DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

[CMS–9070–F]

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: Final rule.

SUMMARY: This final rule identifies reforms in Medicare and Medicaid regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and beneficiaries. This rule increases the ability of health care professionals to devote resources to improving patient care, by eliminating or reducing requirements that impede quality patient care or that divert providing high quality patient care. This is one of several rules that we are finalizing 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: These regulations are effective on July 16, 2012.

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 and Analysis of and Responses to Public Comments'' section for each provision set out in this rule.

SUPPLEMENTARY INFORMATION:

I. Executive Summary for This Final Rule

A. Purpose

In Executive Order 13563, ''Improving Regulations and Regulatory Review'', the President recognized the importance of a streamlined, effective, and efficient regulatory framework designed to promote economic growth, innovation, job-creation, and competitiveness. To achieve a more robust and effective regulatory framework, the President has directed each executive agency to establish a plan for ongoing retrospective review of existing significant regulations to identify those rules that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive or that can be modified to be more effective, efficient, flexible, and streamlined. This final rule responds directly to the President's instructions in Executive Order 13563 by reducing outmoded or unnecessarily burdensome rules, and thereby increasing the ability of health care entities to devote resources to providing high quality patient care.

B. Summary of the Major Provisions

Removes Unnecessary Burdensome Requirements: We have reduced burden to providers and suppliers by modifying, removing, or streamlining current regulations that we have identified as excessively burdensome.

- *End Stage Renal Disease Facilities Life Safety Code:* We have limited mandatory compliance with the Life Safety Code to those ESRD facilities located adjacent to high hazardous occupancies. We clarified that the requirement for sprinklers in facilities housed in high rise buildings is intended to be applicable to those buildings constructed after January 1, 2008.
- *Ambulatory Surgical Centers (ASC) Emergency Equipment:* We have removed the detailed list of emergency equipment that must be available in an ASC's operating room. The current list includes outdated terminology as well as equipment that are not suitable for ASCs that furnish minor procedures that do not require anesthesia.
- *Re-enrollment Bar for Providers and Suppliers:* We have eliminated the unnecessarily punitive enrollment bar for providers and suppliers when it is based on the failure of a provider or supplier to not respond timely to revalidation or other requests for information.
- *Intermediate Care Facilities for Individuals who are Intellectually Disabled (ICR/IID):* We have eliminated the requirement for time-limited agreements for ICFs/IID and replaced the requirement with an open ended agreement which, consistent with nursing facilities, would remain in effect until the Secretary or a State determines that the ICF/IID no longer meets the ICF/IID conditions of participation. We have also added a requirement that a certified ICF/IID must be surveyed, on average, every 12 months with a maximum 15-month survey interval. This action provides States with more flexibility related to the current process.

Removes Obsolete or Duplicative Regulations or Provides Clarifying Information: We have removed requirements in the Code of Federal Regulations (CFR) that have become obsolete and are no longer needed or enforced.

- *OMB Control Numbers for Approved Collections of Information:* We have removed the obsolete list of OMB control numbers, approval numbers, and information collections in the CFR because the list is now displayed on the OMB public Web site. In our quarterly notice of all CMS issuances, we will remind the public that the complete listing is available on the OMB Web site.
- *Appeals of Part A and Part B Claims Determinations:* We have removed obsolete pre-BIPA regulations that apply to initial determinations, re-openings, and appeals of claims under original Medicare. This will eliminate confusion by Medicare beneficiaries, providers, and suppliers regarding which appeals rights and procedures apply.
- *Ambulatory Surgical Centers (ASC) Infection Control Program:* We have removed the obsolete requirement 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 requirement should have been removed when a new condition for coverage dedicated to infection control was adopted.
- *E-prescribing:* We have retired older versions of e-prescribing transactions for Medicare Part D and adopted the newer versions to be in compliance with the current e-prescribing standards.
- *Physical and Occupational Therapist Qualifications:* We have removed the outdated personnel qualifications in the current Medicaid regulations and refer to the updated Medicare regulations.
- *Organ Procurement Organizations (OPOs) Definitions:* We have updated definitions related to organ procurement as the meaning of these definitions has changed over time.
- *Organ Procurement Organizations (OPOs) Administration and Governing Body:* We have removed duplicate regulations. This change does not alter or change the existing regulations related to the requirements that the OPO governing body must meet, such as, having full legal authority for the management of all OPO services.

