privileges had on reducing inappropriate PN usage alone and do not include other positive impacts that RD ordering privileges might have on reducing costs to hospitals, such as potential reductions in nursing time needed for dietary administration when patients switch from inappropriate PN to enteral nutrition or a regular hospital diet.

Based on the studies and these assumptions, we estimate a savings of \$167,730,675 (3,675 hospitals × \$45,641 in savings from reduced inappropriate PN usage = \$167,730,675) annually.

As noted above, the changes we are finalizing might also help hospitals to realize other significant savings. One 2008 study⁴ indicates that patients whose PN regimens were ordered by RDs have significantly fewer days of hyperglycemia (57 percent versus 23 percent) and electrolyte abnormalities (72 percent versus 39 percent) compared with patients whose PN regimens were ordered by physicians. Also, a recent literature review concludes that for at least general surgery and trauma patients, starting enteral feeding as soon as possible reduces infectious complications.⁵ This will most likely translate into decreased length of stays for these patients as well as quicker recovery times and reduced incidents of readmissions after discharge from the hospital. However, we do not have any

⁴ Duffy JK, Gray RL, Roberts S, Glanzer SR, Longoria SL. Independent nutrition order writing by registered dietitians reduces complications associated with nutrition support [abstract]. *J Am Diet Assoc.* 2008; 108 (suppl 1):A9.

⁵ Caitlin S. Curtis et al. “Enteral Feedings in Hospitalized Patients: Early versus Delayed Enteral Nutrition.” *Practical Gastroenterology*, October 2009, pp. 22–30.

reasonable means for estimating these potential cost savings at this time.

More obviously, RDs with ordering privileges will also be able to provide medical nutrition therapy (MNT) and other nutrition services at lower costs than physicians (as well as APRNs and PAs, two categories of non-physician practitioners that have traditionally also devised and written patient dietary plans and orders). This cost savings stems in some part from significant differences in the average salaries between the professions and the time savings achieved by allowing RDs to autonomously plan, order, monitor, and modify services as needed and in a more complete and timely manner than they are currently allowed. We have estimated the savings that would be realized by hospitals through our changes in terms of the physician/APRN/PA time and salaries saved.

Physicians, APRNs, and PAs often lack the training and educational background to manage the nutritional needs of patients with the same efficiency and skill as RDs. The addition of ordering privileges enhances the ability that RDs already have to provide timely, cost-effective, and evidence-based nutrition services as the recognized nutrition experts on a hospital interdisciplinary team. A 2011 review article⁶ discusses a number of additional studies that provide further evidence for the significant differences in nutrition education that exist between physicians and RDs, along with several other studies supporting the cost-effectiveness and positive patient outcomes that hospitals might achieve by granting RDs ordering privileges.

To calculate these cost savings for hospitals, we based our savings estimates on the following assumptions (some of which we have revised from those used in the proposed rule):

- Using the estimate established above, 3,675 hospitals will realize these savings;
- There is an average hourly cost difference of \$69 between RDs on one side (\$57 per hour) and the hourly cost average for physicians, APRNs, and PAs (\$126 per hour) on the other;
- There are on average 7,000 inpatient hospital stays per hospital per year (from AHA Hospital Statistics) with each of these stays requiring at least one dietary plan and orders;
- The average hospital stay is about 5 days (from AHA Hospital Statistics);
- On average, each non-complex dietary order, including ordering and monitoring of laboratory tests,

⁶ Kinn TJ. Clinical order writing privileges. *Support Line.* 2011; 33; 4: 3–10.

subsequent modifications to orders, and dietary orders for discharge/transfer/outpatient follow-up as needed, will take 8 minutes (0.13 hours) of a physician's/APRN's/PA's/RD's time per patient during an average 5-day stay;

- On average, MNT or more complex dietary orders (for example, PN, tube feedings, patients with multiple comorbidities, transition of patient from parenteral to enteral feeding, etc.), including ordering and monitoring of laboratory tests, subsequent modifications to orders, and dietary plans and orders for discharge/transfer/outpatient follow-up as needed, will take 18 minutes (0.30 hours) of a physician's/APRN's/PA's/RD's time per patient during an average 5-day stay; and

- The average number of hospital inpatient stays where the patient is determined to be either "at risk for malnutrition" or "malnourished" and/or requires MNT or a more complex dietary plan and orders for other clinical reasons is 1,400 (or 20 percent of inpatient hospital stays)⁷ per hospital per year, with a remaining average of 5,600 (or 80 percent) of hospital inpatient stays per hospital per year where the patient is determined to be "not at risk for malnutrition" and/or requires a less complex dietary plan and orders.

The resulting savings estimate is \$291,104,100 ((3,675 hospitals × 5,600 inpatient hospital stays × 0.13 hours of a physician's/APRN's/PA's/RD's time × \$69 per hourly cost difference) + (3,675 hospitals × 1,400 inpatient hospital stays × 0.30 hours of a physician's/APRN's/PA's/RD's time × \$69 per hourly cost difference)) annually. These hourly estimates are about 57 percent higher than in the proposed rule, due to the improved estimate for fringe benefits and overhead costs, plus inflation update. However, we have reduced our estimate of hours saved to reflect the likelihood that physician supervision will remain substantial in some cases. When combined with the savings estimate of \$167,730,675 from reduced inappropriate PN usage, this brings the total savings estimate from the CoP changes to \$458,834,775 (or approximately \$459 million) annually. We note again that these estimates exclude some categories of cost increases (for example, internal hospital meetings to plan changes), and some substantial categories of potential savings in medical treatment costs that

we have no current basis for estimating. The net effect of these omitted calculations would be substantially cost saving, and therefore would have no effect on the overall conclusion that the net benefits of this final rule are positive.

We acknowledge several additional kinds of uncertainty in our estimates of the provision's savings. For instance, we have assumed that the time physicians, APRNs or PAs save due to being relieved of diet-ordering duties will equal the time spent by RDs on those duties. RDs, being the experts in this area and more proficient in evaluating and treating the nutritional needs of patients, might actually need less time than physicians, PAs, or APRNs. As we have stated previously, we have based many of our assumptions and estimates on what we believe is the best available evidence we have from our review of the literature in this area. We have also based our overall assumptions and best estimates on our practical, ongoing experiences with hospitals in these matters. Finally, we have restricted our estimates to inpatient hospital stays and we did not include a discussion of hospital outpatient visits for nutritional services and the impact that these changes might have on hospital costs in this area. We invited public comments on the assumptions and estimates we put forth in the analysis in the proposed rule. The comments we received on the impact of this regulatory change are as follows:

Comment: Several commenters agreed with our assumptions that this regulatory change will reduce burden on physicians and create savings for hospitals.

