

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS-3267-P]

RIN 0938-AR49

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would reform Medicare regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, as well as certain regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This proposed rule would increase 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. This is one of several rules that we are proposing 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.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-3267-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **<http://www.regulations.gov>**. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3267-P,
P.O. Box 8010,
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3267-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:
 - a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: Lauren Oviatt, (410) 786-4683.

We have also included a subject matter expert and contact information under the “Provisions of the Proposed Regulations” section for each provision set out in this proposed rule.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Executive Summary for this Proposed Rule

A. 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 proposed 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.

B. Summary of the Major Provisions

We are proposing to reduce regulatory burden on providers and suppliers by modifying, removing, or streamlining current regulations that we believe are excessively burdensome.

- *Radiology services in ambulatory surgical centers:* This proposed rule would reduce the requirements Ambulatory Surgical Centers (ASCs) must meet in order to provide radiological services to match those services they actually perform. ASCs are currently subject to the full hospital requirements for radiology services even though they are only permitted to provide limited radiologic services integral to the performance of certain surgical procedures.
- *Hospital registered dietitian privileges:* We propose to include qualified dietitians as practitioners who may be privileged to order patient diets under the hospital conditions of participation (CoPs).
- *Hospital supervision of radiopharmaceutical preparation:* We propose to revise the Nuclear medicine services CoP to remove the modifier "direct" from the in-house preparation supervision requirement. The presence of a pharmacist, MD, or DO would no longer be required during the delivery of off-hour nuclear medicine tests. These proposed changes are based on the Society of Nuclear Medicine and Molecular Imaging recommendations on this issue.
- *Hospital reclassification of swing-bed services:* We propose to revise the requirements by relocating the swing-bed CoPs to Subpart D, which would classify swing beds as an optional service. This revision would allow a hospital's compliance with "swing bed" requirements to be

evaluated during routine accrediting organization surveys. This would reduce the burden on hospitals by not requiring an additional survey specifically for “swing bed” approval.

- *Transplant centers reports to CMS:* The CoPs require transplant programs to notify CMS of certain changes related to the center’s transplant program. The current system for transplant center data analysis, in effect, requires the centers to submit data which CMS routinely receives through other sources. This creates unnecessary paperwork and burden on the transplant program and does not contribute to Federal oversight. We propose to eliminate 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 would not result in any reduction in Federal oversight of the center. It would, however, enable us to more efficiently use our survey resources. In lieu of the automatic 3-year re-approval cycle, we propose to provide more flexibility in the re-approval cycle to be able to focus survey attention where it is most needed. We would also clarify 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 would be a continuous requirement, as already specified in § 488.61(c).

- *Long term care sprinkler waiver:* All buildings containing long term care (LTC) facilities are required to have automatic sprinkler systems installed throughout the building by August 13, 2013 (§ 483.70(a)(8)). Based on recent public feedback, we believe that some facilities will not be 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 proposing a provision that would allow 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 must 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 (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 and RHC/FQHC physician responsibilities:* The regulations for CAHs, Rural Health Clinics (RHCs), and Federally Qualified Health Centers (FQHCs), require a physician to be present for sufficient periods of time, at least once in every 2 week period, except in extraordinary circumstances. 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 suffer from 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 much less cost. We propose to revise the CAH and RHC/FQHC regulations to eliminate the requirement that a physician must be onsite at least once in every 2-week period.

Clinical Laboratory Improvement Amendments Revisions: This proposed rule would make 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 would prevent confusion on the part of laboratories, reduce the risk of noncompliance, and establish policies under which certain PT referrals by laboratories would 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 proposing to add a clarifying statement that explicitly notes that the requirement to treat proficiency testing (PT) samples in the same manner as patient specimens does not mean that it is acceptable to refer PT samples to another laboratory for testing even if that is the protocol for patient specimens.

- *Intentional referral carve-out:* We are proposing to carve out a narrow exception in our long-standing interpretation of what constitutes an “intentional” referral of PT samples. In these instances, the laboratory would be subject to alternate sanctions.

- *New definitions:* To clarify the stipulations of the intentional referral carve-out, we would also add the following terms, with their definitions, to the regulation: Reflex testing, Confirmatory testing, and repeat PT referral.

Proposals That Would Remove Obsolete or Duplicative Regulations or Provide Clarifying Information: We would remove regulations set out in the Code of Federal Regulations (CFR)

that have become obsolete and are no longer needed or enforced and would clarify other provisions.

- Hospital medical staff: We propose to clarify the requirement that a hospital’s medical staff must be generally composed of physicians but that it may also include, in accordance with State laws, including scope-of-practice laws, other categories of 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 proposing to remove 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 would be 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 proposing 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 payment regulations. We

propose to revise the regulation to conform to the definition in the payment regulations to eliminate possible confusion in the provider community.

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

- Hospital governing body: We are proposing to add a new provision to the “Medical staff” standard of the governing body CoP. This new provision would require a hospital’s governing body to directly consult at least 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 would 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 here. We are also proposing to remove the requirement for a medical staff member, or members, to be on a hospital’s governing body.

- Hospital medical staff: We propose to revise § 482.22 to require that each hospital must have an organized and individual medical staff, distinct to that individual hospital, that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by that individual hospital.

- Practitioners permitted to order hospital outpatient services: We propose to revise 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 propose to update terminology related to “diets” and “therapeutic diets” in the CoPs.

- Request for comment on RHC services: In addition, this proposed regulation seeks 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.

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

- Organ Procurement Organizations (OPOs): We are proposing some technical corrections to the CoPs for OPOs.

- Intermediate Care Facilities for Individuals who are Intellectually Disabled (ICF/IIDs): We are proposing some technical corrections to clarify state survey agency certification survey requirements for ICF/IIDs.

- Rural Health Clinics (RHCs): We propose 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.

C. Summary of Costs and Benefits

1. Overall Impact

This proposed rule would create savings and reduce burden in many areas. Several of the proposed changes would create measurable monetary savings for providers and suppliers, while others would create less tangible savings of time and administrative burden. We estimate one-time savings of \$22 million, and annual recurring savings of \$654 million.

2. Section-by-Section Economic Impact Estimates.

The following table summarizes the provisions, 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 First Year Savings or Benefits (\$ millions)
Ambulatory Surgical Centers • Radiology Services	Recurring annually	≤41
Hospitals • Food and dietetic services • Nuclear medicine services	Recurring annually Recurring annually	83 to 528 39
Transplant Centers • Reports to CMS & Survey Changes	Recurring annually	<1
Long Term Care Facilities • Sprinkler Deadline Extension	One-time	22
Rural Health • CAH & RHC/FQHC Physician responsibilities • CAH Provision of services	Recurring annually Recurring annually	42 <1
CLIA • PT Referral	Recurring annually	2
Total		231 to 676

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V. Regulatory Impact Analysis

I. Background

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 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," finalizes 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," addresses burdensome regulatory requirements for a broader range of healthcare providers and suppliers who provide care to Medicare and Medicaid beneficiaries. This proposed rule is a continuation of those efforts.

II. Provisions of the Proposed Regulations

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 using these requirements. 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 the 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 approved 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. It is important to emphasize that radiologic services are

only permitted in an ASC when they are integral to the procedure being performed. 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, as many ASCs are having great difficulty locating a radiologist to supervise the ASC's radiologic services. In addition, we have discovered the inclusion of the radiologist supervision requirement from the overarching hospital radiologic services CoP appears to be an overly aggressive measure since ASCs do not provide radiologic services that require interpretation for diagnosis. The ASC CoPs 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.