Responds to Stakeholder Concerns: We have identified nomenclature and definition changes that will improve clarity and update our regulations to terms widely used by the public.

- *Removal of the Term ''Recipient'' for Medicaid:* We have removed the term ''recipient'' from current CMS regulations and made a nomenclature

change to replace ''recipient'' with ''beneficiary'' throughout the CFR. In response to comments from the public to discontinue our use of the unflattering term ''recipient'' under Medicaid, we have been using the term ''beneficiary'' to mean all individuals who are eligible for Medicare or Medicaid services.

• *Replace the Term ''Mental Retardation'' with ''Intellectual Disability'':* We have replaced all references in CMS regulations to the unflattering term ''mentally retarded'' with ''individuals who are intellectually disabled'' that has gained wide acceptance in more recent disability laws.

C. Summary of Costs and Benefits

1. Overall Impact

There are cost savings in many areas. Two areas of one-time savings are particularly substantial. First, we estimate that one-time savings to ESRD facilities are likely to range from about $47.5 to $217 million, but we are using $108.7 million as our estimate. Second, we also estimate a one-time savings of $18.5 million to ASCs through reduced emergency equipment requirements. Both of these estimates are conservative and total savings could be significantly higher. The many types of recurring savings that these provisions will create include avoidance of business and payment losses for physicians and other providers that are difficult to estimate but likely to be in the tens of millions of dollars annually through the reforms we propose for re-enrollment and billing processes. We have identified other kinds of savings that providers and patients will realize throughout the preamble. Taking all of the reforms together, we estimate that the overall cost savings that this rule will create will exceed $200 million in the first year. This includes the one-time savings related to ESRD and ASC reforms, as well as the savings to providers in reductions in lost billings, paperwork costs, confusion, and other burden reductions discussed throughout this preamble. All of these potential savings are summarized in the table that follows.

2. Section-by-Section Economic Impact Estimates for 2012

The following chart summarizes the provisions for which we are able to provide specific estimates for savings or burden reductions:

Provisions	Frequency	Likely savings or benefits (millions)	Likely five year saving or benefits (rounded to nearest ten million)
End-Stage Renal Disease (ESRD) Facilities (§ 494.60)	One-Time	$108.7	$110
ASC Emergency Equipment (§ 416.44)	One-Time	18.5	20
Revocation of Enrollment/Billing Privileges (§ 424.535)	Recurring	100.0	500

II. 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.

We received several comments from the public that identified areas for possible future reform. We received comments from different industries including but not limited to national organizations (for example, the American Academy of Family Physicians and the American Academy of Ophthalmology), associations, and hospitals. Suggestions for areas of reform ranged across provider and supplier types and included a variety of ideas on how to streamline requirements, reduce excessive burdens, and increase transparency. We are reviewing these recommendations to determine if and where possible improvements can be made through future rulemaking or other vehicles. We note that some of the recommendations in the comments were closely related to areas being reformed in this rule. Therefore, we have provided responses to those comments in the related sections below.

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

The following is a description of each of the proposals set forth in the October 24, 2011 proposed rule (76 FR 65909). We grouped the proposals into three

categories—(1) Removes unnecessarily burdensome requirements; (2) removes obsolete regulations; and (3) responds to stakeholder concerns. There were 14 specific reforms included in the proposed rule. As noted above, we requested comments on additional areas for future reforms in these three areas or others. We seek to address these goals while maintaining high standards for the quality of care delivered to Medicare and Medicaid beneficiaries.

A. Removes Unnecessarily Burdensome Requirements

The following provisions 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 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 LSC regulations were found to duplicate many provisions of existing State and local fire safety codes covering ESRD facilities. Although the State and local codes protected patients from fire hazards, our rule incorporating the NFPA 101 LSC by reference 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, this is not the case because the evacuation process from fire entails 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 ''high hazardous'' occupancies and those facilities that do not have a readily available exit to the outside for swift, unencumbered evacuation.

