

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

[CMS-9070-P]

RIN 0938-AQ96

Medicare and Medicaid Program; 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 identifies and proposes reforms in Medicare and Medicaid regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and beneficiaries. 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 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-9070-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-9070-P,
P.O. Box 8012,
Baltimore, MD 21244-1850.

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-9070-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:

Ronisha Davis, (410) 786-6882.

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.

I. Background

In January 2011, the President issued Executive Order 13563, “Improving Regulations 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 May 18, 2011, a Preliminary 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 rules that could be eliminated or reformed to improve effectiveness or reduce unnecessary red tape 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. CMS has also identified non-regulatory changes to increase transparency and to become a better business partner.

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 objective is 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. HHS welcomes public suggestions about appropriate reforms. If, at any time, members of the public identify possible reforms to streamline requirements and to reduce existing burdens, HHS will give those suggestions careful consideration. Therefore, along with this proposed rule, we seek ideas from the public to help identify areas for possible reform.

II. Provisions of the Proposed Regulations

The following is a description of each of the proposals set forth in this proposed rule. We have grouped the proposals into three categories-- (1) removes unnecessarily burdensome requirements; (2) removes obsolete regulations; and (3) responds to stakeholder concerns. There are 14 specific reforms included in this proposed rule. As noted above, we seek comments on additional areas for future reforms in these three areas or others.

A. Removes Unnecessarily Burdensome Requirements

The following proposals seek to provide some form of burden relief to providers and suppliers by modifying, removing, or streamlining current regulations that we have identified as excessively burdensome.

1. End-Stage Renal Disease (ESRD) Facilities (§494.60)

Current regulations at 42 CFR part 494 provide Conditions for Coverage (CfCs) for Medicare-participating end-stage renal disease (ESRD) facilities. Effective February 9, 2009, these regulations were updated to include Federal Life Safety Code (LSC) provisions that we applied to ESRD facilities to standardize CMS regulations across provider types. When the new regulation was first promulgated, we believed that standardized application of the LSC was desirable and that the costs for ESRD facilities would not be excessive. However, we have since determined that standardization may not be appropriate given the non-residential and unique characteristics of ESRD facilities and the increased burden created by these requirements without the commensurate benefit. Chapters 20 and 21 of the National Fire Protection Agency's (NFPA) 101 LSC, 2000 Edition, were incorporated by reference in the ESRD regulations at §494.60(e).

When implemented, these Federal LSC regulations were found to duplicate many provisions of already existing State and local fire safety codes covering ESRD facilities. Although the State and local codes protected patients from fire hazards, the NFPA 101 LSC retroactively imposed some additional structural requirements. We believe that some of these additional requirements, such as smoke compartments (per section 20.3.7/21.3.7 of NFPA 101) are unnecessary for most ESRD facilities. Smoke compartments, for example, are required in hospital and ambulatory surgical centers where patients are anesthetized, unconscious, or sleeping overnight. Smoke compartments are unnecessary in ESRD facilities as these compartments support a “defend in place” fire strategy which assumes the occupants of a location cannot immediately evacuate in case of fire. However, in dialysis facilities, the evacuation process from fire is rapid disconnection from the dialysis machine and a quick exit.

In retrospect, the additional structural requirements of NFPA 101 potentially could improve patient safety from fire in specific dialysis facilities that pose a higher risk for life safety from fire by their proximity to a potential fire source or their barriers to prompt evacuation from fire. These higher risk locations are those dialysis facilities that are adjacent to occupancies that contain “industrial high hazard contents” and those facilities that do not have a readily available exit to the outside for swift, unencumbered evacuation.

Data demonstrate that there is an extremely low risk of fire in outpatient dialysis facilities, and there are no recorded patient injuries or death due to fire in the 40 years of the Medicare ESRD program. The Federal Emergency Management Agency’s (FEMA) Topical Fire Report Series (TFRS) documented the low fire risk of ESRD facilities, which ranked lowest (0.1 percent) in fire incidence among all health care facilities. (Medical Facility Fires, TFRS

Volume 9, Issue 4). The reason that the fire risk is so low in dialysis facilities is due to the following combination of factors:

- ESRD facilities do not have fire ignition sources commonly found in other medical facilities, for example, cooking, anesthesia, paint shops, or piped-in gases, and are generally configured with open patient treatment areas providing exits directly to the outside;
- Dialysis patients are not anesthetized and are required at §494.60(d)(2) of the ESRD regulation to be trained in emergency disconnect from their dialysis treatment and evacuation from the building;
- Section 494.60(d)(4) of the ESRD regulation requires that staff be present in the patient treatment area at all times during treatment and therefore immediately available to assist in emergency evacuation.

While the risks of fire are very low in a dialysis facility, the costs of complying with the Federal LSC requirements in dialysis facilities are high. Through research discussed in the following paragraph, CMS has learned that the actual costs for renovation and construction necessary for compliance with the additional requirements of NFPA 101 for dialysis facilities are considerable and profoundly exceed the original government estimate of \$1,960 as published in the preamble to the new 2008 ESRD/LSC regulations.

To estimate the true costs for renovation and construction necessary to comply with the requirements for NFPA 101, in June 2011, CMS asked ESRD providers to provide estimates of the financial impact of implementing four potentially-costly additional requirements of NFPA 101. They included smoke compartment barriers, occupancy separations, hazardous area separations, and upgraded fire alarms. Owners of 3,756 of 5,600 existing certified dialysis

facilities responded to the CMS request for cost projections. The responders represented approximately 70 percent of existing dialysis facilities, including hospital-owned facilities and those owned by small, medium, and large dialysis organizations.

The data collected showed that approximately 50 percent (an estimated 2, 800) of the existing ESRD facilities would require renovations or upgrading of at least one of the four elements to comply with the requirements of NFPA 101. There are several reasons why, in June 2011, approximately 50 percent of existing dialysis facilities had not been renovated to comply with the February 2009 implementation date. The primary reason is the pervasive inconsistency in knowledge, interpretation, and application of NFPA 101 to ESRD facilities that we have become aware of since the 2009 implementation date. There was a high variability in the cost estimates submitted, ranging from a low of \$23,500 to a high of \$222,000 for an existing facility which needed to renovate, construct and upgrade all four components. The average per facility cost estimates submitted for the additional structural requirements of NFPA 101 are as follows:

- Smoke compartments-\$32,544
- Occupancy separation-\$28,139
- Hazardous areas separation-\$16,976

The total average cost for a facility to meet all three would be \$77,659. We suspect that the variability of the estimates may be due to different State and local requirements already in existence, differences in contractor costs, varying building characteristics (for example, age, size, construction type), and the inconsistent interpretations and applications of NFPA 101 that are prevalent across the nation. The wide range of estimates makes it difficult to determine an

average cost related to implementation of NFPA 101. However, using the average costs for the individual structural requirements listed above, if 50 percent or 2,800 facilities required only renovation for hazardous area separation, the savings would be \$47.5 million. If 2,800 facilities required renovation for all three structural requirements, the total savings from the burden reduction at the average estimate for all three would be \$217 million.

These amounts represent a significant financial burden on facilities, with little or no improvement in patient safety from fire for a majority of them. Expenditures of this magnitude would likely divert resources away from areas which do affect dialysis patient safety, such as infection control and prevention.

The cost estimates do not account for the added burden that renovation to comply with NFPA 101 would impose on dialysis patients who must be relocated to other ESRD facilities for their treatments during construction. Significant additional costs would also be incurred by Federal government agencies and State Survey Agencies for oversight activities of LSC surveys which often duplicate State LSC surveys.

Based on information gained since publication of the updated ESRD CfC, we have concluded that the enforcement of the Federal LSC requirements of NFPA 101 add costs out of proportion to any added protection that they may afford in dialysis facilities which are not at higher risk of fire penetration from adjacent industrial “high hazard” occupancies and where swift, unencumbered evacuation to the outside is available. Therefore, we propose revising §494.60(e)(1) to restrict mandatory compliance with the NFPA 101 LSC to those ESRD facilities located adjacent to “high hazardous” occupancies and those facilities whose patient treatment areas are not located at grade level with direct access to the outside. This revision

would retain the NFPA 101 LSC protections for those facilities in higher-risk locations while relieving burden on those for whom the subdivision of building space and other additional LSC requirements of NFPA 101 are unnecessary.

We intend to use the NFPA definition of “high hazard occupancy” found at A.3.3.134.8.2, Annex A, NFPA 101, Life Safety Code 2000, which applies to “occupancies where gasoline and other flammable liquids are handled, used or stored under such conditions that involve possible release of flammable vapors; where grain dust, wood flour or plastic dusts, aluminum or magnesium dust, or other explosive dusts are produced; where hazardous chemicals or explosives are manufactured, stored, or handled; where cotton or other combustible fibers are processed or handled under conditions that might produce flammable flyings; and where other situations of similar hazard exist.”

We note that all ESRD facilities would still be required to comply with State and local fire codes and safety standards under §494.20. We also propose revising §494.60(e)(2) to clarify which ESRD facilities must use sprinkler-equipped buildings: those housed in multi-story buildings of lesser fire protected construction types (Types II(000), III(200), or V(000), as defined in NFPA 101), which were constructed after January 1, 2008; and those housed in high rise buildings over 75 feet in height. We note that this revision would not change the meaning or intent of §494.60(e)(2), but instead would clarify it. That provision states that dialysis facilities participating in Medicare as of October 14, 2008, may continue to use non-sprinklered buildings if such buildings were constructed before January 1, 2008, and State law so permits.

The ESRD CfCs also address other topics related to fire and building safety that will remain in place under our proposed revision. These existing CfC requirements include specific

rules on how to handle chemicals related to the dialysis process, as well as general requirements for appropriate training in emergency preparedness for the staff and patients, including provisions for instructions on disconnecting from the dialysis machine during an emergency and instructions on emergency evacuation. We welcome comments from the public on whether the other ESRD CfCs can be improved in a way that minimizes provider burden while protecting patient safety or, alternately, the extent to which remaining requirements are necessary and appropriate for the care and safety of dialysis patients. Similarly, we note that other CMS regulations include CfCs, and we seek comments on whether we should revisit these or other regulatory provisions or whether existing requirements are necessary and appropriate.