Supervision of radiologic services should be appropriate to the types of procedures conducted by the ASC. 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. The ASC governing body is 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 the 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. It is important to note that the operating surgeon is expected, as part of his or her qualifications in order to be privileged to perform the procedure, to demonstrate competency in using imaging as an integral part of the procedure. If finalized, subsequent ASC interpretive guidance would include additional information that would assist surveyors in determining if the governing body has met these requirements. We believe that supervision of radiologic services used in an ASC by a doctor of medicine or osteopathy (MD/DO) on the ASC's medical staff with appropriate education and experience in radiologic services would be effective in assuring the quality and safety of the radiologic services provided currently in ASCs. We welcome your comments on whether these proposed changes would allow for appropriate oversight of radiologic procedures conducted in ASCs.

We propose 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 propose to remove the existing language at § 416.49(b)(2) and replace it with the requirement that an MD/DO who is qualified by education and experience in accordance with State law and ASC policy must supervise the provision of radiologic services.

Also, we note that there is a technical error in § 416.42(b)(2) of the ASC CfCs and we are proposing to correct this error. Paragraph (b)(2) references "paragraph (d) of this section" but 42 CFR 416.42 does not have a paragraph (d). We propose to correct the error by referencing paragraph (c) of that section instead.

We believe these proposed changes to the ASC radiologic services requirements will assure the safety of these services while being less burdensome for Medicare-certified ASC facilities. We welcome comments from the public on these proposed changes.

Contact for ASC Topics: CAPT Jacqueline Leach, USPHS, 410-786-4282.

B. Intermediate Care Facilities for Individuals who are Intellectually Disabled

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 who are Intellectually Disabled (ICF/IID's) 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 the deletion of § 442.16.

The regulation at § 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 propose that this section be deleted. We also propose to make a corresponding change to § 442.101(d)(3) by deleting 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 ICF/IID's 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 ICF/IIDs put in place in the May 16, 2012 final rule, and will create confusion and barriers to its successful implementation.

Therefore, we propose to delete § 442.110 in its entirety.

The language in § 442.105 and § 442.110 was deleted to make it consistent with the intent of the Burden Reduction I regulatory changes to standardize survey processes of ICF/IIDs with those of nursing facilities and other certified providers with open-ended certification periods.

Contact for ICF/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 a single governing body and the medicals 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, especially public and government-owned institutions. 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 decided to use this proposed rule to rescind part of the new requirement and to propose an alternative. Therefore, we propose to remove the requirement for a medical staff member, or members, to serve on a hospital's governing body. 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 propose 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. While the 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 chief(s) of its medical staff(s) would occur, we would expect that these consultations would occur at least twice during either a fiscal or calendar year. Moreover, 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 would also 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 are proposing 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 here. We believe that 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.

1. 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 long-standing interpretation of the Medical staff CoP at § 482.22 as requiring that each hospital have its own independent medical staff. We also confirmed in the final rule that we do not allow a single corporate medical staff to assume responsibility for the quality of medical care at

multiple hospitals within a multi-hospital system. Despite the fact that over the years some members of the hospital industry have repeatedly requested a change to the prohibition in the CoPs against a single medical staff for multiple hospitals within a corporate system, CMS has maintained the importance of each hospital having its own medical staff at the local level and has maintained that this is the best model for overseeing care delivery and for moving forward with quality improvements.

Many of the comments that we received in response to the corresponding proposed rule (published October 24, 2011 (76 FR 65891)), indicated a clear awareness that we had considered a rule change that would allow for a single medical staff for multiple hospitals, had decided against it, and were nevertheless asking for comments on whether we should strengthen the language to more fully articulate our long-standing interpretation that each hospital have its own organized medical staff. While these commenters did not suggest clarifying changes to the regulatory language, a significant number expressed an understanding of, and support for, our decision to not propose a change and to continue to interpret the CoP as one that does not permit a multi-hospital system to have a single medical staff, but that instead requires that each individual hospital have its own medical staff. Other commenters interpreted our request for comments in the proposed rule as an indication that we were in some way proposing a change to the requirements or proposing a change in our historical interpretation of this CoP.

We continue to believe that it is important and in the best interest of patient care for each hospital to have its own medical staff. For example, a large multi-hospital, multi-regional system that only has a single medical staff may not appropriately be able to address the needs of each individual hospital in each local area. We did not receive public comments on the prior rule that would have adequately addressed this issue. The mixed response from public commenters

regarding our confirmation of the requirement and its interpretation has led us to consider proposing changes to the regulatory language of § 482.22 that would more explicitly communicate our longstanding policy that each hospital must have its own medical staff. Therefore, we propose to clarify the introductory paragraph of § 482.22 to require that each hospital must have an organized and individual medical staff, distinct to that individual hospital, that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by that individual hospital.

Shortly after publication of the May 2012 final rule, it was 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 the provision states that a hospital’s medical staff must include “doctors of medicine or osteopathy,” physicians such as those listed above are inadvertently excluded from the medical staff by the requirement. 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 that it would be appropriate to propose revisions to 42 CFR 482.22(a) that would 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 propose 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. By the proposed substitution of the current terms, “doctors of medicine or osteopathy,” with the term “physicians,” we would be consistent with the statutory language. We also propose to substitute “must include” with “must be composed of” since we believe that this would more accurately reflect the fact that hospital medical staffs are predominantly made up of physicians and that this would also emphasize the vital positions that physicians hold on these medical staffs. The proposed regulatory language

would require that the medical staff must be composed of physicians. Finally, we propose to retain the language allowing for other types of non-physician practitioners (such as APRNs, PAs, RDs, and 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 on the quality of medical care provided to patients in the hospital.

2. Food and Dietetic Services (§ 482.28)

We propose 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 states that “[in] accordance with State law and hospital policy, a dietitian may assess a patient’s nutritional needs and provide recommendations or consultations for patients, but the patient’s diet must be prescribed by the practitioner responsible for the patient’s care.” State survey agencies have applied this requirement to mean that registered dietitians (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.

Through the publication of the October 2011 proposed rule and the May 2012 final rule that followed, it has come to our attention that the regulatory language and the IGs for § 482.28(b) are too restrictive and lack the 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. Without the proposed regulatory changes allowing them to grant appropriate ordering privileges to RDs, hospitals would not be able to effectively realize the improved patient outcomes and overall cost savings that we believe would be possible with such changes. Please note, 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), we are proposing 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, regardless of the modifying term (or lack thereof), as long as each qualified dietitian meets the requirements of his or her respective State laws.

A review of the literature (Kinn TJ. Clinical order writing privileges. Support Line. 2011; 33; 4; 3-10) supports that, in addition to providing safe patient care with improved outcomes, RDs with ordering privileges contribute to decreased patient lengths of stay and provide nutrition services more efficiently, resulting in lower costs for hospitals. A 2010 retrospective cohort study of 1,965 patients at a 613-bed tertiary academic medical center looked at the influence of the RD with ordering privileges on appropriate parenteral nutrition (PN) usage (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). The study showed that inappropriate PN usage decreased from 482 patients to 240 patients during the pre- and post-ordering privileges periods, respectively. The data from this study also demonstrated a 20 percent cost savings in PN usage, which translated to an approximately \$300,000 savings to the hospital over the two-year period. Additionally, the changes proposed in this rule might also help hospitals to realize other significant quality and patient safety improvements as well as savings. A 2008 study 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 (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).