Response: These comments support our expectation that hospitals are likely to exercise the flexibility that this final rule provides.

Comment: One commenter stated that our low estimate for nutrition savings is "arbitrary and implausible." The commenter pointed out that it is based on a public opinion poll taken of dietitians who are not regulatory experts and could not have been expected to know that it is an existing CMS rule, not hospital staff, which has prevented them from assuming duties commensurate with their expertise. The commenter further stated that "the 'low' estimate should be only a few percent below the primary estimate, and reflect the implausibility that any large fraction of hospitals would not take such obvious savings, even though faced with immense cost pressures from the Affordable Care Act provisions that will over time drastically reduce payments to hospitals."

Response: We agree that the previous "low" estimate was below the likely response of hospitals to the new cost-saving option we provide. Furthermore, in this final rule we are adding other categories of professionals who may establish diets, further adding to hospital flexibility. The commenter's point that professionals expert in the performance of their duties do not necessarily understand the ultimate legal source of regulatory requirements they experience in their daily work is valid and important. Nonetheless, we cannot reasonably assume that all hospitals will exercise the flexibility we provide, or do so as soon as permitted. Accordingly, we have modified our estimate.

Comment: One commenter stated their belief that we may have underestimated the possible monetary benefits of this provision. For example, the commenter stated, a dollar estimate of what may be substantial patient health benefits has been omitted.

Response: We agree that there are potentially important and substantial health benefits from allowing the most qualified professional staff to make binding judgments on patient diets. It is quite likely that there will be both morbidity and mortality reduction benefits, as predicted in the professional literature. Nonetheless, we have no empirical data on which to estimate this category of benefit.

Nuclear Medicine Services (§ 482.53)

We proposed, and are finalizing, a change to the current requirement at § 482.53(b)(1), which 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. We are removing the term "direct" from the current requirement. This revision allows for other appropriately trained hospital staff to prepare in-house radiopharmaceuticals under the supervision or oversight of a registered pharmacist or doctor of medicine or osteopathy, but it will not require that such supervision or oversight be exercised by the physical presence in the hospital of one of these professionals, particularly during off-hours when such a professional is not routinely present. The change directly reduces the burden of the current direct supervision requirement where it is most needed— in-house preparation of radiopharmaceuticals for after-hours/emergency performance of nuclear medicine diagnostic procedures.

Based on statistics from the Society of Nuclear Medicine and Molecular

⁷ Barker LA, Gout BS, Crowe TC. Hospital malnutrition: prevalence, identification and impact on patients and the healthcare system. *Int J Environ Res Public Health*. 2011; 8(2): 514–527.

Imaging, an estimated 16 million nuclear medicine imaging and therapeutic procedures are performed each year in the United States. We based our estimated savings for this change on the conservative assumptions that:

- Most hospitals will take advantage of this allowance on supervision since it is consistent with the Society of Nuclear Medicine and Molecular Imaging recommendations on this issue;
- The percentage of nuclear medicine procedures performed off-hours (7 p.m.–7 a.m.) is only 10 percent of all procedures performed (or 1.6 million);
- It requires 15 minutes of an MD/DO/PharmD's time for direct supervision; and
- The average hourly cost for these categories of practitioners in 2014 is \$192 including fringe benefits and overhead costs.

Therefore, we estimate hospitals savings will be \$76.8 million for the change (1.6 million off-hour procedures \times \$192 hourly salary for MD/DO/PharmD \times 15 minutes for direct supervision). We did not receive any public comments on our estimates for savings related to nuclear medicine services.

We are finalizing other revisions to the Hospital CoPs, but we do not believe those provisions will create tangible savings for hospitals.

4. Effects on Transplant Centers and Organ Procurement Organizations

Existing § 482.74(a)(2) requires transplant centers to notify CMS whenever there was a decrease in the center's number of transplants or survival rates that could result in the center being out of compliance with the clinical experience (number of required transplants) or outcome (survival) requirements at § 482.82. We are proposing to eliminate this requirement, which will reduce the burden to any transplant center that must currently report this information to CMS. This requirement functionally duplicates the data reporting and analysis requirements administered through the Health Resources and Services Administration (HRSA) of HHS, HRSA's contractor for the Scientific Registry for Transplant Recipients (SRTR), and a CMS-funded analysis of these SRTR data. These data (hereafter the SRTR data) are equally if not more timely, and equal if not better at identifying transplant center performance problems, than the data we currently collect directly.

We estimate that transplant centers make about 60 notifications each year to CMS according to § 482.74(a)(2). We believe that a staff member, probably the

transplant center administrator, who will be responsible for this notification will need to review the data and notify the medical director of the possibility that the center's volume and/or survival statistics may result in failure to comply with the requirements in § 482.82 of the CoPs. Then the transplant center administrator will need to make the actual submission to CMS. We estimate costs based on average hourly costs of \$192 for the medical director (physician) and \$116 for the administrator. These hourly costs include the average hourly wages for these positions, plus fringe benefits and overhead and an update to 2014, as previously explained. We believe this will require 15 minutes, or .25 hours, of the medical director's time at an hourly wage of \$192 and 30 minutes, or .5 hours, of the transplant center administrator's time at an average hourly cost of \$106 (\$192 hourly cost for medical director \times .25 hours = \$48 (+) \$116 hourly cost for administrator \times .5 hours = \$58 for a total of \$106) for each notification to CMS. Based on our experience with transplant centers, we estimate that transplant centers make about 60 of these notifications each year. Thus, the annual savings to transplant centers from eliminating this requirement for all transplant centers will be about \$6,360 (\$106 for each notification \times 60 notifications = \$6,360).

In addition to the savings realized by the transplant centers, the federal government will realize savings from both the cost of conducting the surveys and the cost of federal staff time in reviewing and maintaining the survey results. The surveys of the organ transplant facilities are usually conducted by both state surveyors and contractors paid by the Federal government. A survey requires an average of 182 hours to complete. Based upon our experience with previous surveys, we estimate that the combined average hourly cost, which includes fringe benefits and overhead, for the surveyors is about \$150. Thus, to conduct a survey costs about \$27,300 (182 hours \times \$150 hourly cost = \$27,300). By reducing the number of surveys by 10, the federal government will sustain an estimated annual savings of \$273,000 (\$27,300 for each survey \times 10 surveys = \$273,000).