However, 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). We believe that the reason 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(c)(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 LSC requirements in dialysis facilities are high. Through research discussed in the following paragraph, CMS learned that the actual costs for renovation and construction necessary for compliance with the additional requirements of NFPA 101 for dialysis facilities were considerable and profoundly exceed the original government estimate of $1,960 per facility, as published in the proposed rule for the 2008 ESRD CfC (70 FR 6242).

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 was 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 requirements would be $77,659. We suspect that the variability of the estimates may be due to differing 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, and we believe that there will be 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 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 proposed 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 will 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 noted that all ESRD facilities would still be required to comply with State and local fire codes and safety standards under § 494.20. We also proposed 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 noted 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 if permitted by State law.

The ESRD CfCs also address other topics related to fire and building safety that will remain in place under our 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 sought 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 sought comments on whether we should revisit these or other regulatory provisions or whether existing requirements are necessary and appropriate.

We received 15 public comments on our proposed changes to the LSC requirements for ESRD facilities. Commenters represented the entire dialysis community, including small, independent dialysis providers, large corporate dialysis organizations, dialysis provider coalitions, a nephrology nursing organization, a dialysis product manufacturer, and individual dialysis community members. Two comments were submitted by building and fire safety organizations.

All of the comments, with one exception, expressed strong support for the proposed rule and its intent to limit the application of the LSC requirements to ESRD facilities whose physical locations present a higher risk to life safety from fire. One commenter generally disagreed with the proposed changes.

Comment: All but one of the commenters supported our rationale for the proposed rule: that there is a historically low fire incidence in outpatient ESRD facilities; that most ESRD facilities provide available direct exits from the patient treatment area level to the outside at grade level; and that dialysis patients are routinely trained in emergency disconnect and evacuation procedures, as required in the ESRD CfCs, facilitating quick evacuation. The commenters concurred that these combined elements make the building and structural ''defend in place'' requirements of the LSC (as incorporated by reference into our regulations), which may differ from those of some State and local fire codes, a significant added burden with little or no gain in patient safety. Commenters also agreed that the requirements of current State and local fire safety codes sufficiently protect dialysis patients, and that many provisions in the LSC provisions are duplicative of those existing codes.

One comment from a building safety association agreed that, due to the overlapping, duplicative, and sometimes conflicting requirements between the LSC and State and local fire and building codes, limited application of the Federal LSC in ESRD would realize cost savings in not duplicating survey activities, but also for the dialysis facilities that may be required to comply with the overlapping and conflicting codes. The commenter also suggested that the cost savings published with the proposed rule were under-estimated.

Some of the commenters agreed that the expenditures for compliance with the LSC would be significantly higher than was predicted in the proposed rule for the 2008 ESRD CfC. One commenter from a large dialysis organization stated that the projection of costs for their facilities alone was just short of $120 million. Several commenters specifically agreed with the preamble language that expenditures for renovations and construction to comply with LSC requirements would divert resources away from issues which have been demonstrated to negatively impact dialysis patients, such as infections.

Many commenters expressed appreciation that we reconsidered the strict application of the LSC to all ESRD facilities and for our responsiveness to the dialysis community's concerns and desire to expend their resources where the greatest patient safety will be realized.

Response: We thank the commenters for their comments. We share the common goals of optimizing the health and safety of dialysis patients and allocating resources where they will benefit patients most. We appreciate your support for these proposed changes.

Comment: Two commenters suggested that more facilities should be included in the proposed exemption from the LSC requirements. One commenter suggested that ESRD facilities that do not have exits at grade level should also be exempted from the LSC requirements. The rationale for this suggestion was that these facilities do not generate a risk equivalent to those facilities located adjacent to ''high hazardous'' occupancies. Another commenter suggested that dialysis facilities providing only home dialysis training and support services be exempted from the LSC, citing the limited provision of on-site dialysis and generally higher staff-to-patient ratios.

Response: While there may be a higher risk of fire when an ESRD facility is located adjacent to a ''high hazardous'' occupancy, we consider the provision of swift, unencumbered evacuation integral to dialysis patients' life safety from fire. Once a dialysis patient has performed emergency disconnection from their treatment, the additional time it may take to traverse stairwells and/or passageways from a non-grade level treatment area to reach an outside exit justifies the additional structural requirements of the LSC provisions for ''defend in place''. Home dialysis patients who may be intermittently receiving their dialysis treatments at the dialysis home training and support facility have the same life safety and fire risks as do in-center dialysis patients. To ensure patient safety, we are not making changes to the proposed regulations in response to these comments.