A number of other studies have also shown the prevalence of malnutrition among hospital patients, estimating that anywhere between 20 and 50 percent of hospital inpatients are either malnourished or at risk for malnutrition, depending on the particular patient population and the criteria used to assess these patients (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). Malnourished surgical patients are two to three times more likely to experience post-operative complications and increased mortality than their more well-nourished counterparts (Gallagher-Allred CR, Coble Voss A, Finn SC, McCamish MA. Malnutrition and clinical outcomes: the case for medical nutrition therapy. *J Am Diet Assoc*. 1996; 96; 361-369). Physicians, APRNs, and PAs 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 RDs who have benefited from curriculums that devote a significant number of educational hours to this area of medicine. 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 and saves valuable time in the care and treatment of patients, time that is now often wasted as RDs must seek out physicians, APRNs, and PAs to write or co-sign dietary orders. A 2011 review article discusses a number of additional studies that provide further evidence for the extensive training and education in nutrition that RDs experience as opposed to the limited exposure that physicians receive to this area of medicine, along with several other studies supporting the cost-effectiveness and positive patient outcomes that hospitals might achieve by granting RDs ordering privileges (Kinn TJ. Clinical order writing privileges. *Support Line*. 2011; 33; 4; 3-10).

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 are proposing 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 dietician 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. We also believe hospitals would realize significant cost savings in many of the areas affected by nutritional care. We welcome public comments on this proposed change.

3. 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 propose to revise the current requirement at § 482.53(b)(1) by removing the term “direct.” The revised requirement would then 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. 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.

The proposed 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 would 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. 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 welcome the public's comments on this proposed change.

4. Outpatient Services (§ 482.54)

We are proposing changes to the requirements at § 482.54, "Outpatient services." Specifically, we are adding a new standard at § 482.54(c), entitled "Orders for outpatient services." We are taking the opportunity to propose these revisions in this rule 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 SC-11-28 (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 where 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, which was preceded by discussions with the various stakeholders groups that first brought the issue to our attention. 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, we believe it is 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 propose 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, 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 practitioner 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 propose herein, 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. This proposed change would clearly establish in regulation CMS policy on the ordering and referral of all outpatient services. We welcome the public's comments on these proposed changes.

5. 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 are proposing 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 during routine AO surveys. By no longer requiring a deemed 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 welcome the public's comments on this proposed change.

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. One of the instances in which transplant centers have to notify us, located at § 482.74(a)(2), is 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 the number of transplants a center performs and survival information for all of the transplant centers. All 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.

In addition, 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 propose 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 as our identification and follow-up process for programs that do not meet § 482.82 would remain unchanged.

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

Subsections § 482.80(c) and 482.82(c) 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 are proposing to remove the exception language for lung transplants from §§ 482.80(c) and 482.82(c).

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 propose to modify this language to make it harmonize 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)). 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 are proposing 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.

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. Despite this requirement, we believe that onsite surveys for some of these transplant centers are not necessary to ensure the health and safety of the patients who receive a transplant in those centers. Moreover, the regulatory requirements described below for selecting the facilities that would undergo an onsite survey do not always effectively target survey resources where they are most needed.

We propose to remove the automatic 3-year re-approval process. We also propose to (1) clarify that the review of mitigating factors may occur at any time if there is non-compliance with the CoPs, and (2) remove language stating that a transplant program is approved for three years, which conflicts with language in § 488.61(c) specifying that compliance with the CoPs is a continuous requirement. The expectation that compliance with CMS requirements is continuous is an expectation that applies to 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 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. We can enforce data submission requirements without conducting an onsite survey. 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.

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 propose that we can take action to address the non-compliance while reserving for CMS's discretion the decision of whether or not to conduct an onsite survey.

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 outlined 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.

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 propose 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 most 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. In certain cases, the MF approval has been made possible pursuant to dialogue and agreement between CMS and the transplant center that the hospital will engage in a clear regimen of quality improvement and there is substantial completion of that regimen. 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 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 MF process.

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 are proposing 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 propose 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 propose 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 propose to remove the word “identify” and replace it with “identity.” The clause would then read, “If the identity of the intended recipient is known . . . “

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 is August 13, 2013. The 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. The Government Accountability Office (GAO) also studied this issue and issued a report entitled “Nursing Home Fire Safety: Recent Fires Highlight Weaknesses in Federal Standards and Oversight” (GAO-04-660, July 16, 2004,

<http://www.gao.gov/products/GAO-04-660>). The GAO analyzed two long term care facility fires in 2003 that resulted in 31 total resident deaths. The report examined Federal fire safety standards and enforcement procedures, as well as results from the fire investigations of these two incidents. The report recommended that fire safety standards for unsprinklered facilities be strengthened and cited sprinklers as the single most effective fire protection feature for long term care. Based on both CMS's analysis and the GAO's report, and under the Secretary's authority at sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act, to issue regulations that promote the health and safety of the residents of long-term care facilities, we finalized a requirement that all long term care facilities must be fully sprinklered by August 13, 2013.

Based on recent public comments and input, we believe that some facilities will not be 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 propose to allow a long term care facility to apply for a temporary deadline extension of the sprinkler system requirement, under very limited circumstances, if they are unable to meet the deadline. An extension will avoid spending funds on structures that will be obsolete in the near future. Our intent is to establish a rigorous review process for all deadline extension requests.

We are proposing 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.

Applications for the extension will only be considered if the delay in meeting the August 13, 2013 deadline is due to the plan for facility replacement or major modification, as described above. A number of facilities, for example, have had plans to replace an old structure with a new replacement nursing home, but have found that it is requiring more time to complete the necessary arrangements and construction. The nursing home's residents will benefit from the improved living environment of the new facility, and an extension of the deadline could avoid wasting funds on sprinklering an old structure that will soon be replaced. Similarly, nursing

home residents may benefit from a nursing home that is undertaking a major modification to improve living conditions, such as converting two-person or three-person rooms to single occupancy. If there is a delay due to such plans, and the construction is cost-effective if the sprinklering is done at the same time as the major modification of the unsprinklered area, then we would consider an extension of the deadline date. We are soliciting public comment as to whether the extension should be limited to just situations in which a replacement facility is being constructed. We are also soliciting public comment regarding these or other factors that may be important when determining whether to approve or deny an extension request, and when determining the appropriate length of the extension time period. However, it is our intent to fashion an extension that is very narrowly defined. The current rule has provided a five-year implementation period designed to ensure time for planning and resource mobilization. We propose to add the possibility of a time-limited extension in order to accommodate plans for major investments by a nursing home in a replacement facility or major modification where the investment, planning, and construction time involved may warrant a further extension and yield even better long term benefits for residents. We also propose 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 propose that a facility could only apply for a single extension renewal. The facility may be granted the additional extension if CMS finds that there are extenuating circumstances beyond the control of the facility that will prevent the facility from being in compliance by the end of the first waiver period. An example is a situation where residents have not yet been able to move to a substantially completed replacement facility due to last minute construction delays outside the control of the facility. Additionally, the facility would be required to meet all other conditions in paragraph (a)(8)(iii) related to applying for the

approval by CMS, submitting its plans to the State and local authorities, and taking the appropriate interim steps to improve safety of the building until the work is completed. We also welcome comments on this proposed provision.

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

F. Rural Health and Primary Care

We have identified several priority areas in the CoPs for CAHs (42 CFR part 485), the CfCs for both RHCs and FQHCs (42 CFR part 491), and the payment provisions for RHCs (42 CFR part 405) for updates and revisions. We believe that these proposed revisions may eliminate or significantly reduce burden where CoPs and CfCs are duplicative, unnecessary and/or burdensome.