We expect that the changes to the transplant center survey process will improve federal oversight of organ transplant programs by allowing more effective targeting of survey and enforcement activities to those programs that most need such attention, and will reduce the burden of hospitals undergoing surveys that may not be

necessary. We estimate that the cost of an onsite survey is \$10,400 per survey multiplied by a reduction of 10 surveys per year for a total of \$104,000 per year. The per-survey cost represents an estimate of the cost of personnel time spent during the onsite survey (hourly cost multiplied by the amount of time spent during a one-week onsite survey). This is consistent with costs reported by several transplant administrators which ranged between \$7,334 and \$15,000.

The reduction of 10 surveys each year out of the approximately 80 annual surveys completed each year represents a 12.5 percent reduction in the number of surveys. We estimate that these 10 surveys could have follow-up through alternative methods (for example, conference calls, plans of correction, etc.). This estimate is based on recent information that 43 programs that had non-compliance with data submission (that will require an onsite survey, if due for re-approval), were only slightly below the compliance threshold of 95 percent and effective follow-up could occur in some cases without an onsite survey. In addition, as part of our follow-up process every six months for non-compliance with patient and graft outcomes, we review about 15 programs every 6 months (approximately 30 programs per year). We estimate \$104,000 in total savings for transplant hospitals each year.

The federal government will also realize a savings due to the staff time required to review and maintain the results of these 10 surveys. We estimate that federal staff spend about 5 hours on each survey reviewing survey results and maintaining those results. Thus, for each survey, we estimate that the federal government will realize a savings of \$750 (5 hours for each survey \times \$150 hourly cost = \$750). For all 10 surveys, we estimate the annual savings will be \$7,500 (\$750 for each survey \times 10 surveys = \$7,500).

We believe that the other changes we are finalizing for transplant centers and OPOs (at §§ 482.80(c), 482.82(c), 486.306, 486.308(b)(1), and 486.344(d)(2)(ii)) will be burden neutral.

These reforms will enable all three types of affected organizations—hospitals, State survey agencies, and Federal oversight staff—to focus resources more effectively and efficiently on detecting and dealing with genuine and important problems in transplant center performance.

5. Effects on Long Term Care Facilities

In issuing the original 2008 rule, we anticipated that the cost of the sprinkler requirement will be substantially reduced by allowing a 5-year transition

period (2008–2013). The extended transition period will permit the cost of new sprinkler systems to be subsumed (at much less expense) under a facility's normal (or accelerated) capital replacement schedule. Due to the financial recession of 2008 and problems in the real estate market, however, the plans for replacement or major modification for some nursing homes have been delayed.

We recently received communications from a number of owners who plan to replace or substantially improve an existing structure, but are unable to do so by the August 13, 2013 deadline. In such a case, the owner is faced with the prospect of investing significant resources to install a system of automatic sprinklers in the old structure by August 13, 2013, only to have those improvements soon superseded by the superior environment of the new structure. We wish to avoid the unnecessary costs involved in sprinklering an old structure that will soon be replaced. We therefore are permitting time-limited extensions of the due date for achieving full sprinkler status. Each case-specific extension will then enable more time for full sprinkler systems to be implemented through the capital replacement or renovation schedule that is feasible for the facility.

Out of approximately 15,800 nursing homes nationwide, our information system indicates that there were 64 facilities as of February 2014 that were not sprinklered, and another 497 that were partially sprinklered for a total of 561 facilities. Nursing homes have made steady progress in sprinkler installation. For example, the current inventory of unsprinklered or partially sprinklered facilities is about 994 fewer than when the February 2013 proposed rule was published (561 v. 1555). However, a much higher proportion of the remaining nursing homes are ones that we believe are building replacement facilities or undergoing major modifications and would be reliant on an extension of time to finish such work while still participating in Medicare. We originally projected that 50 unsprinklered and 75 partially sprinklered facilities would request and qualify for a deadline extension and we continue to believe these estimates are reasonable.

In the case of a deadline extension for replacement of a nursing home, the unsprinklered facilities that are being replaced will still incur the cost of installing sprinklers in the new facility, but they will not need to pay twice for such installation (once in the old facility to meet the August 13, 2013, deadline, and again in the new facility). At an

average estimated installation cost of \$7.95 per square foot and an average space of 50,000 square feet, the avoided cost will be approximately \$19,875,000 (50 facilities times 50,000 S.F. times \$7.95). The partially sprinklered facilities may save some expense since they are combining the sprinkler installation with major modifications. We assume that the partially sprinklered facilities will avoid \$1.00 per square foot in savings through such economies, and assume that the average unsprinklered area is 25,000 square feet. For the partially sprinklered facilities, we therefore project that the aggregate savings is approximately \$1,875,000. The combined aggregate, one-time savings will total \$21,750,000.

6. Effects on Rural Health and Primary Care Providers and Suppliers

CAH and RHC/FQHC Physician Responsibilities (§§ 485.631(b)(2) and 491.8(b)(2))

We are revising the CAH regulations at § 485.631(b)(2) and the RHC/FQHC regulations at § 491.8(b)(2) to eliminate the requirement that a physician must be on-site at least once in every 2-week period (except in extraordinary circumstances) to provide medical care services, medical direction, consultation, and supervision. Based on our experience with CAHs, we estimate that the smaller and more remotely located CAHs, which represent roughly 15 percent of the 1,330 CAHs (that is, 200 CAHs), will be most affected by the removal of this provision and that its removal will produce estimated annual savings of nearly \$3.1 million for CAHs.

We estimate that the majority of CAHs do not incur a burden due to the relatively large volume of services they provide. For these higher-volume CAHs, physicians are regularly onsite to supervise and provide consultation. We believe that these facilities will continue to have frequent physician visits (biweekly or more often), simply as a matter of operation. Therefore, for the majority of CAHs, we do not believe that eliminating the requirement for a biweekly physician visit will significantly reduce their financial and administrative expenses. For about 15 percent of CAHs, roughly 200 CAHs, we estimate the current burden as follows. First, we estimate that a physician, at an hourly cost of \$192 (BLS Wage Data by Area and Occupation, including 100 percent for benefits and overhead costs), spends 6 hours each visit and makes biweekly visits (26 visits per year) to a facility to perform the duties required at § 485.631(b)(2). We estimate these visits cost \$29,952 per CAH per year (6 hours

per visit × 26 visits × \$192 an hour = \$29,952 per CAH per year).