Contact: Thomas Hamilton, 410-786-9493.

2. ASC Emergency Equipment

Section 1832(a)(2)(F)(i) of the Act specifies that Ambulatory Surgical Centers (ASCs) must meet health, safety, and other requirements 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 are adequate to 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 standards if they are certified by one of the national accrediting organizations whose standards meet or exceed the CfCs. The ASC regulations were first published on August 5, 1982 (47 FR 34082). Most of the revisions since then have been payment related with the exception of a final rule published on November 18, 2008 (73 FR 68502) that revised four existing health and

safety CfCs and created three new health and safety CfCs (42 CFR Part §416.41 through §416.43 and §416.49 through §416.52).

Sections 416.44(c)(1) through (c)(9) provide a detailed list of specific emergency equipment that must be available to the ASC's operating room, for example, emergency call system; oxygen; mechanical ventilator assistance equipment including airways, manual breathing bag, and ventilator; cardiac defibrillator; cardiac monitoring equipment; tracheotomy set; laryngoscopes and endotracheal tubes; suction equipment; and emergency medical equipment and supplies specified by the medical staff. In recent years, we have learned from the ASC community that some of this equipment is outdated, while other equipment is not applicable to the emergency needs of all ASCs. The emergency equipment CfC has not been revised since its inception in 1982. To ensure that no ASC is burdened with maintaining unnecessary equipment, we are proposing to revise the requirements for this CfC.

We propose to remove the list of emergency equipment at §416.44(c)(1) through (c)(9) and propose at §416.44(c) to require that ASCs, in conjunction with their governing body and the medical staff, develop policies and procedures which specify the types of emergency equipment that would be appropriate for the facility's patient population, and make the items immediately available at the ASC to handle inter- or post-operative emergencies. We are also proposing that the emergency equipment identified by the ASC meet the current acceptable standards of practice in the ASC industry. We believe that these proposed changes would enable ASCs to better meet current demands, while also ensuring ASCs have the flexibility necessary to respond to emergency needs and incorporate the use of modern equipment most suitable for the procedures performed in the facility.

We note that a potential disadvantage of the approach we propose is that, by allowing ASCs to identify the emergency equipment most appropriate for each individual facility, there could be increased variation in emergency preparedness between different ASCs, even among ASCs that provide very similar services. We therefore invite comment on our proposed approach and on any alternatives to our approach. An example of such an alternative might be for us to categorize ASCs according to the major services they provide (such as ASCs that typically use general anesthesia), and then specify a minimum array of equipment tailored to the various categories of risk.

Contact: Jacqueline Morgan, 410-786-4282.

3. Revocation of Enrollment and Billing Privileges in the Medicare Program (§424.535)

On June 27, 2008, we published a final rule in the **Federal Register** (73 FR 36448) entitled “Medicare Program; Appeals of CMS or CMS Contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges.” In that rule, we added a new provision at §424.535(c) to provide that: “After a provider, supplier, delegated official, or authorizing official has had their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar. The re-enrollment bar is a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation.” The purpose of this provision was to prevent providers and suppliers from being able to immediately re-enroll in Medicare after their billing privileges were revoked.

Section 424.535(a)(1) and §424.535(c), respectively, provide that--(1) Medicare billing privileges may be revoked when a provider or supplier is determined not to be in compliance

with our enrollment requirements; and (2) a post-revocation re-enrollment bar of a minimum of 1 year shall be imposed.

We believe that the re-enrollment bar is unnecessary in certain situations. Accordingly, we propose to eliminate the re-enrollment bar in instances when providers and suppliers have not responded timely to requests for revalidation of enrollment or other requests for information initiated by CMS. Specifically, we propose revising §424.535(c) to expressly provide that the re-enrollment bar would not apply if the revocation is based solely upon the failure of a provider or supplier to respond timely to a revalidation request or other request for information. We believe that this change is appropriate because the re-enrollment bar in such circumstances often results in unnecessarily harsh consequences for the provider or supplier and causes beneficiary access issues in some cases. We have learned of numerous instances when the provider's failure to respond to a revalidation request was unintentional; that is, the provider was not aware of the request due to, for instance, misrouted mail or a clerical mistake. This is different from other revocation reasons, which may be more serious; for example, we revoke providers that have been excluded from Medicare, Medicaid, or other Federal health care programs or that have been convicted of a felony under §424.535(a)(2) and (a)(3), respectively. Finally, there is another, less restrictive regulatory remedy available for addressing a failure to respond timely to a revalidation request. This remedy is discussed below in section II.A.4.c.

Contact: Morgan Burns, 202-690-5145.

4. Deactivation of Medicare Billing Privileges (§424.540)

On April 21, 2006, we published a final rule in the **Federal Register** (71 FR 20753) entitled "Medicare Program; Requirements for Providers and Suppliers to Establish and

Maintain Medicare Enrollment.” As part of that rule, we established provisions for the deactivation of Medicare billing privileges at §424.540.

a. Section 424.540(a)(1)

Section 424.540(a)(1) specifies that Medicare billing privileges may be deactivated if Medicare claims are not submitted for 12 consecutive months. The purpose of this provision was to prevent situations in which unused, idle Medicare billing numbers could be accessed by individuals and entities to submit false claims. Currently, Medicare provider or supplier enrollment billing privileges are deactivated (made ineligible for Medicare billing purposes) for providers or suppliers that have not submitted a Medicare claim for 12 consecutive months. If the deactivated provider does furnish services and attempts to submit a claim after the date of deactivation, the claim would be denied. Therefore, once deactivated, a new provider or supplier enrollment application must be submitted and processed by the Medicare contractor before the billing privileges can be reactivated.

We propose to revise §424.540(a) to apply only to those providers and suppliers who do not submit a Form CMS-855I (the enrollment form for individual physicians and non-physician practitioners) to enroll in the Medicare program. Physicians and non-physician practitioners are deactivated most often due to billing inactivity. To reactivate their Medicare billing privileges, they must resubmit an enrollment application.

We are most concerned with organizations that fail to submit a claim within a 12-month period, since business organizations would generally submit a claim on a more frequent basis. Conversely, we believe that there are instances in which individual practitioners may have a valid reason for not filing claims within a 12-month period. For instance, the practitioner--(1)

may be enrolled in Medicare, but generally only treats non-Medicare patients; or (2) may have two separately-enumerated practice locations listed on its Form CMS-855I, yet typically only performs services at one of them.

Further, the 12-month deactivation and reactivation processes also increase the workload and administrative costs of Medicare contractors. Accordingly, our proposal to revise §424.540 (a) would remove this unnecessary burden without jeopardizing our ability to detect and prevent fraud and abuse. We have issued guidance that requires our contractors to conduct certain verification activities to guard against physician and non-physician practitioner identity theft. We believe that this would lessen the danger that the unused billing numbers of these individuals would be accessed by others to submit false claims.

b. Section 424.540(a)(2)

Section 424.540(a)(2) specifies that a provider or supplier's Medicare billing privileges may be deactivated if it fails to report a change to its enrollment information within 90 calendar days or, for changes in ownership or control, within 30 calendar days. We are not proposing to alter this provision. We believe it is necessary for providers and suppliers to understand the importance of furnishing updated enrollment information to the Medicare program, for incorrect or aged data can lead to improper payments.

c. Section 424.540(a)(3)

We propose to add a new §424.540(a)(3) that would allow us to deactivate, rather than revoke, the Medicare billing privileges of a provider or supplier that fails to furnish complete and accurate information and all supporting documentation within 90 calendar days of receiving notification to submit an enrollment application and supporting documentation, or resubmit and

certify to the accuracy of its enrollment information. Although the deactivated provider or supplier would still have to submit a complete enrollment application to reactivate its billing privileges, it would remain enrolled in Medicare and would not be subject to other, ancillary consequences that a revocation entails: for instance, a prior revocation must be reported in section 3 of the Form CMS-855I application, whereas a prior deactivation need not. In fact, it is for this reason that we believe our proposal would reduce the burden on the provider and supplier communities.

Contact: Morgan Burns, 202-690-5145.

5. Duration of Agreement for Intermediate Care Facilities for the Intellectually Disabled (referred to in current regulations as Intermediate Care Facilities for the Mentally Retarded) (§442.15 through §442.109)

As described elsewhere in this preamble, we are replacing the use of the term “mentally retarded” with the term “intellectually disabled” as described in this program, so we have used the new term in these proposed provisions.

Section 1910 of the Act provides for the certification and approval of Intermediate Care Facilities for the Intellectually Disabled (ICFs/ID). Current regulations at §442.109 and §442.110 address ICFs/ID provider agreements and limit the ICFs/ID provider agreements under Medicaid to annual time limits. We propose to remove the time limited agreements for ICFs/ID at §442.16. We also are proposing to eliminate this requirement at §442.15, §442.109, and §442.110. We propose to replace the requirement with an open ended agreement which, consistent with nursing facilities (NFs), would remain in effect until the Secretary or a State

determines that the ICF/ID no longer meets the conditions of participation for ICFs/ID at subpart I part 483.

Also, we are proposing to add a requirement that a certified ICF/ID must be surveyed on average every 12 months with a maximum 15-month survey interval. Current regulations at 42 CFR 442 require that ICFs/ID be surveyed for compliance with conditions of participation at least every 12 months on a relatively fixed schedule. By contrast, nursing homes must be surveyed for compliance with certification standards at intervals of between 12 and 15 months. We anticipate the proposed change in the certification period would have positive impacts on the care provided in these facilities as well as the efficient and effective operation of State survey agencies responsible for regulating ICFs/ID. We also anticipate that the adoption of flexible survey scheduling would encourage more consistent staffing at levels that support certification standards.

In addition, State survey agency resources are strained by the rigid timelines imposed in the current regulation. For example, if a complaint results in an abbreviated survey 10 or 11 months into the facility's certification period, the current regulation does not allow the State agency to expand the complaint survey for the purpose of completing the requirements of annual certification at the same time. Instead, the State is required to conduct another full survey at 12 months, which is duplicative. More flexibility would allow States to use their survey staff in a targeted fashion, allocating resources where needed to assure resident safety and quality of care, rather than being forced to meet rigid regulatory timelines that do not bear a relationship to the needs of residents.