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

CAHs are currently required 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. At least one member of the professional group must not be a staff member. We propose to remove the requirement that a CAH must develop its patient care policies with the advice of a non-CAH staff member and instead are proposing to allow CAHs flexibility in their approach to developing their patient care policies and procedures. That is, we are proposing that a CAH will no longer be required to include a non-staff member among the group of professional personnel to develop its patient care policies. We believe that this provision is no longer necessary and that the original reasons (lack of local resources and in-house expertise) for including this requirement have been effectively addressed. Also, based on our experience with CAHs and input from the provider community, we believe 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 rates of the non-staff member, and, in many cases, the expense of paying outside personnel a consultation fee.

In 1993, when we finalized the rules on the predecessor to the current CAH program, Essential Access Community Hospitals (EACHs) and Rural Primary Care Hospitals (RPCCHs) (58 FR 30630, May 26, 1993), we declined to expand the policy planning requirements at § 485.635 in a way that would have been more prescriptive and would have required additional sources of expertise and objectivity. At that time, we determined that it was not necessary to require the RPCCHs to consult with rural health networks or to ensure alignment with their State's rural health plan when deciding which services to furnish. In responding to comments suggesting such coordination, we remarked that while such coordination was desirable, no statute actually mandated this, and clinics were already free to work out such arrangements without regulation.

Subsequently, changes were made to the law which responded exactly to those concerns. The Balanced Budget Act (BBA) of 1997 amended the Act at Section 1820 (42 U.S.C. 1395i-4) and replaced the EACH/RPCH program with the Medicare Rural Hospital Flexibility Program (MRHFP). These changes established the CAH program we know today, and, importantly, predicated a State's eligibility to participate in the program on its establishment of a State rural health plan providing for the creation of one or more rural health networks in that State. As set forth in the BBA of 1997, codified at §1820(b) of the Act, a State's rural health plan must promote regionalization of rural health services and improved access to hospital and other health services for that State's rural residents. Moreover, it must be developed in consultation with the

hospital association of the State, rural hospitals located in the State, and the State Office of Rural Health.

The plan must also provide for the creation of at least one rural health network. A rural health network is an organization consisting of at least one CAH and at least one acute care hospital, the members of which have entered into agreements regarding patient referral and transfer, the development and use of communications systems, and the provision of emergency and nonemergency transportation. In addition, each CAH in a network must have an agreement for credentialing and quality assurance with at least one hospital that is a member of the network, or with a QIO or equivalent entity, or with another appropriate and qualified entity identified in the rural health care plan for the State. Taken together, the statutory requirements for a State rural health plan and (at least one) rural network, these mechanisms set out specific processes that serve to promote and support the sound development of a CAHs' patient care policies, such as are required at § 485.635. The additional statutory framework, established in the years since these regulations were first set forth, provides further support for our proposal to set aside the regulatory requirement that a CAH's patient care policies require the input of at least one professional who is not a member of the CAH's staff. Therefore, we propose to remove the statement at the end of § 485.635(a)(2) that states, "...at least one member is not a member of the CAH staff."

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

Except in extraordinary circumstances, a physician is required under §§ 485.631(b)(2) and 491.8(b)(2) to be present in the CAH, RHC or FQHC for sufficient periods of time, meaning at a minimum 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. Section 1861(aa)(2)(B) of the Act requires supervision, guidance, and a periodic physician review of covered services furnished by physician assistants and nurse practitioners in an RHC or an FQHC but it does not prescribe the frequency of the physician visits nor does it require onsite supervision. Section 1820(c)(2)(B)(iv) of the Act requires a CAH to provide physician oversight by a doctor of medicine (MD) or a doctor of osteopathy (DO) for inpatient care that is provided by a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS). The statute does not require the physician to be physically present in the facility to provide the required oversight.

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 suffer from limited access to care due to a shortage of health care professionals, especially physicians. Oftentimes, non-physician practitioners provide these important care services to rural communities with physicians providing oversight. We believe that specifying a specific timeframe for a physician to visit the facility does not ensure better health care. With the development of technology that facilitates “telemedicine,” a physician should have the flexibility to utilize a variety of ways and timeframes to provide medical direction, consultation, supervision, and medical care services, including being on-site at the facility. 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.

Among CAHs there is great variation in the size of the populations they serve and the range and extent of services they offer. We do not believe that a one-size-fits-all requirement as

found in the current regulation is appropriately responsive to this variation. In the case of very small CAHs in frontier areas that offer very limited services and have only one physician on staff, the requirement for an onsite visit at least every 2 weeks may be unduly burdensome. On the other hand, for CAHs that offer a wide 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 well be grossly inadequate. By eliminating the required 2-week visit, we believe CAHs will have the flexibility to determine the appropriate frequency of physician visits.

We therefore propose 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 propose that a doctor of medicine or osteopathy would be present for sufficient periods of time to provide medical direction, consultation and supervision for the services provided in the CAH, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. For RHCs and FQHCs, we propose that physicians would periodically review the clinic or center's patient records, provide medical orders, and provide medical care services to the patients of the clinic or center.

We believe that proposing language to remove these barriers will enhance patient access to care in rural and remote areas. We note that the present review requirements at § 485.631(b)(1)(v) can be fulfilled by a physician working from a remote location.

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

We propose to expand the definition of “physician” at § 491.2 in a way that mirrors the definition of “physician” that appears under the rules governing payment and Medicare agreements in Part 405 at § 405.2401(b). We believe that this change will provide clarity to the supplier community with respect to the requirements for RHCs and FQHCs. We propose to revise the definition as follows: *Physician* means a practitioner who meets the requirements of sections 1861(r) and 1861(aa)(2)(B) and (aa)(3)(B) of the Act and includes (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).

4. Technical Correction

We propose 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. We welcome public comments on this correction and on the other changes proposed for rural health care providers and suppliers.

Contacts for rural health and primary care CoP/CfC issues: Mary Collins, 410-786-3189; Sarah Richardson Fahrendorf, 410-786-3112.

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

We are requesting comment on potential changes we could make to regulatory or other requirements to reduce barriers to the following services:

1. Telehealth services

RHCs that are located in a rural Health Professional Shortage Area (HPSA) or in a county outside of a Metropolitan Statistical Area (MSA) are authorized by law to be telehealth originating sites (the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs). However, RHCs are not authorized to be distant site providers (practitioners furnishing covered telehealth services). Authorized distant site providers include physicians, NPs, PAs, CNMs, clinical nurse specialists (CNSs), CPs, CSWs, and registered dietitians or nutrition professionals.

Although RHC practitioners are eligible to furnish and bill for telehealth distant site services when they are not working at the RHC, they cannot furnish and bill for telehealth services 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 payment 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.

We are interested in exploring ways to allow RHC practitioners to furnish distant site telehealth services in a way that will not result in duplicate payment, especially for services such as mental health services, which are particularly limited in rural areas. Therefore, we are requesting comments on potential changes we could make to Medicare Provider Reimbursement Principles contained in Health Insurance Manual 15-1, Medicare RHC cost report/instructions

contained in Health Insurance Manual 15-2, and other Medicare policies that would allow RHCs to furnish telehealth services. Commenters should address how any suggestions for changes or exceptions would prevent duplicate payment—that is, ensure Medicare is not paying for the same costs to the RHC on the basis of allowable cost and the physician fee schedule under the telehealth benefit. We are particularly interested in comments that address these concerns without adding undue additional cost reporting and compliance burdens on RHCs to “carve out” or separate those costs that would otherwise be paid under the RHC benefit when Medicare is making physician fee schedule payments. Given the interest in encouraging the provision of mental health services in rural areas, we are interested in comments addressing whether changes should apply to all services that could potentially be provided through telehealth or only specific services such as mental health. If commenters believe these changes should only apply to specific services, we are interested in which services should be subject to these special rules and a policy justification for why these services are different than other services that could potentially be subject to special commingling rules.