Next, we estimate current travel expenses associated with the biweekly requirement. We estimate that, for each visit, a physician drives an average of 50 miles round trip and is reimbursed at a rate of \$0.55 (the IRS mileage reimbursement rate) per mile. Thus, each visit costs approximately \$28 (50 miles per visit × \$0.55 per mile) for a total annual burden of \$728 per CAH (\$28 per visit × 26 visits = \$728 annual cost per CAH). We understand that a small number of CAHs, such as those in Hawaii and Alaska, most likely incur significant additional cost for airfare and overnight accommodations. However, we do not have enough data to estimate these various costs.

We believe that eliminating the on-site, bi-weekly physician supervision requirement will reduce the physician supervision burden by 50 percent for each affected CAH. We estimate the savings as follows: \$3.07 million for on-site visits ($[\$29,952 \text{ per CAH}/2] \times 200 \text{ CAHs} = \$2,995,200$) and \$72,800 in travel costs ($[\$728 \text{ per CAH}/2] \times 200 = \$72,800$).

In addition, CAHs are required to document the events in which an extraordinary circumstance will prevent a doctor from visiting the CAH, at a minimum, once in a 2-week period. We estimate the administrative expenses associated with the documentation requirements at § 485.631(b)(2) to be \$5,720 per year. Based on sample data from the Health Resources and Services Administration (HRSA), we estimate that such circumstances may impact about 11 percent of all presently required visits for this subset of 200 CAHs. We estimate that a clerical worker costing \$40 per hour in wages, benefits, and overhead, will be responsible for completing the paperwork, with each incident taking about 0.25 hours to record. Assuming 26 visits per year per CAH, with approximately 11 percent of the required visits being prevented, thereby triggering the paperwork, we estimate that the yearly cost of compliance for these 200 CAHs will be \$5,720 (26 visits per year per CAH × 11 percent × 200 CAHs × 0.25 hour × \$40 per hour = \$5,720 per year). Thus, we estimate a total annual savings for CAHs of nearly \$3.1 million (\$5,720 administrative + \$2,995,200 hourly + \$72,800 travel = \$3,073,720).

For RHCs and FQHCs, we believe burden will be reduced on all such facilities. We estimate that, presently, to perform the duties required at § 491.8(b)(2), each month a physician spends approximately 8 hours (4 hours

each visit, twice a month) on-site at an RHC or FQHC and that these visits require an additional 4 hours of travel time. We estimate a 2-hour round-trip travel time for visits to most RHCs and FQHCs, thus approximately 4 hours per month, and we note that many RHCs and FQHCs require special means of transport which may be more expensive than traveling by car. We estimate travel costs at \$1,950 per clinic annually (\$75 travel cost per visit \times 26 visits per year = \$1,950 per clinic per year). We estimate the costs for time spent for on-site visits to be \$19,968 per RHC or FQHC per year (4 hours/visit \times \$192 an hour \times 26 visits per year = \$19,968 per year).

By eliminating the provision, for each RHC or FQHC we estimate travel expenses will be reduced from \$1,950 to \$663 per year (an annual savings of \$1,287). For RHCs (3,977 total), we estimate an annual savings of \$5.1 million on travel (\$1,287 per year \times 3,977 = \$5,118,399). For FQHCs (5,134 total), we estimate they will realize \$6.6 million in annual savings on travel expenses (\$1,287 per year \times 5,134 = \$6,607,458).

We further estimate that the time spent on biweekly visits will decrease by about one third, from \$19,968 to \$13,319 (a \$6,649 savings) per year for each RHC or FQHC. For all RHCs, we estimate an annual savings of \$26.4 million from fewer hours for on-site clinician visits (\$6,649 per year per RHC \times 3,977 RHCs = \$26,443,073). FQHCs will realize \$34.1 million in annual savings from fewer hours for on-site clinician visits (\$6,649 per year per FQHC \times 5,134 FQHCs = \$34,135,966).

We also estimate the administrative expenses associated with the documentation requirements at § 491.8(b)(2), which are triggered in the event of any “extraordinary circumstances” preventing any of the required bi-weekly physician visits. By comparison to travel and hourly visit costs, these expenses are relatively small. As we estimated for CAHs, we similarly estimate that such circumstances impact about 11 percent of the presently required visits for all RHCs and FQHCs. We estimate that a clerical worker, costing \$40 per hour in wages, benefits, and overhead, will be responsible for completing the paperwork, with each incident taking about 0.25 hours to record. Assuming 26 visits per year, with approximately 11 percent of these being prevented, and thereby triggering the paperwork, we estimate the yearly cost of compliance for RHCs and FQHCs to be \$260,574 (26 visits \times 11 percent \times [3977 RHCs + 5134 FQHCs] \times 0.25/hour \times \$40 per hour =

\$260,574 per year for RHCs and FQHCs). Eliminating the biweekly requirement will eliminate this particular administrative cost entirely for all RHCs and FQHCs, producing a total annual savings of \$113,742 for RHCs and \$146,832 for FQHCs, respectively.

In total, we believe that eliminating the provision will produce annual estimated savings of \$31.7 million for RHCs in travel, hourly, and administrative costs (\$5,118,399 travel + \$26,443,073 hourly + \$113,742 administrative = \$31,675,214). For FQHCs, we estimate that eliminating the provision will produce nearly \$41 million in annual savings. (\$6,607,458 travel + \$34,135,966 hourly + \$146,832 administrative = \$40,890,256 per year). We note that a portion of these savings may be offset by equipment or other costs associated with increased use of telemedicine; however, we lack data with which to reliably estimate such costs. Thus for CAHs, RHCs, and FQHCs, we estimate a total annual savings of \$75,639,190 million.

Provision of Services (§ 485.635(a))

We are removing the requirement that CAHs consult an individual who is not a member of the CAH staff in the development of its patient care policies; instead, we will allow CAHs greater flexibility in their approach. We estimate that removing this requirement will result in a total annual savings of \$266,000 for CAHs which are not part of a rural health network and therefore, in the absence of this final rule, will need to provide orientation for a volunteer to be able to serve in this capacity. No original estimates were made regarding this requirement, which was in fact initially developed for another provider type (43 FR 30520 and 43 FR 5373), but later assumed as a requirement for CAHs in 1997 (62 FR 46037).