Contact: Thomas Hamilton, 410-786-9493.

B. Removes Obsolete or Duplicative Regulations or Provides Clarifying Information

The following proposals seek to remove requirements in the Code of Federal Regulations (CFR) that are no longer needed or enforced. We have identified regulations that have become obsolete and need to be updated.

1. OMB Control Numbers for Approved Collections of Information (§400.300 and §400.310)

Part 400 subpart C requires the collection and display of control numbers assigned by the Office of Management and Budget (OMB) to collections of information contained in CMS regulations. The chart at §400.310 that displays the OMB control numbers has not been updated since December 8, 1995. We believe that, it is no longer necessary to maintain the chart, because an inventory of currently approved CMS information collections, including OMB control numbers, is displayed on a public website at <http://www.reginfo.gov/public/do/PRAMain>. The website provides more timely access to the OMB control numbers for CMS information collection requests than the process of publishing updates in the CFR. Also, as part of our quarterly notice of CMS issuances, which is published each quarter in the **Federal Register**, we will remind reviewers where they can find the most current list of information collections and OMB control numbers. For these reasons, we are proposing to remove and reserve subpart C since the content of the information contained in this subpart is obsolete and more readily available on the public website.

Contact: Ronisha Davis, 410-786-6882.

2. Removal of Obsolete Provisions Related to Initial Determinations, Appeals, and Reopenings of Part A and Part B Claims and Entitlement Determinations (§405.701 through §405.877)

In this rule, we propose to remove the obsolete provisions contained in 42 CFR part 405 subparts G and H governing initial determinations, appeals, and reopenings of Part A and Part B claims, and determinations and appeals regarding an individual's entitlement to benefits under Part A and Part B of Medicare. Section 1869 of the Act and 42 CFR part 405 subpart I set forth the current policies for such determinations, appeals, and reopenings.

On November 15, 2002, we published a comprehensive proposed rule in the **Federal Register** (67 FR 69312), entitled "Changes to the Medicare Claims Appeal Procedures," to implement the relevant claims and appeals provisions contained in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554). In this proposed rule, we established, in one location (part 405 subpart I), provisions governing all aspects of Part A and Part B claims appeals. In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) made further changes to the Medicare claims appeals process. On March 8, 2005, we published an interim final rule with comment period in the **Federal Register** (70 FR 11420) to implement provisions of the proposed rule, and to explain how the recently enacted MMA provisions would be implemented. On December 9, 2009, we published a final rule in the **Federal Register** (74 FR 65296) entitled, "Changes to the Medicare Claims Appeal Procedures," responding to comments received on the interim final rule implementing part 405 subpart I.

Part 405 subparts G and H contain the policies for initial determinations, appeals, and

reopenings of Medicare Part A and Part B claims, before the effective date of BIPA (referred to as “pre-BIPA appeals”). In addition, part 405 subparts G and H contain provisions regarding initial determinations and appeals with respect to an individual’s entitlement to Medicare Parts A and B. Under subparts G and H, initial determinations and appeals with respect to an individual’s entitlement to Medicare Parts A and B were conducted by the Social Security Administration (SSA) and governed by the provisions set forth in 20 CFR part 404 subpart J. Under part 405 subpart I, we explain that the SSA makes initial determinations regarding an individual’s entitlement to Medicare Parts A and B, and conducts reconsiderations of those initial determinations, in accordance with 20 CFR part 404, subpart J (see 42 CFR §405.904). However, entitlement appeals beyond the reconsideration level (that is, to an Administrative Law Judge, the Medicare Appeals Council, or Federal District Court) are governed by the appeals procedures set forth in part 405 subpart I.

The provisions in part 405 subpart I were intended to replace the provisions in part 405 subparts G and H once all pre-BIPA appeals were completed. However, we determined it was necessary to establish a phased-in implementation approach for part 405 subpart I appeals, and to maintain the existing provisions in subparts G and H until the completion of all pre-BIPA appeals (see, 74 FR 11424). With the publication of the December 9, 2009 final rule, some pre-BIPA appeals had not been completed. Thus, we were unable to remove the appeals provisions in subparts G and H at that time.

In this rule, we propose to remove the obsolete provisions since it is our expectation that in the 6 years since publication of the March 8, 2005 interim final rule, any party with a pending pre-BIPA appeal would have received an appeal decision or would have brought the pending

matter to our attention. We believe that removing these regulations would eliminate any possible confusion among Medicare beneficiaries, providers, suppliers, and their representatives with respect to the applicable appeal rights and procedures. However, while we believe that all pre-BIPA appeals have been processed, we cannot be completely certain that no pending pre-BIPA appeals currently exist. In order to ensure that parties receive due process for their claim disputes, we propose that any newly identified pre-BIPA appeals be handled under the current appeals provisions set forth in part 405 subpart I. (We note that all reopening actions, regardless of whether the determination or decision was made under the pre-BIPA process, initial determinations on claims, and, as explained above, initial determinations and appeals with respect to Medicare entitlement, are currently processed under the applicable procedures in part 405 subpart I.) We believe that maintaining a separate pre-BIPA claim appeals process in the unlikely event such an appeal is discovered is inefficient and impracticable. Using the current appeals process under subpart I, for all appeal requests filed on or after the effective date of this rule, as finalized, would reduce potential confusion about applicable appeal procedures, and would enable parties to take advantage of the reduced decision-making timeframes and other process improvements offered throughout part 405 subpart I (for example, panel reviews during the Qualified Independent Contractor (QIC) reconsideration process for claims denied as not medically reasonable and necessary (see §405.968(c)), and the right to escalate cases to the next level of appeal when the QIC, Administrative Law Judge (ALJ) or Medicare Appeals Council does not issue a decision within the applicable adjudication timeframe (see §405.970, §405.1104, and §405.1132).

Table 1 below illustrates how we propose to process any pre-BIPA Part A appeals

identified after the effective date of this rule, as finalized, under our current regulations at part 405 subpart I. If a party demonstrates that they had requested reconsideration under part 405 subpart G, but did not receive a decision or dismissal, the party would be entitled to request a redetermination, followed by a QIC reconsideration, ALJ hearing, Medicare Appeals Council review, and judicial review in accordance with the provisions in part 405 subpart I. If a party demonstrates that they received a reconsideration decision and requested an ALJ hearing under part 405 subpart G but did not receive an ALJ hearing decision or dismissal, the party would be entitled to request a QIC reconsideration, followed by an ALJ hearing, Medicare Appeals Council review, and judicial review in accordance with the provisions in part 405 subpart I. If a party demonstrates that they received an ALJ hearing decision under subpart G, and requested but did not receive a decision, dismissal or denial of review notice from the Departmental Appeals Board, the party would be entitled to request Medicare Appeals Council review under part 405 subpart I.

Table 1 -- Pre-BIPA Part A Appeals	
Pending Pre-BIPA Level of Appeal in part 405 subpart G	Appeal resumes at the following level in part 405 subpart I
Reconsideration (§405.710)	Redetermination (§405.940)
ALJ Hearing (§405.720)	QIC Reconsideration (§405.960)
Departmental Appeals Board Review (§405.724)	Medicare Appeals Council Review (§405.1100)

Table 2 below illustrates how we propose to process any pre-BIPA Part B appeals identified after the effective date of this rule, as finalized, under our current regulations at part

405 subpart I. If a party demonstrates that they requested a carrier review of an initial determination under subpart H, but did not receive a carrier review determination or dismissal, the party would be entitled to request a redetermination, followed by QIC reconsideration, ALJ hearing, Medicare Appeals Council review and judicial review in accordance with the provisions in part 405 subpart I. If a party demonstrates that they received a carrier review determination and requested a carrier hearing but did not receive a carrier hearing officer decision or dismissal under subpart H, the party would be entitled to request a QIC reconsideration followed by an ALJ hearing, Medicare Appeals Council review and judicial review in accordance with the provisions in part 405 subpart I. If a party demonstrates that they received a carrier hearing officer decision, and requested but did not receive an ALJ hearing decision or dismissal under subpart H, the party would be directed to request a QIC reconsideration, followed by an ALJ hearing, Medicare Appeals Council review and judicial review in accordance with the provisions in part 405 subpart I. Finally, if a party demonstrates that they received an ALJ hearing decision under subpart H, and requested but did not receive a decision, dismissal or denial of review notice from the Departmental Appeals Board under subpart H, the party would be entitled to request Medicare Appeals Council review under part 405 subpart I.

We are proposing that parties seek a QIC reconsideration before requesting and receiving a hearing before an ALJ under subpart I for several reasons. First, we note that several subpart I procedural requirements at the ALJ level of appeal are predicated on a QIC conducting a reconsideration. For example, the right to request an ALJ hearing under §405.1000 and §405.1002 is premised on a party being dissatisfied with a QIC reconsideration decision. In addition, under §405.966(a)(2) and §405.1028, absent a showing of good cause, evidence not

submitted before the issuance of the QIC reconsideration by a provider, supplier, or beneficiary represented by a provider or supplier would be excluded from consideration by the ALJ. Thus, channeling appeals through the QIC reconsideration level would ensure that parties are afforded an opportunity to submit relevant evidence without having to demonstrate good cause for not submitting it during the pre-BIPA process. Second, we believe channeling pre-BIPA appeals through the QIC reconsideration process would benefit parties. For example, we believe parties would benefit from the panel review by physicians and other appropriate health care professionals at the QIC level when claims are denied as not medically reasonable and necessary under section 1862(a)(1)(A) of the Act. We also believe the administrative record would be more fully developed with respect to the medical and scientific evidence considered by such panels. Third, in order for a party to seek expedited access to judicial review under §405.990, the party must first have received a QIC reconsideration, or the appeal must have been escalated from the QIC to the ALJ level (see, §405.990(b)). To ensure a party may seek expedited access to judicial review, if such review is appropriate, we are proposing to channel pre-BIPA appeals through the QIC reconsideration process when the party has not received an ALJ decision. Finally, as noted above, we believe that having one set of rules apply to all appeals would eliminate the confusion and uncertainty regarding the appropriate procedures to follow should there be any existing pre-BIPA appeals.