2. Hospice Services

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. RHCs are not statutorily authorized to be hospice providers, and can only treat hospice beneficiaries for medical conditions not related to their terminal illness.

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 a beneficiary’s terminal illness. While RHC practitioners are eligible to furnish and bill for hospice services when they are not working at the RHC, they cannot furnish and bill for

hospice services as an RHC practitioner because RHCs are not authorized to be attending physicians for hospice. 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 payment to a practitioner while that practitioner is working for the RHC would result in duplicate Medicare payment for the hospice service; once through the Medicare RHC cost report and again through the Medicare Part B physician fee schedule payment.

We are interested in exploring ways to allow RHC practitioners to furnish hospice services in a way that will not result in duplicate payment, especially in areas with limited hospice providers. Therefore, we are requesting comments on potential changes we could make to Medicare Provider Reimbursement Principles contained in Health Insurance Manual 15-1, Medicare RHC cost report/instructions contained in Health Insurance Manual 15-2, and other Medicare policies that would allow RHCs to furnish hospice services. Commenters should address how any suggestions for changes or exceptions would prevent duplicate payment—that is, ensure Medicare is not paying for the same costs to the RHC on the basis of allowable cost and the physician fee schedule under the hospice benefit. We are particularly interested in comments that address these concerns without adding undue additional cost reporting and compliance burdens on RHCs to “carve out” or separate those costs that would otherwise be paid under the RHC benefit when Medicare is making hospice payments.

3. Home Health Services

RHCs that are located in an area in which there exists 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. The care must be provided under a written treatment plan that is established and periodically reviewed by a physician, NP, or PA.

Despite the authority for RHCs to provide home health services, there are relatively few RHCs that provide this service. We are seeking data and comments on a) the need for home health services in communities served by RHCs; b) barriers to providing these services, c) data regarding any difficulties beneficiaries face in accessing home health services in those communities or any shortages in home health agencies; and d) possible strategies to reduce or eliminate the identified barriers that comply with our legislative authority and the need for administrative accountability.

4. Other Services

We welcome comments on other services that RHCs would like to provide but are not able to do so. Please 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.

Contact for RHC 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), Public Law 100-578. The purpose of CLIA is to provide quality standards for laboratory testing to ensure the accuracy and reliability of laboratory test results for all Americans. Under the authority of 42 U.S.C. 263a(f), 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.

The regulations also 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 seeks certification. 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, the Committee on Energy and Commerce report from Sept. 9, 1988 (100th Congress 2nd Session, House of Representatives, Report 100-899, page 15, Identified Problems and Concerns) noted that “The Committee’s investigation focused particularly on proficiency testing because it is considered one of the best measures of laboratory performance. It is arguably the most important measure, since it reviews actual test results rather than merely gauging the potential for good results.” 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. 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 elected to violate those bars (H.R.Rep. No. 100-899, 100th Congress, 2d Session, at 16 and 24, 1988 U.S.C.C.A.N. 3828).

We propose 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 send a patient specimen to another laboratory for reflex or confirmatory 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 its standard operating procedure, and the results are reported as part of the proficiency testing program.

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 its standard operating procedure, and the results are reported as part of the proficiency testing program.

Any laboratory that we determine intentionally referred its PT samples to another laboratory for analysis may have its certification revoked for at least one year. 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 reflex or confirmatory 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 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 treat 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. 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 longstanding 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 believe it would be appropriate to afford an infrequent and narrowly crafted carve-out 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 or confirmatory testing. Laboratories would still be 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 referrals, even if related to reflex or confirmatory 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 possibly do to further ensure laboratory awareness of this prohibition. We believe it would be appropriate to insert, into that part of the regulation that discusses the treatment of PT samples in the same manner as the laboratory would treat a patient specimen, a cross reference reminding laboratories that such treatment must not include referral of a PT sample to another laboratory.

We therefore propose to make two changes to the CLIA regulations relevant to PT referral. The first would be to add a statement to § 493.801(b) to explicitly note that the

requirement to treat 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 treat 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 would be to carve out a narrow exception in our longstanding interpretation of what constitutes an "intentional" referral. We note, 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 propose that when CMS determines that a PT sample was referred to another laboratory for analysis, but the requested testing was limited to reflex or confirmatory 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 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 or confirmatory testing, it is not a repeat PT referral, and it occurred while acting in full conformance with the laboratory’s written, legally accurate and adequate standard operating procedure as outlined in this preamble. The key to this carve-out is the expectation that laboratories will ensure that improper referrals are addressed and eliminated, or we will find that future referrals are intentional. The carve-out 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 longstanding 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 welcome public comments on these proposed changes.

Furthermore, we note that the “Taking Essential Steps for Testing Act of 2012” (Pub. L. 112-202), enacted on December 4, 2012, amends section 353 of the Public Health Service Act to provide the Secretary with the discretion to substitute intermediate sanctions in lieu of the 2-year prohibition on the owner and operator when a CLIA certificate is revoked due to intentional PT referral, and to consider imposing alternative sanctions in lieu of revocation in

such cases as well. We generally intend to undertake further rule-making to implement the Taking Essential Steps for Testing Act of 2012, and invite comment on such action. In the meantime, since we are already proposing changes in this rule to § 493.801, we are proposing at this time to change the “will” to “ may” in the second sentence of § 493.801(b)(4) to ensure that this section is in compliance with the Taking Essential Steps for Testing Act of 2012. Contact for CLIA issues: Melissa Singer, (410) 786-0365.

III. Collection of Information Requirements

This proposed rule does not impose any new information collection, recordkeeping or third-party disclosure requirements. However, this proposed rule would create certain savings related to information collection, recordkeeping or third-party disclosure requirements. While we detail all of the estimated savings of this proposed rule in the regulatory impact analysis, the following paragraph provides a brief summary of the estimated savings associated with the information collection request (ICR) approved under OMB control number 0938-1069.

This proposed rule would reduce the reporting requirements for transplant centers and organ procurement organizations. As stated later in the regulatory impact analysis, we are proposing to eliminate 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). After the requisite notice and comment periods, we will submit a revision of the currently approved ICR for OMB review and approval.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will

consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

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.

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 proposed 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 proposed rule would create ongoing cost savings to providers and suppliers in many areas. Other changes we have proposed would 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 financial savings are summarized in the table that follows. We welcome 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 solicit comments on either our estimates of likely savings or the specific regulatory changes that drive 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	2544	≤41
Hospitals • Food and dietetic services • Nuclear medicine services	Recurring Annually Recurring Annually	4,900	83 to 528 39
Transplant Centers • Reports to CMS & Survey Changes	Recurring Annually	60	<1
Long Term Care Facilities		125	

Issue	Frequency	Number of Affected Entities	Likely Savings or Benefits (\$ millions)
<ul style="list-style-type: none"> Sprinkler Deadline Extension 	One-time		22
Rural Health			
<ul style="list-style-type: none"> CAH & RHC/FQHC Physician responsibilities 	Recurring Annually	9311	42
<ul style="list-style-type: none"> CAH Provision of services 	Recurring Annually	665	<1
CLIA		3	
<ul style="list-style-type: none"> PT Referral 	Recurring Annually		2
Total			231 to 676

*This table includes entries only for those proposed reforms that we think would have a measurable economic effect

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 x 4 quarters), the total savings would be \$40.7 million (\$16,000 x 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 2544 ASCs, based on current data and the total number of Medicare certified ASCs (5300 as of December 2011).