Comment: Three commenters requested further clarification regarding the provision of exits from the patient treatment level to grade level. The commenters inquired whether ESRD facilities which were slightly above grade level and supplied interior Americans with Disabilities Act (ADA)-compliant accessibility ramps from patient treatment areas to grade level (for example, down 5–10 feet) would be considered as providing exits at grade level, and therefore exempt from the LSC requirements.

Response: The terminology for the provision of exit ''to the outside at grade level from the patient treatment area level'' is intended to apply to ESRD facilities that are on the ground/grade level of a building where patients do not have to traverse up or down stairways or passageways within the building to evacuate to the outside. ADA-compliant accessibility ramps in the exit area that provide ease of access between the patient treatment level and the outside street level would not be considered stairways or passageways. An ESRD facility which provides one or more exits to the outside at grade level from the patient treatment level, and a patients' exit path which includes an ADA-compliant accessibility ramp to the outside would be exempt from the LSC requirement, as long as it was not located adjacent to a high hazardous occupancy.

Comment: Three commenters requested further clarification of how ''adjacent to'' would be defined. All three commenters suggested that the definition of ''adjacent to'' should be equivalent to sharing a wall with the other occupancy. One added that sharing a ceiling or floor with the other occupancy should be included in the definition.

Response: We recognize that there are different definitions of the term ''adjacent'', and use it in reference to ESRD facilities that share a common wall, floor, or ceiling with a high hazardous occupancy. Because of the higher risk of fire occurrence in high hazardous occupancies, sharing a common wall, floor, or ceiling increases the risk of fire penetration to the ESRD facility. This increased risk makes the additional structural requirements of the LSC appropriate for patient protection.

Comment: Two commenters requested further clarification regarding the definition of a ''high hazardous occupancy'', and suggested the definition from the preamble language be retained.

Response: As stated in the preamble to the proposed rule, we use the definition of ''high hazardous occupancy'' from the National Fire Protection Association (NFPA) 101, 2000 Edition at section A.3.3.134.8.2: ''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 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.''

Comment: Two commenters requested clarification regarding the proposed language change for ESRD facilities that require sprinkler systems. The first issue raised was how to determine when a building was constructed. The second issue raised was whether the language in the proposed rule indicating that ESRD facilities located in high rise buildings are required to have sprinkler systems would be binding regardless of the building construction date.

Response: We appreciate the comments pointing out ambiguities in the proposed rule language, which was intended to clarify, but not change, the sprinkler requirement finalized in the April 15, 2008 ESRD CfC final rule (73 FR20370), and set out at § 494.60(e)(2). For the purposes of the sprinkler requirement, the date of building ''construction'' is the date the structural permit approvals and plan reviews were completed by the authority having jurisdiction.

Regarding sprinklers in high-rise buildings, the commenters are correct that the requirement for sprinklers in facilities housed in high rise buildings was intended to be applicable to those buildings constructed after January 1, 2008. We have revised the language in the final rule accordingly.

Comment: Two commenters believe that the effective date for compliance with the LSC requirement of February 9, 2009, the date published in the ESRD CfC Final Rule published in 2008, is no longer meaningful. The commenters stated the uncertainties about the applicability and scope of the LSC requirements that have existed since the ESRD CfC Final Rule have prevented facilities from undergoing the necessary construction for compliance, and that a phase-in period would be needed for applicable facilities. One commenter suggested that a new effective date for compliance be established at 12 months from the date of publication of this rule.

Response: We recognize that the delay in enforcement of the LSC requirements for ESRD facilities may appear to make the February 9, 2009 date less meaningful, but that date will still be used to determine whether the building housing an ESRD facility which must comply with the LSC requirement is considered ''new'' or ''existing''. We did not make any changes based on this comment.