Table 2 -- Pre-BIPA Part B Appeals	
Pending Pre-BIPA Level of Appeal in part 405 subpart H	Appeal resumes at the following level in part 405 subpart I
Review of Initial Determination (§405.807)	Redetermination (§405.940)
Carrier Hearing (§ 405.821)	QIC Reconsideration (§405.960)
ALJ Hearing (§ 405.855)	QIC Reconsideration (§405.960)
Departmental Appeals Board Review (§ 405.856)	Medicare Appeals Council Review (§ 405.1100)

With very limited exceptions as noted below, the provisions in subparts G and H related to the processing of initial determinations, reopenings, and appeals of claims under Part A and Part B of Medicare, and determinations and appeals regarding an individual's entitlement to benefits under Part A and Part B of Medicare are obsolete because of the new procedures set forth in subpart I. We propose to remove all such obsolete provisions. The provisions in subparts G and H identified below are either unrelated to claims or entitlement appeals and are still in effect, or were inadvertently not included in subpart I, and accordingly, would be retained and redesignated to subpart I.

We propose to retain §405.706, "Decisions of utilization review committees," and redesignate the section as §405.925 in subpart I. This regulatory provision explains that--(1) the decisions made by the utilization review committees are not initial determinations made by the Secretary within the meaning of section 1869 of the Act; (2) are not subject to the appeal; and (3) further explains how utilization review committee decisions may be used in payment and coverage decisions. In drafting the regulations under part 405 subpart I, we inadvertently omitted this section. For clarity, and to ensure that beneficiaries and providers understand that utilization review committee decisions are not appealable, and in furtherance of our goal to

include all relevant claims appeals procedures in one place, we are proposing to retain §405.706, and redesignate it as §405.925.

In addition, we propose to retain §405.874, “Appeals of CMS or a CMS contractor,” and redesignate the provisions as §405.800, §405.803, §405.806, §405.809, §405.812, §405.815, and §405.818. These provisions set forth, among other things, the procedures related to denials of provider or supplier enrollment applications, revocations of Medicare provider or supplier billing privileges, and the appeal rights afforded to the parties to those determinations. As these procedures do not relate directly to initial determinations and appeals of Medicare claims, they were not included in part 405 subpart I. However, these provisions are not obsolete and are still applicable to provider and supplier enrollment actions. We also note that we are making minor technical edits to the current text to refine the section.

Finally, we also propose to remove §405.753 and §405.877 (“Appeal of a categorization of a device.”). These regulations are obsolete because they no longer comport with the definition of “national coverage determination” in section 1869(f) of the Act, as amended by section 522 of BIPA. The Food and Drug Administration's (FDA) categorization of a product as a category A device is not a determination of whether or not the item is covered under title XVIII of the Act. Under §405.203(c), we use the FDA categorization in making a coverage decision. Thus, our decision (acting on the FDA's categorization) to deny a claim for a category A device is an initial determination that is subject to review through the claims appeals process.

Contact: Flosetta Rowry, 410-786-8492.

3. ASC Infection Control Program (§416.44)

In existing regulations at 42 CFR §416.51, we require all ASCs to adhere to regulations

regarding Infection Control, which include the requirement that all ASCs develop an infection control program. The regulations also describe how ASCs must set up their infection control program, such as the requirement that the ASC designate a qualified professional who has training in infection control and the ASC's obligation to establish a plan of action regarding preventing, identifying, and managing infections and communicable diseases.

Current regulations also contain a provision for infection control that is located within the physical environment standard in 42 CFR §416.44(a)(3). The requirement states that an ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to the appropriate authorities. This regulatory requirement was part of the original CfCs first published for ASCs in 1982. Publication of the November, 2008 ASC final rule elevated the infection control requirements from a standard level under the Environment condition to a separate condition level requirement, thus making the regulatory requirement in the Environment CfC duplicative. The Infection Control CfC located at §416.51 expands and broadens the infection control requirements that were part of the original ASC requirements in the Environment CfC. Therefore, we propose to remove the requirement at §416.44(a)(3), located in the Environment CfC, as it is unnecessary and obsolete. We believe this change would alleviate any duplicative efforts and confusion regarding the infection control requirements.

Contact: Jacqueline Morgan, 410-786-4282.

4. E-prescribing (§423.160)

The MMA amended title XVIII of the Act to establish a voluntary prescription drug benefit program. Under those provisions, prescription Drug Plan (PDP) sponsors and Medicare

Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA-PD) are required to establish electronic prescription drug programs to provide for electronic transmittal of certain information to the prescribing provider and dispensing pharmacy and pharmacist. This includes information about eligibility, benefits (including drugs included in the applicable formulary, any tiered formulary structure and any requirements for prior authorization), the drug being prescribed or dispensed and other drugs listed in the medication history, as well as the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed. The MMA directed the Secretary to promulgate uniform standards for the electronic transmission of this data.

In the November 7, 2005, final rule (70 FR 67568), entitled “Medicare Program; E-Prescribing and the Prescription Drug Program,” CMS adopted three e-prescribing foundation standards to be used for e-prescribing for the Medicare Part D program. The three foundation standards are--(1) the National Council for Prescription Drug Programs (NCPDP) SCRIPT version 5.0., which provides for communications between the prescriber and dispenser; (2) the NCPDP Telecommunication Standard Version 5 release 1 (NCPDP Telecom 5.1) and equivalent NCPDP Batch Standard Batch Implementation Guide version 1.,1 which is the transaction between the dispenser and the Plan, and the ASC X12N 270/271 Health Care Eligibility Benefit Inquiry and Response, Version 4010; and (3) the Addenda to Health Care Eligibility Inquiry and Response, Version 4010A1 (4010/4010A) for conducting eligibility and benefit inquiries between the prescriber and Plan Sponsor. The latter two transactions, NCPDP Telecom 5.1 and the 4010/4010A are also adopted as HIPAA transaction standards.

In the November 7, 2005 final rule, we discussed the means for updating the Part D

e-prescribing standards. In instances in which an e-prescribing standard has also been adopted as a HIPAA transaction standard in 45 CFR Part 162, the process for updating the e-prescribing standard would have to be coordinated with the maintenance and modification of the applicable HIPAA transaction standard. In the January 16, 2009 final rule, entitled "Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards" (74 FR 3296), we revised §162.1102, §162.1202, §162.1302, §162.1402, §162.1502, §162.1602, §162.1702, and §162.1802 to adopt the ASC X12 Technical Reports Type 3, Version 005010 (Version 5010), as a replacement of the current X12 Version 4010 and 4010A1 standards (Version 4010/4010A). Covered entities conducting HIPAA standards are required to use Version 5010 by January 1, 2012. The complete discussion of these standards may be found in the January 16, 2009 final rule (74 FR 3296).

In the same final rule, effective January 1, 2012, we revised §162.1102, §162.1202, §162.1302, and §162.1802 by adding a new paragraph (c) to each of these sections to adopt the NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (collectively, Version D.0) in place of the NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (collectively, Version 5.1), for the following retail pharmacy drug transactions: health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits.

Therefore, for consistency with the current HIPAA transaction standards, and the need for covered entities (prescribers and dispensers) to comply with HIPAA, we propose to revise

§423.160(b)(3), to--1) update Version 4010/4010A with Version 5010; 2) adopt the NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2); and 3) retire NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1) and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 1 (Version 1.1), for transmitting eligibility inquiries and responses between dispensers and Part D sponsors with an effective date of January 1, 2012.

Contact: Andrew Morgan, 410-786-2543.

5. Physical and Occupational Therapist Qualifications (§440.110)

Current regulations detail provider qualifications for a ‘qualified physical therapist’ under Medicaid at 42 CFR §440.110(a)(2). Section 440.110(b)(2) details the provider qualifications for a ‘qualified occupational therapist’ under Medicaid. These current regulations contain outdated terminology referencing several professional organizations. Also some of the current qualification requirements do not address individuals who have been trained outside of the United States, or refer to outdated requirements, which could unintentionally exclude otherwise qualified therapists resulting in diminished access to care for Medicaid beneficiaries.

Medicare regulations at §484.4 were updated through a November 27, 2007 final rule (72 FR 66406), effective January 1, 2008. While these personnel qualifications are detailed under home health services, we indicated in the preamble to the November 27, 2007 final rule, that therapy services must be provided according to the same standards and policies in all settings, to the extent possible and consistent with statute, and revised multiple regulations to cross-reference the personnel qualifications for therapists in §484.4 to the personnel

requirements in many other sections.

We are proposing at §440.110 to remove the outdated personnel qualifications language in the current Medicaid regulations and instead cross reference the updated Medicare personnel qualifications for physical therapists and occupational therapists under §484.4. This proposal has the potential to broaden the scope of providers that may be able to provide PT and OT services, by streamlining the qualifications so that certain providers are not excluded from providing services under Medicaid. In addition, it strengthens the consistency of standards across Medicare and Medicaid.

Contact: Adrienne Delozier, 410-786-0278.

6. Definition of Donor Document (§486.302)

Section 486.302 includes the following definition: “Donor document is any documented indication of an individual’s choice in regard to donation that meets the requirements of the governing State law.” In recent years, the concept of the donor document and the opportunities for individuals to express their wishes concerning organ and/or tissue donation have changed. An individual can indicate his or her wishes not only on a driver’s license through a State’s Department of Motor Vehicles, but also on various registries or even in separate documents. Therefore, we believe that our definition in §486.302 should be updated. Moreover, the focus on patient rights has increased over the last several years. For example, we published a final rule on November 19, 2010 entitled, “Changes to the Hospital and Critical Access Hospital Conditions of Participation to Ensure Visitation Rights for All Patients” (CMS-3228-F). In light of this increased focus, we believe that the current definition, does not fully allow for the various ways individuals can express their choices in the donor process. In addition, we believe it is important

to emphasize that the decision to donate organs and/or tissue before death is the decision of the individual.