Based on our experience, we are aware that many CAHs use volunteers, such as current board members, community residents with a medical background, or others, to fulfill the current requirements at § 485.635(a)(2). That is, many CAHs use a volunteer as the non-CAH staff person who provides advice and assists in the development of the CAH’s patient care policies. In some cases, the CAH must also invest time to make such an individual familiar with the CAH’s policies and procedures. Based on our experience, we estimate that a CAH typically spends about \$50 an hour for eight hours, annually, including any time required for orientation, to involve an outside individual in the development of its

patient care policies. We also estimate that 665 of about 1,330 CAHs are part of a rural health network and can utilize a non-staff individual that is part of the network to fulfill this requirement. Thus, we estimate the savings based on the CAHs that are not in a network and are therefore required to pay an individual to assist with developing the policies and procedures. Thus, we estimate a total annual savings of \$266,000 (\$50 \times 8 hours = \$400 per CAH \times 665 CAHs = \$266,000).

RHC/FQHC Definition of a Physician (§ 491.2)

The definition of a physician in the RHC/FQHC CoP regulations does not conform to the definition of a physician in the payment and Medicare agreement regulations in Part 405 for these types of suppliers. We are revising the regulation at § 491.2 by stating the specific functions of a doctor of medicine or osteopathy required in the statute (sections 1861(aa)(2)(B) and (aa)(3) of the Act) to eliminate possible confusion in the supplier community and to facilitate the development of more specialized primary care clinics, such as those providing dental services. We believe that this change will allow for an expansion of patient services and for additional health benefits for which we do not have a basis to estimate.

7. Effects on Laboratories

In this final rule, we are making a number of clarifications and changes pertaining to the regulations governing PT referral under CLIA. We are also responding to comments made in response to the proposed changes, including making further clarifications to ensure conformance between the TEST Act and the regulations.

The first clarification is to add a statement to § 493.801(b) to explicitly note that the requirement to test 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. The second change establishes a narrow exception in our long-standing interpretation of what constitutes an “intentional” referral. In these instances, the laboratory will be subject to alternative sanctions in lieu of potential principal sanctions. Alternative sanctions may include any combination of civil money penalties, directed plan of correction (such as required remedial training of staff), temporary suspension of Medicare or Medicaid payments, or other sanctions specified in accordance with CMS regulations. Finally, we are adding

definitions for the following four terms to the regulation: reflex testing, confirmatory testing, and distributive testing.

From 2007 through 2011 there were 41 cases of cited, intentional PT referral. Of these 41 cases, we estimate that 13 will have fit the terms of this final rule, ranging from a low of 1 in any year (in 2009) to a high of 5 (in 2011). Based on discussions with the most recently affected laboratories, we estimate that the average cost of the sanctions applicable under current regulations is approximately \$578,400 per laboratory. The largest single type of cost is the expense to the laboratory or hospital to contract out for management of the laboratory, and to pay laboratory director fees, due to the 2-year ban of the owner and operator pursuant to revocation of the CLIA certificate. We have not included legal expenses in this cost estimate, as it is not possible to estimate the extent to which laboratories may still appeal the imposition of the alternative sanctions in this final rule. We therefore estimate the annual fiscal savings of the changes to range from a low of \$578,400 (1 laboratory) to a high of \$2.9 million (5 laboratories), with an annual average estimated savings of \$1.7 million (about 3 laboratories per year on average). While the macro savings may not be large, the costs to the individual laboratory or hospital that is affected can be significant.

We note, however, that the \$1.7 million estimated savings to laboratories may overstate or understate the provision's net societal benefits. To the extent that new managers or support staff are putting forth effort (for example, familiarizing themselves with laboratories that they have not previously operated) as part of new management arrangements, society's resources would indeed be freed for other uses by the regulatory change. However, because laboratory director and management duties would be performed (by someone) with or without the change, some portion of the management director fees may not represent actual labor costs, but would instead involve a transfer of value (for example, from a temporarily-banned lab director who would receive severance pay in the absence of the regulatory change, to the hospital or laboratory no longer needing to make the severance payments). We lack data to estimate how much of the \$1.7 million total is a transfer of this type, rather than a net societal benefit.

8. Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small

entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that the great majority of the providers that will be affected by CMS rules are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business. Accordingly, the usual practice of CMS is to treat all providers and suppliers as small entities in analyzing the effects of our rules.

This final rule will save affected entities approximately \$660 million a year. Most of these savings will accrue to hospitals. Although the overall magnitude of the paperwork, staffing, and related cost reductions to hospitals and CAHs under this rule is economically significant, these savings are likely to be a fraction of one percent of total hospital costs. Total national inpatient hospital spending is approximately nine hundred billion dollars a year, or an average of about \$150 million per hospital, and our primary estimate of the net effect of these proposals on reducing hospital costs is about \$540 million annually. This is an average of about \$87,000 in savings for the 6,200 hospitals (including CAHs) that are regulated through the CoPs and is well under one percent of annual spending. It will be higher in larger hospitals, and lower in smaller hospitals, since these savings will be roughly proportional to patient volume.

Under HHS guidelines for Regulatory Flexibility Analysis, actions that do not negatively affect costs or revenues by more than 3 percent a year are not economically significant. We believe that no hospitals of any size will be negatively affected. Accordingly, we have determined that this final rule will not have a significant economic impact on a substantial number of small entities, and certify that a Final Regulatory Flexibility Analysis is not required. Notwithstanding this conclusion, we believe that this RIA and the preamble as a whole meet the requirements of the RFA for such an analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of

a metropolitan statistical area and has fewer than 100 beds. For the preceding reasons, we have determined that this final rule will reduce costs and will therefore not have a significant negative impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that is approximately \$141 million. This final rule does not contain any mandates.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that impose substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

D. Alternatives Considered

From within the entire body of CoPs and CfCs, the most viable candidates for reform were those identified by stakeholders, by recent research, or by experts as unusually burdensome if not unchanged. This subset of the universe of standards is the focus of this final rule. For all of the provisions, we considered not making these changes. Ultimately, we saw no good reasons not to propose and finalize these burden-reducing changes. The great majority of the comments we received agreed with our proposals and reasoning.

For LTC facilities, we considered the option of not making any changes to the rule. However, we were persuaded by the contacts we received that bona fide efforts were being made by the nursing homes in question to achieve the best results for residents. We believe that the benefits to residents of having new, modern and fully-equipped facilities are substantial, and that the public interest is served by avoiding wastage of funds spent on retrofitting an older structure when that structure is soon to be replaced or substantially improved. We also considered the option of granting extensions of the due date when a replacement or substantial renovation is not contemplated. However, we believe that an approach that limits extensions to situations where a replacement facility or substantial renovation is involved will best balance the advisability of timely achievement to full sprinkler status and the special

challenges involved in large-scale construction projects.