We note that the \$40.7 million estimated savings to ASCs may represent an overstatement of the provision's net social benefits. To the extent that radiologists are putting forth effort (for example, transporting themselves to ASCs) to perform radiology supervision, society's resources would indeed be freed for other uses by the proposed change. However, because the radiologic services in question do not involve any diagnostic activity, some portion of the radiology supervision fees may not represent actual labor costs, but would instead involve a transfer of value from radiologists (who currently receive supervision fees without having any diagnostics to supervise) to ASCs (which, if the proposed rule is finalized, would no longer pay those fees). We lack data to estimate how much of the \$40.7 million total is a transfer of this type, rather than a net social benefit. We welcome your comments on these estimates.

2. Effects on Intermediate Care Facilities for Individuals who are Intellectually Disabled

Because we are proposing only technical corrections, we do not estimate any costs or savings for ICF/IIDs based on this proposed 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 proposed rule. We use the following average hourly wages for registered dietitians, advanced practice registered nurses, physician assistants, pharmacists, and physicians respectively: \$35, \$57, \$57, \$69, and \$124 (BLS Wage Data by Area and Occupation, including both hourly wages and fringe benefits, at <http://www.bls.gov/bls/blswage.htm> and <http://www.bls.gov/ncs/ect/>).

Ordering Privileges for Registered Dietitians (RDs) (Food and dietetic services § 482.28)

We propose to revise 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 proposing revisions to § 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 a qualified dietitian as authorized by the medical staff and in accordance with State law. With these proposed changes to the current requirements, a hospital would 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 would 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 proposed 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

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

RDs. The study presented its figures in 2003 dollars, and to adjust to a comparable figure in 2012 dollars we used the increase in the Consumer Price Index (CPI-U) over this period. Since that index is up about 25 percent, our savings estimate, rounded, is \$169,000.

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 (included in this estimate would also be those hospitals who might decide against granting these privileges and therefore would also not realize these savings). Additionally, an October 2008 study² 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 found 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 led us to question how heavily we should rely on it for the purposes of estimating how many hospitals would take advantage of this proposed 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 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

² 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.

respondents from the 1,500 clinical nutrition managers surveyed). Weil et al. also reference current CMS requirements and policy regarding RD ordering privileges in their study's discussion where they state, "...independent prescriptive authority via clinical privileges would not be a CMS-accepted pathway for RDs to write orders..." Mention of the CMS requirements here leads us to believe that our requirements (included in the survey response "regulatory agencies" as used in the study) might present a more significant barrier than the results of the survey indicate.

Because there is still some degree of uncertainty involved in estimating how many hospitals would actually take advantage of this proposed allowance under the CoPs, we have chosen to present a range of savings estimates, using 4,655 (or 95 percent) as both our most likely estimate and as the upper bound of affected hospitals and 15 percent (from the survey cited above), or 735 hospitals, as the lower bound. However, our extensive experience with hospitals, hospital organizations, and RD professional organizations leads us to believe that if the change proposed here is finalized, a significant number of hospitals would move to grant RDs ordering privileges. Therefore, we believe that the upper bound estimate of potential hospital savings provided here is the more realistic and reliable end of the range.

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 would have lower PN usage due to lower patient censuses and would thus have lower savings;
- We adjusted the savings relative to average bed size for hospitals of 164 beds (from AHA Hospital Statistics), meaning that average annual savings would 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.

Based on the studies and these assumptions, we estimate savings ranging from \$33,546,135 (735 hospitals x \$45,641 in savings from reduced inappropriate PN usage = \$33,546,135) to \$212,458,855 (4,655 hospitals x \$45,641 in savings from reduced inappropriate PN usage = \$212,458,855).

As noted above, the proposed changes might also help hospitals to realize other significant savings. One 2008 study³ 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. This would 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 reasonable means for estimating these potential cost savings at this time.

More obviously, RDs with ordering privileges would 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

³ 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

and in a more complete and timely manner than they are currently allowed. While we can estimate with reasonable certainty the savings that might be realized by hospitals through our proposed changes in terms of the physician/APRN/PA time and salaries saved, it would be more difficult to reasonably estimate the potential savings and benefits that would result from these professionals now having potentially more time to devote their attentions to those aspects of patient care for which they are trained and qualified. 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 article⁴ 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:

- Using the wide range of estimates established above, between 735 and 4,655 hospitals would realize these savings;
- There is an average hourly salary difference of \$44 between RDs on one side (\$35 per hour) and the hourly salary average for physicians, APRNs, and PAs (\$79 per hour) on the other;

⁴ Kinn TJ. Clinical order writing privileges. Support Line. 2011; 33; 4; 3-10.

- 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, subsequent modifications to orders, and dietary orders for discharge/transfer/outpatient follow-up as needed, would take 10 minutes (0.17 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 co-morbidities, 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, would take 25 minutes (0.42 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)⁵ 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 ranges from \$49,803,600 ((735 hospitals x 5,600 inpatient hospital stays x 0.17 hours of a physician's/APRN's/PA's/RD's time x \$44 per hourly wage difference) + (735 hospitals x 1,400 inpatient hospital stays x 0.42 hours of a

⁵ 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

physician's/APRN's/PA's/RD's time x \$44 per hourly wage difference)) to \$315,422,800 annually ((4,655 hospitals x 5,600 inpatient hospital stays x 0.17 hours of a physician's/APRN's/PA's/RD's time x \$44 per hourly wage difference) + (4,655 hospitals x 1,400 inpatient hospital stays x 0.42 hours of a physician's/APRN's/PA's/RD's time x \$44 per hourly wage difference)). When combined with the savings estimate of \$33,546,135 to \$212,458,855 from reduced inappropriate PN usage, this brings the total savings estimate from the proposed CoP changes \$83,349,735 to \$527,881,655 (or approximately \$528 million) annually.

We acknowledge several additional kinds of uncertainty in our estimates of the proposed provision's savings. For instance, we have assumed that the time physicians, APRNs or PAs save due to being relieved of diet-ordering duties would 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 conservative side of 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 and prevailing conventional wisdom 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 proposed changes might have on hospital costs in this area. We welcome public comments on the assumptions and estimates we have put forth in this analysis.

Nuclear medicine services (§ 482.53)

We propose 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 propose to remove the term “direct” from the current requirement. This revision would allow 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 would 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 would not be routinely present. 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.

Based on statistics from the Society of Nuclear Medicine and Molecular 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 would take advantage of this proposed 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 PM—7 AM) is only 10 percent of all procedures performed (or 1.6 million);
- It would require 15 minutes of an MD/DO/PharmD’s time for direct supervision; and
- The average hourly salary for these two categories of practitioners is \$97.

Therefore, we estimate hospitals savings would be \$38.8 million for the change proposed (1.6 million off-hour procedures x \$97 hourly salary for MD/DO/PharmD x 15 minutes for direct supervision).

We proposed other revisions to the Hospital CoPs, but we do not believe those provisions would create tangible savings for hospitals. We welcome public comments on these assumptions and estimates.