We propose replacing the current definition of “donor document” in §486.302 with the following definition, “[D]onor document means any documented indication of an individual’s choice that was executed by the patient, in accordance with any applicable State law, before his or her death, and that states his or her wishes regarding organ and/or tissue donation.” This new definition modifies the current definition in two ways. First, while the current definition refers to “an individual’s choice” it does not recognize the right of the individual to identify their wishes more specifically. Donor documents may simply allow for the choice of whether or not to be an organ and/or tissue donor, however, some individuals may choose to use documents that allow them to express their wishes in more detail. For example, some people may choose to be an organ donor, but not a tissue donor. Others may not want to consent to the donation of specific organs. Therefore, we believe our proposed definition should cover documents or other ways for individuals to express their wishes more specifically, and we have modified the definition accordingly.

Second, we also believe that it is important to include the requirement that the donor document be “executed by the patient.” While this may appear self-evident, we want to emphasize that the decision by a living person to donate organs and/or tissue after his or her death is always a voluntary decision. Therefore, we have modified the definition to account for this.

These changes to the definition of the donor document only affect the documentation of an individual’s wishes concerning organ and/or tissue donation while they are alive and can

legally make those decisions. In the absence of a valid donor document, the donation decisions would rest with the individual who is legally responsible for making these decisions, usually the person's next of kin.

Contact: Jacqueline Morgan, 410-786-4282.

7. Administration and Governing Body (§486.324)

On May 31, 2006, we published a final rule in the **Federal Register** (71 FR 30982) entitled, "Conditions for Coverage for Organ Procurement Organizations (OPOs)." The final rule established several requirements, for OPOs at §486.324, including a number of requirements related to the administration and governing body of an OPO. Due to an error in publishing the final rule, paragraph (e) was inadvertently inserted twice (71 FR 31052).

We are proposing to remove the duplicate paragraph (e), which appears immediately after §486.324(d). It does not alter or change the legal requirement, nor does it create a change in information collection requirements or other regulatory burden.

Contact: Jacqueline Morgan, 410-786-4282.

8. Requirement for Enrolling in the Medicare Program (§424.510)

We have identified an incorrect reference in §424.510(a), due to a typographic error. We are proposing to replace the incorrect reference to paragraph (c) (the effective date for reimbursement for providers and suppliers seeking accreditation from a CMS-approved accreditation organization) with a reference to paragraph (d) (the enrollment requirements).

Contact: Morgan Burns, 202-690-5145

C. Responds to Stakeholder Concerns

The following proposals seek to respond to some of the concerns and feedback that we

have received from the public. In the comment period associated with this proposed rule, we welcome additional suggestions from stakeholders. We have identified nomenclature and definition changes that would hopefully increase transparency and enhance our relationship with the public.

Nomenclature Changes

1. Redefining the Term “Beneficiary” (§400.200 through §400.203)

In response to comments from the public to discontinue our use of the term “recipient” under Medicaid, we have been using the term “beneficiary” to mean all individuals who are entitled to, or eligible for, Medicare or Medicaid services. We are proposing to add a definition of “beneficiary” in §400.200 that applies to patients under the Medicare and Medicaid programs. We would remove the terms “beneficiary” and “recipient” from §400.202 and §400.203, respectively, and we would make a nomenclature change to replace “recipient” with “beneficiary” throughout 42 CFR chapter IV. The action to refer to beneficiaries instead of recipients has already been implemented. We are simply conforming our regulations to our current use of the term “beneficiary.” In creating this definition it is not our intent to exclude or include anyone who would or would not have previously been understood to be a beneficiary. We welcome comments on whether this definition could be improved to attain that objective.

Contact: Ronisha Davis, 410-786-6882.

2. Replace the Terms “Mental Retardation” and “Mentally Retarded” with “Intellectual Disability” and “Intellectually Disabled” throughout 42 CFR title IV.

We are proposing to change the terminology we use in the program currently called Intermediate Care Facilities for the Mentally Retarded. Section 1905 (d) of the Act states that,

“The term “intermediate care facility for the mentally retarded” means an institution (or distinct part thereof) for the mentally retarded or persons with related conditions....” In 2010, Rosa’s Law (Pub. L. 111-256) amended statutory language in several health and education statues, directing that “in amending the regulations to carry out this Act, a Federal agency shall ensure that the regulations clearly state-- (A) that an intellectual disability was formerly termed “mental retardation”; and (B) that individuals with intellectual disabilities were formerly termed “individuals who are mentally retarded.”

CMS regulations at 42 CFR chapter IV include numerous references to “mental retardation.” These regulatory provisions reflect the statutory benefit category at section 1905(d) of the Act, which uses the term “mental retardation” in the facility type designation, “Intermediate Care Facility for the Mentally Retarded.” Rosa’s Law did not specifically list the Act within its scope, and therefore did not require any change to existing CMS regulations. However, consistent with Rosa’s Law and in response to numerous inquiries from provider and advocate organizations as to when CMS will comply with the spirit of Rosa’s Law, we propose to adopt the term “intellectual disability” (as used under Rosa’s Law) in our regulations at §400.203. We would define the term “intellectually disabled” to mean the condition that was previously referred to as “mentally retarded” in section 1919(e)(7)(G)(ii) of the Act. This nomenclature change does not represent any change in information collection requirements or other burden for the provider community or the State survey agencies. Current forms may be used by the State survey agencies until current supplies are exhausted. The change would require revision of forms CMS-3070G and CMS-3070H, as discussed below.

Contact: Peggye Wilkerson, 410-786-4857.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. Removes Unnecessarily Burdensome Requirements

1. ICRs Regarding End-Stage Renal Disease Facilities Condition for Coverage: Physical Environment (§494.60)

In this rule, we are proposing to limit the number of ESRD facilities that must meet the LSC requirements found in chapters 20 and 21 of NFPA 101. This proposal would reduce burden on ESRD facilities in terms of costly structural modifications. However, this proposed change does not impact any information collections under the Paperwork Reduction Act.

2. ICRs Regarding Condition for Coverage: Emergency Equipment – Ambulatory Surgical Centers (ASCs) (§416.44)

Proposed §416.44(c) would require ASCs to coordinate, develop, and revise ASC policies and procedures that would specify the types of emergency equipment required for use in the ASC's operating room. The equipment must be immediately available for use during emergency situations, be appropriate for the facility's patient population and be maintained by appropriate personnel. The burden associated with these requirements is the time and effort required by an ASC to develop revised policies and procedures governing the identification and maintenance of emergency equipment that would typically be required to address the intra- or post-operative emergency complications specific to the types of procedures performed in the ASC and the needs of their specific patient population.

We believe that approximately 5,200 ASCs would have to comply with these requirements. We estimate that proposed §416.44(c) would impose a one-time burden of two hours associated with revising the policies and procedures pertaining to the list of the emergency equipment and supplies maintained and commonly used by the ASC during emergency responses to their specific patient population. The total burden associated with this task would be approximately 5,200 hours. The total cost associated with this requirement would be \$468,000 (5,200 x \$90 - based on an hourly nurse's salary (\$45.00 x 2 hours), including fringe benefits, as specified by the Bureau of Labor Statistics for 2009).

Consistent with this proposed change, we will submit a revision to control number 0938-1071 (expiration date October 31, 2012) to the Office of Management and Budget for review.

3. ICRs Regarding Revocation of Enrollment and Billing Privileges in the Medicare Program (§424.535)

In this rule, we are proposing to eliminate the re-enrollment bar in instances when Medicare providers and suppliers have not responded timely to requests for revalidation of enrollment or other requests for information. This would allow providers and suppliers to attempt to re-enroll in Medicare sooner than would be the case if the re-enrollment bar applied. However, the overall information collection burden involved – specifically, the need to submit a Form CMS-855 initial enrollment application – would not change. Our proposed revision would therefore neither increase nor decrease the existing information collection burden related to this requirement.

4. ICRs Regarding Deactivation of Medicare Billing Privileges (§424.540)

In this rule, we are proposing to restrict the deactivation provisions in §424.540(a)(1) to providers and suppliers that do not complete the Form CMS-855I application. Physicians and non-physician practitioners would therefore not have their Medicare billing privileges deactivated if they did not bill Medicare for 12 consecutive months.

We estimate that an average of approximately 12,000 physicians and non-physician practitioners have been deactivated each year pursuant to §424.540(a)(1). These individuals have been required to submit a complete Form CMS-855I application to their Medicare contractor in order to reactivate their Medicare billing privileges. With our proposed change, however, this step would no longer be necessary because the deactivation would not have occurred.

For purposes of this ICR, we estimate that 10,800 physicians and non-physician practitioners (or 90 percent of the aforementioned 12,000 total) would continue to submit Form CMS-855I (OMB No. 0938-0685) reactivation applications absent our proposed change. The estimated “per application” burden of completing the application is 5 hours, at a per hour cost of \$50. This results in a total savings in collection of information costs for Medicare-enrolled physicians and non-physician practitioners of approximately \$2.7 million per year (10,800 X 5 X \$50). Consistent with this proposed change, we will submit a revision to control number 0938-0685 to the Office of Management and Budget for review.

5. ICRs Regarding Duration of Agreement for ICFs/ID (§442.15)

In this rule, we are proposing to remove the time limited agreements for intermediate care facilities. There is no reduction in burden or cost for the intermediate care facility providers but the regulation change would help to reduce the paperwork and staff time required by State agencies in processing temporary extensions of the provider agreements that are required until the onsite survey occurs. In addition, providers and State agencies would no longer face the uncertainty created by the issuance of the multiple temporary extensions due to the provider agreements. Consistent with this proposed change, we will submit a revision to control number 0938-0062.

B. Removes Obsolete or Duplicative Regulations or Provides Clarifying Information

1. ICRs Regarding Display of Currently Valid OMB Control Numbers (§400.310)

In this rule, we are proposing to remove the chart at §400.310 that display OMB control numbers because the information has become obsolete. This proposal would not produce any

reduction or increase in burden, but would ensure that the public is viewing the most current information regarding OMB control numbers.

2. ICRs Regarding Initial Determinations, Reconsiderations, Appeals, and Reopenings under Medicare Part A and B (§405.701 through §405.877)

The provisions in part 405 subparts G and H that we are proposing to remove primarily are obsolete and no longer in use. We do not expect an increase or reduction in burden, but believe that it would be beneficial to ensure that providers or suppliers affected are using the post BIPA appeals process.