Comment: One commenter agreed that most ESRD facilities are covered by

State and local fire and building safety codes. For example, the commenter stated that 43 of 50 States have adopted the International Fire Code in coordination with the International Building Code. The commenter suggested that there would be no reason in such jurisdictions that enforce a current building code and life safety and maintenance code to require enforcement of a LSC requirement. The commenter suggested that a LSC requirement would be appropriate for enforcement in jurisdictions where there is no State or local code. Although the commenter stated that ''most states, and most large population jurisdictions'' do have and enforce such current codes, they suggested that this rule apply only to those ESRD facilities located in jurisdictions that do not adopt a current national model building and fire code.

Response: We do not currently maintain an accounting of the fire and building safety codes adopted in individual States and local jurisdictions. Also, we do not adopt CfCs that vary by jurisdiction, although CMS defers to state law where such laws impose stricter standards than CMS requirements. We believe that limiting required adherence to the NFPA LSC requirements based on ESRD location is appropriate and did not make any changes in response to this comment.

Comment: Several commenters expressed concerns about the ESRD survey process in conjunction with the LSC. The issues they raised included how the designation of ESRD facilities as exempt from LSC requirements would be made; who would conduct the LSC compliance surveys; what education those survey personnel would receive to prevent inconsistent and inaccurate application; and how the enforcement of the LSC for the applicable facilities would be implemented. Some commenters provided suggestions relevant to these topics.

Response: We appreciate the many suggestions for assuring a smooth, efficient, and consistent method for implementing a standardized ESRD LSC compliance survey and enforcement process for applicable facilities. We will take them into consideration in the development of such a process.

Comment: The sole opposing commenter agreed that there is low risk and few fire incidents in outpatient ESRD facilities, and suggested that this is because ''a majority of'' ESRD facilities already meet the requirements of NFPA 101.

Response: We agree that application of a fire and building safety code may reduce injuries from fire. However, the ESRD CfCs did not include a Medicare LSC requirement until 2008, and, as stated in the preamble to the proposed rule, there have been no reported patient injuries or deaths due to fire in dialysis facilities in the 35 years of the Medicare ESRD program. We believe this comment supports the conclusion that existing State and local fire and building safety codes were adequately protecting patients and staff prior to the ESRD CfC requirement finalized in 2008. In the preamble to the proposed rule, we noted that all ESRD facilities must continue to comply with State and local fire codes and safety standards under § 494.20.

Comment: The opposing commenter also expressed concern that the procedure for emergency disconnect from hemodialysis treatment is ''potentially life threatening if carried out by a dialysis patient.'' The commenter cited a CMS publication from 2002, which listed instructions for an emergency disconnection procedure.

Response: We appreciate the commenter's concern; however cited the publication is 10 years old and no longer reflects current standards. In the 2008 ESRD Conditions for Coverage at § 494.60(d)(2), we require that all dialysis patients be instructed in how to disconnect themselves from treatment and evacuate in case of emergency. We contend that it is the unencumbered evacuation process that is primary to outpatient ESRD life safety from fire. We did not make any changes in response to this comment.

We received three public comments that suggested areas of ESRD policy for possible future reform.

Comment: Two commenters expressed concerns about the mandatory reporting of infection data to the Centers for Disease Control and Prevention (CDC) system, the National Healthcare Safety Network (NHSN) that is included in the ESRD Quality Incentive Program (QIP). The commenters support the requirement for infection data reporting as an incentive to improve care, but detailed multiple reasons why NHSN was burdensome, cumbersome, and, because it is a manual data entry system, subject to error and inaccurate data. One commenter outlined predicted labor costs for enrollment and manual data submission to NHSN, and estimated that it would cost in excess of $1,000,000 total for existing ESRD facilities. Both commenters suggested that we arrange an alternative method for mandatory infection data submission to NHSN, such as direct electronic data transfer and/or batch data submission.

Response: We are aware of the many concerns regarding the mandatory infection data submission to NHSN that is included in the ESRD QIP, and are currently working with the CDC to explore methods for facilitating the use of NHSN as a reliable national system for this important ESRD infection data.

Comment: One commenter addressed burdens of obtaining and documenting data regarding ESRD patients' co-morbid conditions for the purpose of claiming the case-mix adjustments in the ESRD Prospective Payment System (PPS). The commenter provided reasons why the required documentation of this patient information was difficult and costly to obtain, resulting in loss of revenue, due to under-reporting and the costs of collecting, reviewing, and auditing medical records.