4. Effects on Transplant Centers and Organ Procurement Organizations

Existing section 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 would 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 would be responsible for this notification would 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 would need to make the actual submission to CMS. We believe this would require 15 minutes, or .25 hours, of the medical director's time at an hourly wage of \$140 and 30 minutes, or .5 hours, of the transplant center administrator's time at an average hourly wage of \$70 ($\$140 \text{ hourly wage for medical director} \times .25 \text{ hours} = \35 (+) $\$70 \text{ hourly wage for administrator} \times .5 \text{ hours} = \35 for a total of \$70) for each notification to CMS. Based on our experience with transplant centers, we estimate that transplant centers make about 60 of these notifications each year. Thus, the annual savings to transplant centers from eliminating this requirement for all transplant centers would be about \$4,200 ($\$70 \text{ for each notification} \times 60 \text{ notifications} = \$4,200$).

In addition to the savings for transplant centers, the federal government would also sustain a savings due to federal staff not having to review and maintain these 60 notifications. Based on our experience with these notifications, we estimate that federal staff spend 20 minutes or .33 hours for each notification. The federal staff involved in reviewing and maintaining these notifications earn an average of \$55 an hour. Thus, we estimate that the federal government would realize a savings of \$18 ($\$55 \times .33 = \18.15 or about \$18) for each notification. For all 60 notifications, the federal government would realize an annual savings of \$1,080 ($\$18 \text{ for each notification} \times 60 \text{ notifications} = \$1,080$).

We expect that the changes proposed to the transplant center survey process would 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 would 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 rate 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 would 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.

In addition to the savings realized by the transplant centers, the federal government would 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. We estimate that the combined average hourly salary for the surveyors is \$146. Thus, to conduct a survey costs about \$26,572 (182 hours x \$146 hourly wage = \$26,572). By reducing the number of surveys by 10, the federal government would sustain an annual savings of \$265,720 (\$26,572 for each survey x 10 surveys = \$265,720).

The federal government would 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 would realize a savings of \$275 (5 hours for each survey x \$55 hourly wage = \$275). For all 10 surveys, we estimate the annual savings would be \$2,750 (\$275 for each survey x 10 surveys = \$2,750).

We believe that the other changes we have proposed for transplant centers and OPOs (at §§ 482.80(c), 482.82(c), 486.306, 486.308(b)(1), and 486.344(d)(2)(ii)) would 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 would be substantially reduced by allowing a 5-year transition period (2008-2013). The extended transition period would 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 propose to permit time-limited extensions of the due date for achieving full sprinkler status. Each case-specific extension would 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 169 facilities as of January 2012 that were not sprinklered, and another 1386 that were partially sprinklered for a total of 1555 facilities. Nursing homes have made steady progress in sprinkler installation, and we expect these numbers to decline considerably as August 13, 2013 approaches. We therefore project that 50 unsprinklered facilities will request and qualify for a deadline extension because they are building a full replacement facility that will not be ready by the deadline date, and an additional 75 partially-sprinklered nursing homes will request and qualify for an extension. These estimates are based on our examination of requests we have received from nursing homes in one large State, and generalized to the nation. We invite public comment on these estimates and on the fiscal savings estimates, described below.

In the case of a deadline extension for replacement of a nursing home, the unsprinklered facilities that are being replaced would still incur the cost of installing sprinklers in the new facility, but they would 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 would 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 would

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 would 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 propose 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 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 about 15 percent of the 1,330 CAHs (that is, 200 CAHs) would be affected by the removal of this provision and that its removal would produce estimated annual savings of nearly \$1.6 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 salary of \$95, spends 6 hours each visit and makes approximately two visits per month (26 visits per year) in a facility to perform the duties required

at § 485.631(b)(2). We estimate these annual visits alone cost \$14,820 per CAH per year (6 hours per visit x 26 visits x \$95 an hour = \$14,820 per CAH per year).

Next, we estimate current travel expenses associated with the biweekly requirement. Based on our experience with CAHs, we estimate that they spend approximately \$780 for physician travel expenses each year. We estimate that, for each visit, a physician drives an average of 50 miles round trip and is reimbursed for gas at a rate of \$0.55 (the IRS mileage reimbursement rate) per mile. Thus, each visit costs approximately \$30 (50 miles per visit x \$0.55 per mile) for a total annual burden of \$780 per CAH (\$30 per visit x 26 visits = \$780 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 and request comment in this area.

We believe that, in the absence of a requirement for biweekly physician visits, about half of all CAHs will increase their use of telemedicine, where appropriate, and will be able to reduce the total number of visits as a result of following efficient, site-specific planning efforts prompted by real-time needs. These changes would result in savings in both hourly and travel expenses for CAHs that choose to increase their use of telemedicine. We believe that eliminating the on-site, bi-weekly physician supervision would produce an annual estimated savings of half of all current physician supervision costs for approximately 200 CAHs. We estimate the savings as follows: \$1.5 million for on-site visits ($\$14,820/2 \times 200$ CAHs= $\$1,482,000$) and \$78,000 in travel costs ($\$780/2 \times 200 = \$78,000$).

Since CAHs are required to document the events in which an extraordinary circumstance would 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 \$2,699.84 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 earning \$18.88 per hour would 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, we estimate that the yearly cost of compliance for these 200 CAHs would be \$2,670 (26 visits per year per CAH x 11 percent x 200 CAHs x 0.25 hour x \$18.88 per hour = \$2,699.84 per year).

Thus, we estimate a total annual savings for CAHs of nearly \$1.6 million (\$2,670 + \$1,482,000 + \$78,000 = \$1,562,670). For RHCs and FQHCs, we believe our proposal would reduce burden 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 x 26 visits per year = \$1,950 per clinic per year). We estimate the costs for time spent for on-site visits to be \$9,880 per RHC or FQHC per year (4 hours/visit x \$95 an hour x 26 visits per year = \$9,880 per year).

By eliminating the provision, for each RHC or FQHC we estimate travel expenses would drop by about two-thirds (by \$1,287, or from \$1,950 to \$663, per year); we further estimate that the time spent on biweekly visits would decrease by a third (by \$3,260), thus from \$9,880 to

\$6,620 per year. Just as with CAHs, we believe clinics' and centers' travel expenses would decrease in conjunction with an increase in the use of telemedicine, where appropriate, and as a result of site-specific planning efforts prompted by real-time needs rather than routine. 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 would realize \$6.6 million in annual savings on travel expenses ($\$1,287$ per year \times 5,134 = $\$6,607,458$).

RHCs would realize \$12.9 million, and FQHCs \$16.7 million, in annual savings from fewer hours for on-site clinician visits ($\$3,260$ per year per RHC or FQHC per year). For RHCs, ($\$3,260 \times 3,977 = \$12,965,020$); for FQHCs, this means \$16.7 million in annual savings ($\$3,260 \times 5,134 = \$16,736,840$).

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 earning \$18.88 per hour would 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, we estimate the yearly cost of compliance for RHCs and FQHCs to be \$122,991 ($26 \text{ visits} \times 11 \text{ percent} \times [3977 \text{ RHCs} + 5134 \text{ FQHCs}] \times 0.25/\text{hour} \times \$18.88 \text{ per hour} = \$122,991$ per year for RHCs and FQHCs). Eliminating the biweekly requirement would eliminate this particular administrative cost entirely for all RHCs and FQHCs, producing a total annual savings of \$53,686 for RHCs and \$69,305 for FQHCs, respectively.

In total, we believe that eliminating the provision would produce annual estimated savings of \$18.1 million for RHCs in travel, hourly, and administrative costs (\$5,118,399 travel + \$12,965,020 hourly + \$53,686 administrative = \$18, 137,105). For FQHCs, we estimate that eliminating the provision would produce \$23.4 million in annual savings. (\$6,607,458 travel + \$16,736,840 hourly + \$69,305 administrative = \$23,413,603 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.