3. ICRs Regarding Condition for Coverage: Infection Control – Ambulatory Surgical Centers (ASCs) (§416.44)

In this rule, we are proposing to remove the requirement at §416.44(a)(3) regarding infection control that is duplicative of §416.51. The removal of this requirement would not result in any reduced or additional burden on ASCs, but would alleviate any duplicative efforts and confusion regarding the infection control requirements.

4. ICRs Regarding Standards for Electronic Prescribing (§423.160)

In this rule, we are proposing to update the current e-prescribing standards to mirror the HIPAA standards that will be in effect as of January 1, 2012. There is no burden (addition or reduction) associated with this proposal.

5. ICRs Regarding Physical Therapy, Occupational Therapy, and Services for Individuals with Speech, Hearing, and Language Disorders (§440.110)

In this rule, we are proposing to update and align provider qualifications for PT and OT professionals. This proposal has the potential to broaden the scope of providers that may be able

to provide PT and OT services, by streamlining the qualifications so that certain providers are not excluded from providing services under Medicaid. However, this proposed change does not impact any information collections under the paperwork reduction Act.

6. ICRs Regarding Definitions (§486.302)

In this rule, we are proposing to modify the definition of “donor document” to improve the ability of patients to indicate their wishes regarding the donation of organs and tissue, while also emphasizing that the patient’s decision is voluntary. We do not expect that there would be any changes in the collection of information requirements for OPOs. We anticipate that the enhanced ability individuals initially would have to more specifically identify their wishes would reduce burden associated with vague and unclear designations.

7. ICRs Regarding Condition: Administration and Governing Body (§486.324)

In this rule, we are proposing the removal of the duplicate paragraph (e) of §486.324. This proposal would not result in any change in information collection or other regulatory burden.

8. ICRs Regarding Requirement for Enrolling in the Medicare Program (§424.510)

In this rule, we are proposing to correct a typographical error found in §424.510(a). This proposal would create no change in information collection or other regulatory burden.

C. Responds to Stakeholder Concerns

Nomenclature Changes

1. ICRs Regarding General Definitions (§400.200)

In this rule, we are proposing to add a definition of “beneficiary” in §400.200 that applies to patients under the Medicare and Medicaid programs. This proposal would create no change in information collection or other regulatory burden.

2. ICRs Regarding Definitions specific to Medicaid (§400.203)

In this rule, we are proposing to add to the regulations a definition of “intellectual disability” for purposes of the Medicaid program that would define it, consistent with Rosa’s law (Pub. L. 111-256), as the condition formerly referred to as “mental retardation” and we would replace all references in CMS regulations to, “mental retardation” with “intellectual disability.” Furthermore, we propose to replace the term “mentally retarded,” as defined in section 1919(e)(7)(G)(ii) of the Act, with “intellectually disabled.” This proposal would create no change in information collection or other regulatory burden. The change would require revision of forms CMS-3070G and CMS-3070H, which are approved under OMB control number 0938-0062 (expiration date April 30, 2013). CMS will submit this collection to OMB for review.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS-9070-P]

Fax: (202) 395-5806; or

Email: OIRA_submission@omb.eop.gov

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 impact 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 (February 2, 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), and Executive Order 13132 on Federalism (August 4, 1999).

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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. 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 proposed rule would reduce costs to regulated entities and to patients by more than \$100 million,

perhaps as much a \$200 million in the first year. It would also create significant life savings benefits. It is therefore an economically significant rule under section 3(f)(1) of Executive Order 12866. Accordingly, this proposed rule was reviewed by the Office of Management and Budget.

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 proposal 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. Overall Impact

There are cost savings in many areas. Two areas of one-time savings are particularly substantial. First, as indicated earlier in the preamble, we estimate that one-time savings to ESRD facilities are likely to range from about \$47.5 to \$217 million. Second, we also estimate a one-time savings of \$18.5 million to ASCs through reduced emergency equipment requirements. Both of these estimates are uncertain and total savings could be significantly higher. Among the many types of recurring savings that these proposals would create, physicians and other providers would avoid business and payment losses that are difficult to estimate but likely to be

in the tens of millions of dollars annually through the reforms we propose for reenrollment and billing processes. We have identified other kinds of savings that providers and patients will realize throughout this preamble. All of these are summarized in the table that follows.

Table 3. Section-by-Section Economic Impact Estimates.

Section	Frequency	Likely Savings or Benefits (millions)
A. Removes Unnecessarily Burdensome Requirements		
1. End-Stage Renal Disease (ESRD) Facilities (§494.60)	One-Time	\$108.7
2. ASC Emergency Equipment (§416.44)	One-Time	\$18.5
3. Revocation of Enrollment/Billing Privileges (§424.535)	Recurring	\$10.0
4. Deactivation of Medicare Billing Privileges (§424.540)	Recurring	\$26.7
5. Duration of Agreement for ICFs/ID (§442.15-§442.109)	Recurring	<\$1
B. Removes Obsolete or Duplicative Regulations		
1. OMB Control Numbers for Information Collection (§400.300 and §400.310)	Recurring	<\$1
2. Removal of Obsolete Provisions Related to Processing Part A and Part B Claims and Entitlement Determinations (§405.701 through §405.877)	Recurring	<\$1
3. ASC Infection Control Program (§416.44)	Recurring	<\$1
4. E-prescribing (§423.160)	Recurring	<\$1
5. Physical and Occupational Therapist Qualifications (§440.110)	Recurring	<\$1
6. Definition of Donor Document (§486.302)	Recurring	See Text
7. Administration and Governing Body (§486.324)	Recurring	<\$1
8. Requirement for Enrolling in the Medicare Program (§424.510)	Recurring	<\$1
C. Responds to Stakeholder Concerns		
Nomenclature Changes		
1. Redefining the Term “Beneficiary” (§400.200 through §400.203)	Recurring	<\$1
2. Replace “Mental Retardation” terminology with “Intellectual Disability” (throughout 42 CFR title IV)	Recurring	See Text

There are two areas of potentially significant benefits, above and beyond cost savings to providers. First, improved organ donation consent language that would enable prospective donors to specify their intentions more clearly would have a positive effect on organ donation. There are approximately 8,000 cadaveric organ donors annually in the United States. These donors provide a total of about 21,000 transplanted organs (see the OPTN/SRTR Annual Report at <http://optn.transplant.hrsa.gov/ar2009/>). The decision to make a firm, written decision on whether or not to be a potential donor, and on the willingness of families to honor that decision, can turn on very small issues of personal preference. We believe that the change we propose could and likely would tip that decision in some cases. However, we do not have a basis for quantifying this potential increase in donations. We welcome comment on the extent to which this policy change may increase organ donation and any information that would assist in quantifying these impacts.

In addition, while Rosa's Law began the elimination of official Federal government use of the pejorative term "mental retardation," our proposal would complete this step for CMS regulations. The reform undoubtedly has substantial value to millions of Americans, not only to the intellectually disabled but also to their families and friends, and also to the many millions who simply object to such labeling. However, we have no data that would enable a precise calculation of this value.

Taking all of the proposed reforms together, we estimate that the overall cost savings that this rule would create may approach \$200 million in the first year. This includes the one-time savings related to ESRD reforms, as well as the savings to providers in lost billings, paperwork costs, confusion, and other burden reductions discussed throughout this preamble.

C. Anticipated Impacts.

The potential cost savings from reduced ESRD requirements are discussed extensively in that preamble section on those reforms. Assuming that the average cost for a facility to meet three structural standards would have been \$77,659, and that one half of all facilities would have needed to make one half of these investments, total savings would be \$108.7 million (2,800 x (\$77,659/2)).

The only other large one-time savings estimates are those resulting from reforms of Ambulatory Surgical Center Emergency equipment requirements, and reforms in the revocations or deactivation of billing privileges. As to ASC, we estimate that the three most costly types of equipment are as follows: tracheostomy kit \$100.00, cricothyrotomy kit \$200.00 and mechanical ventilator \$12,000. We utilized fiscal year 2010 surveyor worksheets completed by the States when conducting ASC surveys to project the distribution of the types of ASC services nationally. We estimate that about two-thirds of the approximately Medicare 5,200 certified ASCs are functioning as multipurpose facilities. Those that are not multipurpose facilities would not have to spend \$12,300 in total for costly equipment that would not be utilized. We have estimated the savings by breaking down each specialty type of ASC that would not be considered a multipurpose facility and that may not eliminate all three pieces of equipment or choose just one or two depending on the needs of the facility (1500 ASCs x \$12,300 = total savings of about \$18.5 million).

With respect to the revocation reform, the number of affected providers is certainly very small as a proportion of the total universe of over one million Medicare providers, of whom over 900,000 are physicians and other practitioners. Based on administrative data, we estimate that

the number of affected physicians and other practitioners that would be affected by this reform is between 1,000 and 2,000, a fraction of one percent of these. We have no statistical data on the resultant economic effects; but if the average provider loses as little as \$10,000 in billable Medicare patient care services as a result of deactivation, total lost business for 1,000 providers could be \$10 million annually. In this regard, gross annual physician practice revenue in America approaches \$1 million a year (see, for example, the practice expense data in <http://www.modernmedicine.com/modernmedicine/article/articleDetail.jsp?id=143141>). Since Medicare pays about one third of revenue received for professional services such as physician care, the loss we estimate is one or two weeks of Medicare billing, on average. We welcome additional information on the likely magnitude and frequency of such losses.