Regarding the revisions to the CLIA regulations, we focused our proposals on reflex or confirmatory testing, and changes to ensure that the regulations are in conformance with the “Taking Essential Steps for Testing Act of 2012” (Pub. L. 112–202, the “TEST Act”), enacted on December 4, 2012. In response to comments, we added distributive testing to the same category as reflex or confirmatory testing. Such cases, where the laboratory has followed its written, legally accurate and adequate standard operating procedure for the testing of patient specimens in full, and the PT referral is not a repeat PT referral, provide a reasonable basis for the Secretary to determine that the referral was not intentional. We are finalizing our proposals.

E. Uncertainty

Our estimates of the effects of this regulation are subject to significant uncertainty. While the Department is confident that these reforms will provide flexibilities to facilities that will yield major cost savings, there are uncertainties about the magnitude of these effects. In addition, as we previously explained, there may be significant additional health benefits. Thus, we are confident that the rule will yield substantial net benefits. In this analysis we have provided estimates to suggest the potential savings these reforms could achieve under certain assumptions. We appreciate that those assumptions are simplified, and that actual results could be substantially higher or lower. Although there is uncertainty concerning the magnitude of all of our estimates, we do not have the data to provide probable estimates as to the range of possibilities, or to estimate all categories of possible costs and benefits, including health effects. We illustratively presented one possible lower bound—for food and dietetic services—in the proposed rule. We

requested comments addressing this lower bound estimate, as well as the missing or uncertain effects of other provisions, by professional societies, individual providers, provider associations, academics, and others.

Comment: We received one comment stating that we should have provided more “low” estimates than just the one we provided for the dietitian change. The commenter further suggested that, for other reforms in this rule, the low estimate should be set at some rounded percentage, such as 25 percent below the primary estimate, to show the substantial uncertainty of these estimates and to avoid misleading the public as to the precision that the analysis supports.

The same commenter also stated that our proposed estimated benefits could be “considerably higher” than estimated, both through uncertainty and because in various places the preamble identifies potentially higher benefits than were assigned dollar values. The commenter suggested that the potential benefits of each reform be shown at some rounded percentage, such as 25 percent higher, as a “high” estimate in the accounting statement. Without a “high” estimate, the “primary” estimate gives a misleading impression of greater precision than the analysis supports.

Response: We agree with the comment. Unfortunately, we have no empirical basis for estimating with any precision either higher or lower savings estimates. Accordingly, we have revised our estimates to show potential savings both higher and lower than those in the proposed rule. As a judgmental estimate, we believe that savings could be at least 30 percent higher, or 30 percent lower, than our primary estimates for each category of savings. These revisions are shown in the accounting statement and table.

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), we have prepared an accounting statement. As previously explained, achieving the full scope of potential savings will depend on future decisions by hospitals, by State regulators and others. Many other factors will influence long-term results. Therefore, we have limited our projections to a five year period, provided upper and lower bound estimates that, with one exception, are 30 percent higher and 30 percent lower than our primary estimate, and rounded all estimates to the nearest \$10 million. The exception is that for the dietary reforms estimate we are using a lower bound uptake rate by hospitals of 15 percent, which is 80 percent less than our primary estimate. Thus, these upper and lower bounds allow for the proportion of hospitals electing to reform dietary services to be substantially higher or lower than our primary estimate. Also, although we believe there are health benefits of this final rule from improved diets, we have no basis for estimating those. In addition to the estimates previously addressed in this RIA, we are also assuming that the 75 percent take up rate for reforms in dietary services that we project as our primary estimate will not be reached in the first year, and base our annualized estimate on a 60 percent rate in the first year. The annualized estimates also reflect that the long term care facility savings are one-time. Accordingly, we estimate the overall cost savings that this rule creates will be approximately \$230 million to \$830 million per year annualized over the next 5 years. Our primary estimate is that annualized savings will be about \$640 million. Over a 5-year period, our primary estimate is that total cost savings will be approximately \$3.2 billion.

TABLE 2—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS

[\$in millions]

Category	Primary estimate	Lower bound	Upper bound	Units		
				Year dollars	Discount rate (percent)	Period covered
Benefits	None					
Costs:						
Annualized Monetized reductions in Costs	–\$640	–\$230	–\$830	2014	7	2014–2018
	–\$640	–\$230	–\$830	2014	3	2014–2018
Transfers	None					

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 442

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 493

Administrative practice and procedure, Grant programs—health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare &

Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

- 1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub.L. 106–113 (113 Stat. 1501A–332), sec. 3201 of Pub.L. 112–96 (126 Stat. 156), and sec. 632 of Pub. L. 112–240 (126 Stat. 2354).

§ 413.24 [Amended]

- 2. In § 413.24, paragraph (d)(5)(i)(A) is amended by removing the reference “§ 482.66” and by adding in its place, the reference “§ 482.58”.

§ 413.114 [Amended]

- 3. In § 413.114(b), the definition of “Swing-bed hospital” is amended by removing the reference “§ 482.66” and by adding in its place, the reference “§ 482.58”.

PART 416—AMBULATORY SURGICAL SERVICES

- 4. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

- 5. Section 416.42 is amended by revising paragraph (b)(2) to read as follows:

§ 416.42 Condition for coverage—Surgical services.

* * * * *

(b) * * *

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA), or an anesthesiologist’s assistant as defined in § 410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (c) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist’s assistant, under the supervision of an anesthesiologist.

* * * * *

- 6. Section 416.49 is amended by revising paragraph (b) to read as follows:

§ 416.49 Condition for coverage—Laboratory and radiologic services.

* * * * *

(b) *Standard: Radiologic services.* (1) 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) of this chapter.

(2) If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring all radiologic services are provided in accordance with the requirements of this section.

PART 440—SERVICES: GENERAL PROVISIONS

- 7. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 440.1 [Amended]

- 8. In § 440.1, in the entry for section 1913, the reference “and 482.66” is removed and the reference “and 482.58” is added in its place.

PART 442—STANDARDS FOR PAYMENT TO NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

- 9. The authority citation for part 442 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

- 10. Section 442.101(d)(3)(ii) is revised to read as follows:

§ 442.101 Obtaining certification.

* * * * *

(d) * * *

(3) * * *

(ii) The facility submits an acceptable plan of correction covering the remaining deficiencies.