Response: The requirement for documentation of certain co-morbidities, for the purpose of receiving additional payment for those conditions, is a condition of payment. That is, ESRD facilities have the option of providing appropriate, designated criteria in the medical record to support the co-morbidity in order to receive a payment adjustment for those co-morbidities. For example, there must be documentation that a patient had a positive chest x-ray or positive sputum in order to receive the payment adjustment for certain bacterial pneumonias. ESRD facilities can choose not to provide appropriate documentation, but they will not receive the payment adjustment. Because these payments are elective and not mandatory, we consider the associated paperwork requirements to be appropriate.

Comment: One commenter recommended revisions to the ESRD CfC addressing Patients' Rights (42 CFR 494.70(a)(7)) that would clarify expectations for educating ESRD patients on their options for dialysis modalities and settings.

Response: We appreciate the commenter's suggestions, and will take them into consideration for possible future reform.

Comment: One commenter suggested an annual CMS review and update of the ESRD CfCs, to reflect the dynamic clinical and technological aspects of the dialysis industry.

Response: We recognize the dynamic nature of dialysis care and treatment, but when new standards of care are developed, it may take years to determine the appropriateness of precise requirements. With this understanding, we strive to develop regulations that allow room for providers and suppliers to appropriately

adopt new standards of care without having to wait for new regulations.

The above summarizes the ESRD LSC provision made in our proposed rule and the comments we received. We are finalizing the policies above as proposed and clarifying in the regulatory text that the requirement for sprinklers in facilities housed in high rise buildings was intended to be applicable to those buildings constructed after January 1, 2008.

Contact: Lauren Oviatt, 410–786–4683.

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 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 these equipment requirements are outdated, while other equipment requirements would not be 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 proposed to revise the requirements for this CfC.

In the October 24, 2011 proposed rule (76 FR 65909 through 65911), we proposed to remove the list of emergency equipment at § 416.44(c)(1) through (c)(9) and proposed 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 intra- or post-operative emergencies. We also proposed that the emergency equipment identified by an ASC meet the current acceptable standards of practice in the ASC industry. We stated that we believe 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 received ten public comments on our proposed changes to the ASC emergency equipment requirements. Commenters included organizations and associations that represent surgeons, anesthesiologists, nurse anesthetists, gastroenterologists, hospitals, state health commissions, ophthalmologists, health policy and ambulatory surgical centers.

Seven out of the ten comments that we received expressed support for the proposed rule and its intent to remove the prescribed list of outdated and unnecessary emergency equipment from the current ASC regulations. Two commenters opposed the removal of the list and recommended the current regulation requirements stay in place. One commenter opposed the removal of the list, but offered an alternative list of emergency equipment for ASCs.

Comment: Several commenters supported our rationale for the proposed rule. The commenters concurred that the proposed changes would allow ASCs to have more flexibility to respond to emergency needs and also incorporate the use of modern and specific emergency equipment most suitable for the procedures performed in each facility.

Response: We thank the commenters for their support. We share the common goals of optimizing the health and safety of ASC patients and allowing ASCs to allocate their resources to the most current and specific emergency equipment that is tailored to the needs of patients who receive treatment in their facilities.

Comment: One commenter opposed the elimination of the current emergency equipment list and instead offered an alternative list of emergency equipment that ASCs must have available in an emergency situation.

Response: As we stated in the proposed rule preamble, the purpose of removing the outdated list of emergency equipment is to remove the burden of requiring ASCs to maintain unnecessary equipment, incorporate the use of modern emergency equipment, and give the ASC the flexibility to meet the needs of patients for the procedures performed in ASC facilities. We would like to reiterate that the removal of the prescribed list of emergency equipment in no way relieves the ASCs of maintaining a comprehensive supply of emergency equipment and supplies that are necessary to respond to a patient emergency in an ASC facility. Under this final rule, an ASC's governing body and medical staff are required to work in conjunction to develop policies and procedures which specify the types of emergency equipment appropriate for the facility and to make all of these items immediately available at the ASC to handle intra- or post-operative emergencies. Every ASC will be required to have emergency equipment in its facility that meets current acceptable standards of practice for the types of surgeries performed in the ASC. Moreover, we believe replacing the current list of emergency equipment with a revised standard list of emergency equipment would create the same problems that we are trying to eliminate in terms of mandating acquisition of the same equipment by every ASC, even when some of that equipment is not needed for the types of surgeries performed in a particular ASC. In addition, removing a prescriptive list of emergency equipment will eliminate the need to continually update the ASC regulations with a revised list whenever there is a new piece of equipment whose use becomes standard for handling various types of surgical emergencies.