With respect to deactivation of Medicare billing privileges, based on existing enrollment data we believe that about 12,000 physicians and non-physician practitioners may be affected annually. While the information collection consequences are relatively small (see the Information Collection section of this preamble), the problems this creates for both providers and patients are more substantial, including confusion about which bills are paid, chains of correspondence between the provider, the patient, and the Medicare contractor, and even in many cases an inability of providers to obtain reimbursement for services provided. Furthermore, although the direct paperwork costs are small, the amount of time and effort involved may deter some of these providers from even attempting to reactivate their billing privileges. Nonetheless, even if the average lost billing amounts (over and above amounts previously calculated for deactivations) are only on average \$2,000, total annual costs in patient services that were unbilled or simply not provided would be \$24 million (12,000 providers x \$2,000), in addition to

the \$2.7 million we estimate in reduced information collection costs. In this regard, we point out that \$2,000 represents only a fraction of one percent of average annual physician billing to Medicare, or less than one week of billing lost. We believe that losses are likely to be this low because this problem is most likely to occur with providers whose practices include relatively few Medicare patients, or who otherwise do not depend heavily on Medicare reimbursements (for example, part-time practices and those nearing retirement). We welcome additional information on the likely magnitude and frequency of such losses, and on physician and other provider situations most likely to be affected by such losses.

Of the remaining reforms, most have minor cost savings as shown in Table 1 through entries of \$1 million or less. We welcome comments on whether some of these proposed reforms may create larger savings that we have failed to identify.

D. 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 cost savings, we are uncertain 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 would yield net benefits. In this analysis we provided some illustrative estimates to suggest the potential savings these reforms could achieve under certain assumptions.

We welcome comments on ways to better estimate the likely effects of these reforms.

E. 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. We estimate that the overall cost savings that this rule would create may approach \$200 million in the first year. This includes the one-time savings related to ESRD reforms, as well as the savings to providers in lost billings, paperwork costs, confusion, and other burden reductions discussed throughout this preamble. There are also potentially substantial life-saving benefits that could reach hundreds of millions of dollars annually. Annualized savings are shown in the accounting statement below.

Table 4. Accounting Statement (dollars in millions)

Category	Primary Estimate	Year Dollars	Discount Rate	Period Covered
Benefits				
Unquantified Qualitative Value of Lives Saved Through Increases in Organ Donations	Potentially hundreds of lives saved but no precise estimate	2012	7%	2012-16
	Potentially hundreds of lives saved but no precise estimate	2012	3%	2012-16
Annualized savings from reduced ESRD facility investments and reduced ASC costs (see Table 3)	\$30	2012	7%	2012-16
	\$30	2012	3%	2012-16
Annualized savings to providers from billing improvements and other reforms (see Table 3)	\$40	2012	7%	2012-16
	\$40	2012	3%	2012-16
Costs				
None				
Transfers				
None				

F. Regulatory Flexibility Act.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities when proposed rules create a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other Medicare or Medicaid providers and suppliers are small entities, either by nonprofit status or by

having revenues of \$7.0 million to \$34.5 million in any 1 year. Individuals and States are not included in the definition of a “small entity.” This proposed rule would reduce costs to tens of thousands of physicians, ASCs, ESRD facilities, and other small entities. Provisions in this proposed rule would benefit some providers or suppliers in all or virtually all of the industries identified as “Ambulatory Health Care Services” under the Census Bureau’s North American Industry Classification System (NAICS, codes 621111 through 621999). While most of the effects would be minimal (for example, eliminating obsolete and redundant or confusing regulatory requirements), we estimate that the impact on at least several thousand of these small entities would be economically significant. The purpose of the RFA is to reduce burdens on regulated entities, and HHS interprets the RFA as requiring an Initial Regulatory Flexibility Analysis (IRFA) only when a proposed rule creates an adverse economic impact. Accordingly, we certify that this proposed rule would not have a significant economic impact on a substantial number of small entities. HHS nonetheless voluntarily prepares an IRFA for rules that, like this one, create a significant positive economic impact by reducing burden on small entities. In this case all of the economic effects of the proposed rule are positive, and some are economically significant. In particular, provisions that allow physicians and other providers and suppliers to continue to participate in Medicare despite correspondence mishaps would save as many as 12,000 small entity providers annually thousands, and in some cases tens of thousands, of dollars in lost revenues, as well as reduce costs of confusion and correspondence to both these providers and their patients. Most of these providers are physicians, but other affected professionals include clinical psychologists, physician assistants, nurse practitioners, and physical therapists. Substantial savings would also accrue to most of about 6,500 ESRD providers from our proposal

to eliminate fire safety requirements that are vital in residential provider settings, but unnecessary in ambulatory care facilities such as these. Approximately half of the 5,200 ASCs would benefit from more sensible emergency equipment policies. In addition, while we cannot estimate the number of positively affected entities for every provision we propose, these reforms would benefit about 6,400 Intermediate Care Facilities through elimination of pejorative nomenclature that pervasively affects their names and operations. All of the provisions included in the proposed rule aim to identify and eliminate duplicative, overlapping, outdated and conflicting regulatory requirements that unnecessarily add confusion or costs to various providers or patients as they attempt to navigate excessive or obsolete or contradictory regulatory requirements. By making these changes, we believe health professionals would have increased resources to devote to improving patient care, increasing accessibility to care and reducing associated health care costs. We invite and welcome comments on any and all of the provisions of the proposed rule with regard to the impacts of the burden reductions, as well as alternatives, if any, we should consider in the final rule or in future rulemaking on other regulatory provisions.

In addition, section 1102(b) of the Social Security 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. This rule has no direct effects on hospitals. Therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not

have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act

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 expenditures in any 1 year of \$100 million in 1995 dollars, updated annually for inflation on either State, local, or tribal governments, or the private sector. In 2011, that threshold is approximately \$136 million. This proposed rule mandates no new expenditures by either State, local, or tribal governments, or the private sector.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

List of Subjects

42 CFR Part 400

Grant programs-health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 416

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

42 CFR Part 423

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

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Part 442

Grant programs-health, Health facilities, Health professions, Medicaid, Nursing homes,

Reporting and recordkeeping requirements.

42 CFR Part 486

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

42 CFR Part 494

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

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 400--INTRODUCTION; DEFINITIONS

- 1. The authority citation for part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

Subpart B--Definitions

- 2. Section 400.200 is amended by adding the definition of “beneficiary” in alphabetical order to read as follows:

§400.200 General definitions.

* * * * *

Beneficiary means a person who is entitled to Medicare benefits and/or has been determined to be eligible for Medicaid.

* * * * *

§400.202 [Amended]

- 3. Section 400.202 is amended by removing the definition of “beneficiary.”

- 4. Section 400.203 is amended by removing the definition of “recipient” and adding the definition of “intellectual disability” in alphabetical order to read as follows:

§400.203 Definitions specific to Medicaid.

* * * * *

Intellectual disability means the condition that was previously referred to as mental retardation.

* * * * *

Subpart C [REMOVED and RESERVED]

5. Subpart C, consisting of §§400.300 and 400.310, is removed and reserved.

PART 405--FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

6. The authority citation for Part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

7. Redesignate §405.706 in subpart G as §405.925 in subpart I.

Subpart G--[Removed and Reserved]

8. Remove and reserve subpart G consisting of §405.701 through §405.705 and §405.708 through §405.753.

9. Subpart H is revised to read as follows:

Subpart H--Appeals Under the Medicare Part B Program

Sec.

405.800 Appeals of CMS or a CMS contractor.

405.803 Appeals rights.

405.806 Impact of reversal of contractor determinations on claims processing.

405.809 Reinstatement of provider or supplier billing privileges following corrective action.

405.812 Effective date for DMEPOS supplier's billing privileges.

405.815 Submission of claims.

405.818 Deadline for processing provider enrollment initial determinations.

Authority: Secs. 1102, 1866(j), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395cc(j), and 1395hh).

Subpart H--Appeals Under the Medicare Part B Program

§405.800 Appeals of CMS or a CMS contractor.

A CMS contractor's (that is, a carrier, Fiscal Intermediary or Medicare Administrative Contractor (MAC)) determination that a provider or supplier fails to meet the requirements for Medicare billing privileges.

(a) Denial of a provider or supplier enrollment application. If CMS or a CMS contractor denies a provider's or supplier's enrollment application, CMS or the CMS contractor notifies the provider or supplier by certified mail. The notice includes the following:

(1) The reason for the denial in sufficient detail to allow the provider or supplier to understand the nature of its deficiencies.

(2) The right to appeal in accordance with part 498 of this chapter.

(3) The address to which the written appeal must be mailed.

(b) Revocation of Medicare billing privileges —(1) Notice of revocation. If CMS or a CMS contractor revokes a provider's or supplier's Medicare billing privileges, CMS or a CMS contractor notifies the supplier by certified mail. The notice must include the following:

(i) The reason for the revocation in sufficient detail for the provider or supplier to understand the nature of its deficiencies.

(ii) The right to appeal in accordance with part 498 of this chapter.

(iii) The address to which the written appeal must be mailed.

(2) Effective date of revocation. The revocation of a provider's or supplier's billing privileges is effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier, except if the revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational. When a revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation or the date that CMS or its contractor determined that the provider or supplier was no longer operational.

(3) Payment after revocation. Medicare does not pay, and the CMS contractor rejects, claims for services submitted with a service date on or after the effective date of a provider's or supplier's revocation.

§405.803 Appeals rights.

(a) A provider or supplier may appeal the initial determination to deny a provider or supplier's enrollment application, or if applicable, to revoke current billing privileges by following the procedures specified in part 498 of this chapter.

(b) The reconsideration of a determination to deny or revoke a provider or supplier's Medicare billing privileges is handled by a CMS Regional Office or a contractor hearing officer not involved in the initial determination.

(c) Providers and suppliers have the opportunity to submit evidence related to the enrollment action. Providers and suppliers must, at the time of their request, submit all evidence that they want to be considered.

(d) If supporting evidence is not submitted with the appeal request, the contractor contacts the provider or supplier to try to obtain the evidence.

(e) If the provider or supplier fails to submit the evidence before the contractor issues its decision, the provider or supplier is precluded from introducing new evidence at higher levels of the appeals process.

§405.806 Impact of reversal of contractor determinations on claims processing.

(a) Claims for services furnished to Medicare beneficiaries during a period in which the supplier billing privileges were not effective are rejected.

(b) If a supplier is determined not to have qualified for billing privileges in one period but qualified in another, Medicare contractors process claims for services furnished to beneficiaries during the period for which the supplier was Medicare-qualified. Subpart C of this part sets forth the requirements for the recovery of overpayments.