We welcome public comments on these assumptions and estimates.

Provision of Services (§ 485.635(a))

We propose to remove 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 would allow CAHs greater flexibility in their approach. We estimate that removing this requirement would 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 proposed rule, would 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 ($\$50 \times 8 \text{ hours} = \$400 \text{ per CAH} \times 665 \text{ CAHs} = \$266,000$). We welcome public comments on these assumptions and estimates.

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 propose to revise the regulation at § 491.2 to more closely conform with the physician definition in the Part 405 regulations 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 proposed rule, we would make a number of clarifications and changes pertaining to the regulations governing PT referral under CLIA. The first would be to add a statement to § 493.801(b) to explicitly note that the requirement to treat 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 proposed change would carve out a narrow exception in our longstanding interpretation of what constitutes an

“intentional” referral. In these instances, the laboratory would 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 propose that definitions for the following three terms would be added to the regulation: Reflex testing, Confirmatory testing, and repeat PT referral.

From 2007 through 2011 there were 41 cases of cited, intentional PT referral. Of these 41 cases, we estimate that 13 would have fit the terms of this proposed 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 proposed rule. We therefore estimate the annual fiscal savings of the proposed 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 benefits. For example, if the prior management is fired instead

of being reassigned to other duties for the two year period, some of the costs of paying for the new management's salaries, benefits and training may be able to be drawn from funding that had previously been earmarked to pay those expenses for their predecessors. That is, the costs associated with the new employee could be offset by the savings gained when the former employee is terminated. Any such offset would result in lower savings than is estimated above. There are also, however, unknowns that may result in larger savings than estimated above. For example, we have no data on whether terminated management historically received severance packages. If they did, those costs would have to be added to the costs we noted above. While we recognize these potential inaccuracies in our estimates, we lack data to account for these considerations. We welcome comments on this issue.

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 would 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 HHS is to treat all providers and suppliers as small entities in analyzing the effects of our rules.

This proposed rule would save affected entities almost \$700 million a year. Most of these savings would accrue to hospitals. While this is a large amount in total, the average saving per affected hospital is less than one half million dollars per year. 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 less than \$700 million annually. This is an average of about \$90,000 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 would be higher in larger hospitals, and lower in smaller hospitals, since these savings would be roughly proportional to patient volume.

Under HHS guidelines for RFA, 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 proposed rule would not have a significant economic impact on a substantial number of small entities, and certify that an Initial RFA 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 603 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 proposed 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 2012, that is approximately \$139 million. This proposed 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 would impose substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule would 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 proposed rule. For all of the proposed provisions, we considered not making these changes. Ultimately, we saw no good reasons not to propose these burden reducing changes. We welcome comments on whether we properly selected the best candidates for change, and welcome suggestions for additional reform candidates from the entire body of CoPs.

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 would best balance the advisability of timely achievement to full sprinkler status and the special challenges involved in large-scale construction projects.

Regarding the proposed revisions to the CLIA regulations, we focused our proposals exclusively on reflex or confirmatory testing. Such cases, where the laboratory has followed its standard operating procedure in full, provide a reasonable basis for the Secretary to determine that the referral was not intentional.

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 benefits, including health effects. We have illustratively presented one possible lower bound—for food and dietetic services—in the preceding analysis and in the Accounting Statement that follows. We welcome 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.

F. Accounting Statement

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. We estimate the overall cost savings that this rule would create would be approximately \$231 million to \$676 million in the first year, and \$209 million to \$654 million per year thereafter, or about \$214 million to \$659 million annualized over the next 5 years. Over a 5-year period, our primary estimate is that cost savings would be approximately \$3.3 billion, though they could be as low as about \$1 billion.

Table 2-- Accounting Statement: Classification of Estimated Costs and Savings

(\$in Millions)

<u>Category</u>	<u>Primary Estimate and Upper Bound</u>	<u>Lower Bound</u>	<u>Units</u>		
			<u>Year Dollars</u>	<u>Discount Rate</u>	<u>Period Covered</u>
Benefits	None				
Costs					
<u>Annualized Monetized reductions in Costs</u>	-\$659	-\$214	2012	7%	2013-17

	-\$659	-\$214	2012	3%	2013-17
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 416

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

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 proposes to amend 42 CFR as set forth below:

PART 416-- AMBULATORY SURGICAL SERVICES

1. 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).

Subpart C--Specific Conditions for Coverage

2. 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.

* * * * *

3. 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) 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.

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

4. 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.

Subpart C—Certification of ICF/IIDs

5. 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]

6. Section 442.105 is removed and reserved.

§ 442.110 [Removed and Reserved]

7. Section 442.110 is removed and reserved.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

8. 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.

Subpart C – Basic Hospital Functions

9. 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.

* * * * *

10. Section 482.22 is amended by revising the introductory text and paragraph (a) introductory text to read as follows:

§ 482.22 Condition of participation: Medical staff.

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

(a) Standard: Eligibility and process for appointment to medical staff. The medical staff must be composed of physicians. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of non-physician practitioners who are determined to be eligible for appointment by the governing body.

* * * * *

11. 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 dietician as authorized by the medical staff and in accordance with State law.

* * * * *

Subpart D -- Optional Hospital Services

12. 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.

* * * * *

13. 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 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 hospital for ordering the applicable outpatient services for their patients.

Subpart E –Requirements for Specialty Hospitals.

§ 482.66 [Redesignated as § 482.58]

14. Redesignate § 482.66 in Subpart E as § 482.58 in Subpart D.

§ 482.74 [Amended]

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

16. 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.

* * * * *

17. 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

18. 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).

Subpart B—Requirements for Long-Term Care Facilities

19. 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.

20. 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.

(B) It demonstrates that it has made the necessary financial commitments to complete the building replacement or modification.

(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

21. 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)).

Subpart F--Conditions of Participation: Critical Access Hospitals (CAHs)

22. Section 485.631 is amended by revising paragraph (b)(2) to read as follows:

§ 485.631 Condition of participation: Staffing and staff responsibilities.

* * * * *

(b) * * *

(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.

* * * * *

23. 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**

24. 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).

**Subpart G—Requirements for Certification and Designation and Conditions for Coverage:
Organ Procurement Organizations**

25. 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.

* * * * *

26. 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.

* * * * *

27. 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

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

Authority: Secs. 1102 and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302 and 1395(hh)); Section 6111 of the Patient Protection and Affordable Care Act (Pub. L. 111–148)

Subpart A--General Provisions

29. 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 paragraph (c)(2).
- 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 § 482.82(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) * * *

(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 demonstrating compliance with the requirement at § 482.82(c)(2)(ii)(C) 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

30. 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).

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

31. Section 491.2 is amended by revising the definition of “physician” to read as follows:

§ 491.2 Definitions.

* * * * *

Physician means a practitioner who meets the requirements of sections 1861(r) and 1861(aa)(2)(B) and (aa)(3)(B) of the Act and includes:

(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).

* * * * *

32. 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

33. 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)).

Subpart A—General Provisions

34. Section 493.2 is amended by adding the definitions of “confirmatory testing”, “reflex testing”, and “repeat proficiency testing referral,” 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.

* * * * *

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.

Repeat proficiency testing referral means a second instance in which a proficiency testing sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory's proficiency testing program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved accreditation organizations).

* * * * *

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

35. 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 or confirmatory testing at another laboratory, the laboratory should treat 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 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.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)
(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance;
and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

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CMS-3267-P

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Kathleen Sebelius,

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