* * * * *

§ 442.105 [Removed and Reserved]

- 11. Section 442.105 is removed and reserved.

- 12. Section 442.110 is revised to read as follows:

§ 442.110 Certification period for ICF/IID with standard-level deficiencies.

Facilities with standard-level deficiencies may be certified under § 442.101 with a condition that the certification will continue if either of the following applies:

(a) The survey agency finds that all deficiencies have been satisfactorily corrected.

(b) The survey agency finds that the facility has made substantial progress in correcting the deficiencies and has a new plan of correction that is acceptable.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 13. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 14. Section 482.12 is amended by revising the introductory text and adding paragraph (a)(10) to read as follows:

§ 482.12 Condition of participation: Governing body.

There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

(a) * * *

(10) Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the hospital. For a multi-hospital system using a single governing body, the single multi-hospital system governing body must 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 of this paragraph (a).

* * * * *

■ 15. Section 482.22 is amended by—

■ a. Revising the introductory text and paragraph (a) introductory text.

■ b. Adding a new paragraph (b)(4).

The revisions and addition read as follows:

§ 482.22 Condition of participation: Medical staff.

The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital.

(a) *Standard: Eligibility and process for appointment to medical staff.* The medical staff must be composed of doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at § 482.12(c)(1)) and non-physician practitioners who are determined to be eligible for appointment by the governing body.

* * * * *

(b) * * *

(4) If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:

(i) The medical staff members of each separately certified hospital in the system (that is, all medical staff members who hold specific privileges to practice at that hospital) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital;

(ii) 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;

(iii) The unified and 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

(iv) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place

to ensure that issues localized to particular hospitals are duly considered and addressed.

* * * * *

■ 16. Section 482.28 is amended by revising paragraphs (b)(1) and (2) to read as follows:

§ 482.28 Condition of participation: Food and dietetic services.

* * * * *

(b) * * *

(1) Individual patient nutritional needs must be met in accordance with recognized dietary practices.

(2) 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.

* * * * *

■ 17. Section 482.53 is amended by revising paragraph (b)(1) to read as follows:

§ 482.53 Condition of participation: Nuclear medicine services.

* * * * *

(b) * * *

(1) In-house preparation of radiopharmaceuticals is by, or under the supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

* * * * *

■ 18. Section 482.54 is amended by adding paragraph (c) to read as follows:

§ 482.54 Condition of participation: Outpatient services.

* * * * *

(c) *Standard: Orders for outpatient services.* Outpatient services must be ordered by a practitioner who meets the following conditions:

(1) Is responsible for the care of the patient.

(2) Is licensed in the State where he or she provides care to the patient.

(3) Is acting within his or her scope of practice under State law.

(4) Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:

(i) All practitioners who are appointed to the hospital's medical staff and who have been granted privileges to order the applicable outpatient services.

(ii) All practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the medical staff and the hospital for

ordering the applicable outpatient services for their patients.

§ 482.66 [Redesignated as § 482.58]

■ 19. Redesignate § 482.66 as § 482.58 and transfer the section from Subpart E to Subpart D.

§ 482.74 [Amended]

■ 20. Section 482.74 is amended by removing paragraph (a)(2) and redesignating paragraphs (a)(3) and (4) as paragraphs (a)(2) and (3) respectively.

■ 21. Section 482.80 is amended by—

■ a. Revising paragraph (c) introductory text.

■ b. Removing paragraph (c)(2).

■ c. Redesignating paragraph (c)(3) as paragraph (c)(2).

The revision reads as follows:

§ 482.80 Condition of participation: Data submission, clinical experience, and outcome requirements for initial approval of transplant centers.

* * * * *

(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

* * * * *

■ 22. Section 482.82 is amended by—

■ a. Revising paragraphs (a) and (b).

■ b. Revising paragraph (c) introductory text.

■ c. Removing paragraph (c)(2).

■ d. Redesignating paragraph (c)(3) as paragraph (c)(2).

The revisions read as follows:

§ 482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.

* * * * *

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donors) performed during the prior 3 years. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up.

(b) *Standard: Clinical experience.* To be considered for re-approval, an organ-specific transplant center must generally perform an average of 10 transplants per year during the prior 3 years.

(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

* * * * *

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 23. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 24. Section 483.5 is amended by adding paragraph (f) to read as follows:

§ 483.5 Definitions.

* * * * *

(f) *Major modification* means the modification of more than 50 percent, or more than 4,500 square feet, of the smoke compartment.

■ 25. Section 483.70 is amended by adding paragraphs (a)(8)(iii) and (iv) to read as follows:

§ 483.70 Physical environment.

* * * * *

(a) * * *

(8) * * *

(iii) Subject to approval by CMS, a long term care facility may be granted an extension of the sprinkler installation deadline for a time period not to exceed 2 years from August 13, 2013, if the facility meets all of the following conditions:

(A) It is in the process of replacing its current building, or undergoing major modifications to improve the living conditions for residents in all unsprinklered living areas that requires the movement of corridor, room, partition, or structural walls or supports, in addition to the installation of a sprinkler system; or, has had its planned sprinkler installation so impaired by a disaster or emergency, as indicated by a declaration under section 319 of the Public Health Service Act, that CMS finds it would be impractical to meet the sprinkler installation due date.

(B) It demonstrates that it has made the necessary financial commitments to complete the building replacement or modification; or pursuant to a declared disaster or emergency, CMS finds it impractical to make reasonable and necessary financial commitments.

(C) Before applying for the deadline extension, it has submitted plans to

State and local authorities that are necessary for approval of the replacement building or major modification that includes the required sprinkler installation, and has received approval of the plans from State and local authorities.

(D) It agrees to complete interim steps to improve fire safety, as determined by CMS.

(iv) An extension granted under paragraph (a)(8)(iii) of this section may be renewed once, for an additional period not to exceed 1 year, if the following conditions are met:

(A) CMS finds that extenuating circumstances beyond the control of the facility will prevent full compliance with the provisions in paragraph (a)(8)(i) of this section by the end of the first waiver period.

(B) All other conditions of paragraph (a)(8)(iii) of this section are met.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 26. The authority citation for Part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

§ 485.606 [Amended]

■ 27. In § 485.606, paragraph (a)(2) is amended by removing the reference “§ 482.66” and by adding in its place, the reference “§ 482.58”.

■ 28. Section 485.631 is amended by revising paragraph (b)(1)(v), removing paragraph (b)(1)(vi), and revising paragraph (b)(2) to read as follows:

§ 485.631 Condition of participation: Staffing and staff responsibilities.