(c) If a revocation of a supplier's billing privileges is reversed upon appeal, the supplier's billing privileges are reinstated back to the date that the revocation became effective.

(d) If the denial of a supplier's billing privileges is reversed upon appeal and becomes binding, then the appeal decision establishes the date that the supplier's billing privileges become effective.

§405.809 Reinstatement of provider or supplier billing privileges following corrective action.

If a provider or supplier completes a corrective action plan and provides sufficient evidence to the CMS contractor that it has complied fully with the Medicare requirements, the CMS contractor may reinstate the provider's or supplier's billing privileges. The CMS contractor

may pay for services furnished on or after the effective date of the reinstatement. The effective date is based on the date the provider or supplier is in compliance with all Medicare requirements. A CMS contractor's refusal to reinstate a supplier's billing privileges based on a corrective action plan is not an initial determination under part 498 of this chapter.

§405.812 Effective date for DMEPOS supplier's billing privileges.

If a CMS contractor, contractor hearing officer, or ALJ determines that a DMEPOS supplier's denied enrollment application meets the standards in §424.57 of this chapter and any other requirements that may apply, the determination establishes the effective date of the billing privileges as not earlier than the date the carrier made the determination to deny the DMEPOS supplier's enrollment application. Claims are rejected for services furnished before that effective date.

§405.815 Submission of claims.

A provider or supplier succeeding in having its enrollment application denial or billing privileges revocation reversed in a binding decision, or in having its billing privileges reinstated, may submit claims to the CMS contractor for services furnished during periods of Medicare qualification, subject to the limitations in §424.44 of this chapter, regarding the timely filing of claims. If the claims previously were filed timely but were rejected, they are considered filed timely upon resubmission. Previously denied claims for items or services furnished during a period of denial or revocation may be resubmitted to CMS within 1 year after the date of reinstatement or reversal.

§405.818 Deadline for processing provider enrollment initial determinations.

Contractors approve or deny complete provider or supplier enrollment applications to

approval or denial within the following timeframes:

(a) Initial enrollments-- Contractors process new enrollment applications within 180 days of receipt.

(b) Revalidation of existing enrollments-- Contractors process revalidations within 180 days of receipt.

(c) Change-of-information and reassignment of payment request-- Contractors process change-of-information and reassignment of payment requests within 90 days of receipt.

PART 416--AMBULATORY SURGICAL SERVICES

10. 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

11. Section 416.44 is amended by--

a. Removing paragraph (a)(3).

b. Revising paragraph (c).

The revisions read as follows:

§416.44 Condition for coverage--Environment.

* * * * *

(c) Standard: Emergency equipment. The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC’s operating room. The equipment must meet the following requirements:

(1) Be immediately available for use during emergency situations.

(2) Be appropriate for the facility’s patient population.

(3) Be maintained by appropriate personnel.

* * * * *

PART 423--VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

12. The authority citation for Part 423 continues to read as follows:

Authority: Section 1860D-4(e) of the Social Security Act (42 U.S.C 1395w-104(e)).

Subpart D--Cost Control and Quality Improvement Requirements

13. Section 423.160 is amended by revising paragraph (b)(3) to read as follows:

§423.160 Standards for electronic prescribing.

* * * * *

(b) * * *

(3) Eligibility. (i) The Accredited Standards Committee X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 5010, April 2008, ASC X12N/005010x279 (incorporated by reference in paragraph (c)(2)(i) of this section), for transmitting eligibility inquiries and responses between prescribers and Part D sponsors.

(ii) The National Council for Prescription Drug Programs Telecommunication Standard Specification, Version D, Release 0 (Version D.0), August 2007, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 2 (Version 1.2), January 2006 supporting Telecommunications Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, for the NCPDP Data Record in the Detail Data Record (incorporated by reference in paragraph (c)(1)(iii) of this section), for transmitting eligibility inquiries and responses between dispensers and Part D sponsors.

* * * * *

PART 424--CONDITIONS FOR MEDICARE PAYMENT

14. The authority citation for Part 424 continues to read as follows:

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

Subpart P--Requirements for Establishing and Maintaining Medicare Billing Privileges

15. Section 424.510 is amended by revising paragraph (a) to read as follows:

§424.510 Requirements for enrolling in the Medicare program.

(a) Providers and suppliers must submit enrollment information on the applicable enrollment application. Once the provider or supplier successfully completes the enrollment process, including, if applicable, a State survey and certification or accreditation process, CMS enrolls the provider or supplier into the Medicare program. To be enrolled, a provider or supplier must meet enrollment requirements specified in paragraph (d) of this section.

* * * * *

16. Section 424.535 is amended by revising paragraph (c) to read as follows:

§424.535 Revocation of enrollment and billing privileges in the Medicare program.

* * * * *

(c) Reapplying after revocation. After a provider, supplier, delegated official, or authorizing official has had their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar. The re-enrollment bar is a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation. The re-enrollment bar does not apply in the event a revocation of Medicare billing privileges is imposed under paragraph (a)(1) of this section based

upon a provider or supplier’s failure to respond timely to a revalidation request or other request for information.

* * * * *

17. Section 424.540(a) is revised to read as follows:

§424.540 Deactivation of Medicare billing privileges.

(a) Reasons for deactivation. CMS may deactivate the Medicare billing privileges of a provider or supplier for any of the following reasons:

(1) The provider or supplier does not submit any Medicare claims for 12 consecutive calendar months. This requirement does not apply to suppliers that enroll in the Medicare program using a Form CMS-855I. The 12-month period will begin the 1st day of the 1st month without a claims submission through the last day of the 12th month without a submitted claim.

(2) The provider or supplier does not report a change to the information supplied on the enrollment application within 90 calendar days of when the change occurred. Changes that must be reported include, but are not limited to, a change in practice location, a change of any managing employee, and a change in billing services. A change in ownership or control must be reported within 30 calendar days as specified in §424.520(b) and §424.550(b).

(3) The provider or supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information.

* * * * *

PART 440--SERVICES: GENERAL PROVISIONS

18. The authority citation for Part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 302).

Subpart A--Definitions

19. Section 440.110 is amended by revising paragraphs (a)(2) and (b)(2) to read as follows:

§440.110 Physical therapy, occupational therapy, and services for individuals with speech, hearing, and language disorders.

(a) * * *

(2) A “qualified physical therapist” is an individual who meets personnel qualifications for a physical therapist at §484.4.

(b)* * *

(2) A “qualified occupational therapist” is an individual who meets personnel qualifications for an occupational therapist at §484.4.

* * * * *

PART 442--STANDARDS FOR PAYMENT TO NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED

20. 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 B--Provider Agreements

21. Section 442.15 is revised to read as follows:

§442.15 Duration of agreement for ICFs/ID.

(a) The agreement for an ICF/MR remains in effect until the Secretary determines that the facility no longer meets the applicable requirements. The State Survey Agency must conduct a survey of the facility to determine compliance with the requirements at a survey interval of no greater than 15 months.

(b) FFP is available for services furnished by a facility for up to 30 days after its agreement expires or terminates under the conditions specified in §441.11 of this subchapter.

§442.16 [REMOVED and RESERVED]

22. Section 442.16 is removed and reserved.

Subpart C--Certification of ICFs/ID

23. Section 442.109 is revised to read as follows:

§442.109 Certification period for ICFs/ID: General provisions.

(a) A survey agency may certify a facility that fully meets applicable requirements. The State Survey Agency must conduct a survey of each ICF/MR not later than 15 months after the last day of the previous survey.

(b) The statewide average interval between surveys must be 12 months or less, computed in accordance with paragraph (c) of this section.

(c) The statewide average interval is computed at the end of each Federal fiscal year by comparing the last day of the most recent survey for each participating facility to the last day of each facility's previous survey.

24. Section 442.110 is amended by revising paragraph (b) to read as follows:

§442.110 Certification period for ICFs/ID with standard-level deficiencies.

* * * * *

(b) The survey agency may certify a facility for a period that ends no later than 60 days after the last day specified in the plan for correcting deficiencies. The certification period must not exceed 15 months, including the period allowed for corrections.

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**PART 486--CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES
FURNISHED BY SUPPLIERS**

25. 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**

26. Section 486.302 is amended by revising the definition of “donor document” to read as follows:

§486.302 Definitions.

* * * * *

Donor document means any documented indication of an individual’s choice that was executed by the patient, in accordance with any applicable State law, prior to his or her death, and that states his or her wishes regarding organ and/or tissue donation.

* * * * *

§ 486.324 [Amended]

27. Section 486.324 is amended by removing the second paragraph (e).

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

28. The authority citation for Part 494 continues to read as follows:

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

Subpart B—Patient Safety

29. Section 494.60(e) is revised to read as follows:

§494.60 Condition: Physical environment.

* * * * *

(e) Standard: Fire safety. (1) Except as provided in paragraph (e)(2) of this section, by February 9, 2009, dialysis facilities that are located adjacent to high hazardous occupancies or do not provide one or more exits to the outside at grade level from the patient treatment area level, must comply with applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at §403.744(a)(1)(i) of this chapter).

(2) Notwithstanding paragraph (e)(1) of this section, dialysis facilities participating in Medicare as of October 14, 2008 that require sprinkler systems are those housed in multi-story buildings of construction Types II(000), III(200), or V(000), as defined in the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at §403.744(a)(1)(i) of this chapter), section 21.1.6.3, which were constructed after January 1, 2008; and those housed in high rise buildings over 75 feet in height.

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Nomenclature Changes

30. In 42 CFR chapter IV, remove “Recipient” and “Recipients” wherever they appear and add in their place “Beneficiary” and “Beneficiaries,” respectively.

31. In 42 CFR chapter IV, remove “Mental Retardation,” “Mentally Retarded” and the abbreviated form “MR” wherever they appear and add in their place “Intellectual Disability,” “Intellectually Disabled” and “ID,” respectively.

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

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: July 28, 2011

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Approved: October 6, 2011

Kathleen Sebelius,

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BILLING CODE 4120-01-P

[FR Doc. 2011-27176 Filed 10/18/2011 at 11:15 am; Publication Date: 10/24/2011]