* * * * *

(b) * * *

(1) * * *

(v) Periodically reviews and signs a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants only to the extent required under State law where State law requires record reviews or co-signatures, or both, by a collaborating physician.

(2) A doctor of medicine or osteopathy is 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 or electronic communication for consultation,

assistance with medical emergencies, or patient referral.

* * * * *

■ 29. Section 485.635 is amended by revising paragraph (a)(2) to read as follows:

§ 485.635 Condition of participation: Provision of services.

(a) * * *

(2) The policies are developed with the advice of members of the CAH's professional healthcare staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.631(a)(1).

* * * * *

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 30. The authority citation for Part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 31. Section 486.306 is amended by revising paragraph (a) to read as follows:

§ 486.306 OPO service area size designation and documentation requirements.

(a) *General documentation requirement.* An OPO must make available to CMS documentation verifying that the OPO meets the requirements of paragraphs (b) and (c) of this section at the time of application and throughout the period of its designation.

* * * * *

■ 32. Section 486.308 is amended by revising paragraph (b)(1) to read as follows:

§ 486.308 Designation of one OPO for each service area.

* * * * *

(b) * * *

(1) *General.* An OPO is normally designated for a 4-year agreement cycle. The period may be shorter, for example, if an OPO has voluntarily terminated its agreement with CMS and CMS selects a successor OPO for the balance of the 4-year agreement cycle. In rare situations, a designation period may be longer, for example, a designation may be extended if additional time is needed to select a successor OPO to replace an OPO that has been de-certified.

* * * * *

■ 33. Section 486.344 is amended by revising paragraph (d)(2)(ii) to read as follows:

§ 486.344 Condition: Evaluation and management of potential donors and organ placement and recovery.

* * * * *

(d) * * *

(2) * * *

(ii) If the identity of the intended recipient is known, the OPO has a procedure to ensure that prior to organ recovery, an individual from the OPO's staff compares the blood type of the donor with the blood type of the intended recipient, and the accuracy of the comparison is verified by a different individual;

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 34. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302, 1320a-7j, and 1395hh); Pub. L. 110-149, 121 Stat. 1819.

■ 35. Section 488.61 is amended by—

■ a. Removing paragraph (a)(7).

■ b. Revising paragraphs (c) introductory text, (c)(1) introductory text, and (c)(1)(ii).

■ c. Removing paragraph (c)(2) and redesignating paragraphs (c)(3), (4), and (5) as paragraphs (c)(2), (3) and (4), respectively.

■ d. Revising newly designated paragraphs (c)(2), (c)(3)(i) and (c)(3)(ii).

■ e. Adding paragraph (c)(3)(v).

■ f. Revising paragraph (e).

The revisions and addition read as follows:

§ 488.61 Special procedures for approval and re-approval of organ transplant centers.

* * * * *

(c) *Re-approval procedures.* Once Medicare-approved, transplant centers, including kidney transplant centers, must be in continuous compliance with all the conditions of participation for transplant centers at §§ 482.72 through 482.104 of this chapter, except for § 482.80 (initial approval requirements).

(1) CMS will review the transplant center's data on an on-going basis and in making re-approval determinations.

* * * * *

(ii) To determine compliance with the clinical experience and outcome requirements at § 482.82(b) and (c) of this chapter, CMS will review the data contained in the most recent OPTN Data Report for the previous 3 years and 1-year patient and graft survival data contained in the most recent SRTR center-specific reports.

(2) CMS may choose to review the transplant center for compliance with §§ 482.72 through 482.76 and 482.90 through 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A.

(3) * * *

(i) The extent to which outcome measures are met or exceeded.

(ii) Availability of Medicare-approved transplant centers in the area.

* * * * *

(v) Program improvements that substantially address root causes of graft failures or patient deaths, have been implemented and institutionalized on a sustainable basis, and that are supported by recent outcomes data such that CMS finds that the program demonstrates compliance with the requirement at § 482.82(c)(2)(ii)(C) of this chapter that the number of observed events divided by the number of expected events not be greater than 1.5.

* * * * *

(e) *Transplant Center Inactivity.* A transplant center may remain inactive and retain its Medicare approval for a period not to exceed 12 months. A transplant center must notify CMS upon its voluntary inactivation as required by § 482.74(a)(3) of this chapter.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 36. The authority citation for Part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 37. Section 491.2 is amended by revising the definition of "physician" to read as follows:

§ 491.2 Definitions.

* * * * *

Physician means the following:

(1) As it pertains to the supervision, collaboration, and oversight requirements in sections 1861(aa)(2)(B) and (aa)(3) of the Act, a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State in which the function is performed; and

(2) Within limitations as to the specific services furnished, a doctor of dental surgery or of dental medicine, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor (see section 1861(r) of the Act for specific limitations).

* * * * *

■ 38. Section 491.8 is amended by revising paragraphs (a)(6) and (b) to read as follows:

§ 491.8 Staffing and staff responsibilities.

(a) * * *

(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for RHCs, a nurse practitioner, physician assistant, or certified nurse-midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.

(b) *Physician responsibilities.* The physician performs the following:

(1) Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff.

(2) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and the services provided to Federal program patients.

(3) Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

* * * * *

PART 493—LABORATORY REQUIREMENTS

■ 39. The authority citation for Part 493 continues to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)).

■ 40. Section 493.2 is amended by adding the definitions of “confirmatory testing,” “distributive testing,” and “reflex testing,” in alphabetical order to read as follows:

§ 493.2 Definitions.

* * * * *

Confirmatory testing means testing performed by a second analytical procedure that could be used to substantiate or bring into question the result of an initial laboratory test.

* * * * *

Distributive testing means laboratory testing performed on the same specimen, or an aliquot of it, that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test. When such testing occurs at multiple locations with different CLIA certificates, it is considered distributive testing.

* * * * *

Reflex testing means confirmatory or additional laboratory testing that is automatically requested by a laboratory under its standard operating procedures for patient specimens when the laboratory's findings indicate test results that are abnormal, are outside a predetermined range, or meet other pre-established criteria for additional testing.

* * * * *

■ 41. Section 493.801 is amended by revising paragraphs (b) introductory text and (b)(4) to read as follows:

§ 493.801 Condition: Enrollment and testing of samples.

* * * * *

(b) *Standard: Testing of proficiency testing samples.* The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency

testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

* * * * *

(4) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least 1 year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with § 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

* * * * *

Dated: October 24, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: March 18, 2014.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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