Comment: We received two comments that suggested the emergency equipment list remain in place since it is the same list of equipment required for hospital surgery that is located in the current hospital Conditions of Participation.

Response: We note that the list of equipment required for hospitals at 42 CFR 482.51(d)(3), while similar to that in the current ASC rule at 42 CFR 416.44(c), is not worded identically and is in some cases less specific, providing more flexibility to hospitals. Further, as

we stated in the previous response, we are still requiring ASCs to identify and maintain a comprehensive, current and appropriate set of emergency equipment, supplies and medications that meet current standards of practice, and which will enable the ASC to appropriately respond to anticipated emergencies that are specific to the types of surgery performed in the ASC as well as being appropriate to the ASC's patient population. In addition, because hospital operating room suites typically handle a wider range of surgeries, including more complex surgeries than those performed in an ASC, it is reasonable that there would be differences in the standards for hospitals as compared to ASCs. We believe the requirement we have proposed for ASCs is appropriate to assure the safety of ASC patients without creating undue burdens on ASCs.

Comment: One commenter that supported our proposed changes to the emergency equipment requirement noted the Malignant Hyperthermia Association of the United States recommendation that all facilities that administer malignant hyperthermia-triggering anesthetics should stock a minimum of 36 vials of dantrolene sodium for injection.

Response: We thank the commenter for their support of the proposed rule. Currently, the ASC requirements do not mandate that ASCs stock a prescribed supply of any specific medication needed to handle specific intra-operative or post-surgical emergencies, such as malignant hyperthermia. However, we would expect that ASCs that perform procedures using anesthetics that involve a risk of malignant hyperthermia would address this risk in the emergency procedures they develop, and would stock appropriate supplies, including medications, to handle such emergencies. The proposed changes to the standard governing emergency equipment and supplies requires that ASCs meet the current acceptable standards of practice, and that all Medicare-certified ASC facilities incorporate the identified emergency equipment, supplies and medications that are most suitable for the potential emergencies associated with the procedures performed in the ASC, and the population the ASC serves.

Therefore, for the reasons set forth above, we are finalizing our proposal, without modification, to remove the list of emergency equipment at § 416.44(c)(1) through (c)(9). Further, we are finalizing our proposal to modify § 416.44(c) to require that ASCs, in conjunction with their governing body and the medical staff, develop policies and procedures specifying the types of emergency equipment that are 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 finalizing our proposal that the emergency equipment identified by the ASC meet the current acceptable standards of practice in the ASC industry. CMS will monitor the implementation of this change in emergency equipment requirements and will revisit the issue if it is determined to have an adverse impact on patients.

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 Medicare billing privileges were revoked.

In our October 24, 2011 proposed rule, we proposed to revise § 424.535(c) to eliminate the re-enrollment bar in instances where providers and suppliers have had their billing privileges revoked under § 424.535(a) solely for failing to respond timely to a CMS revalidation request or other request for information. As we explained in the proposed rule, 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 where 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, when providers have been excluded from Medicare, Medicaid or other Federal health care programs or have been convicted of a felony as described in § 424.535(a)(2) and (a)(3), respectively. Moreover, there is another, less restrictive regulatory remedy available for addressing a failure to respond timely to a revalidation request. This remedy was identified in proposed § 424.540(a)(3).

We received 9 public comments on our proposed change to § 424.535(c). The comments, which we have summarized, and our responses, are as follows:

Comment: Many commenters expressed support for our proposed revision to § 424.535(c). They agreed with our view that the imposition of a re-enrollment bar is unduly harsh in cases where a revocation is based solely upon the provider or supplier's failure to respond timely to a revalidation request or other request for information. Several commenters added that a re-enrollment bar in such instances could also cause beneficiary access issues. Another commenter stated that a re-enrollment bar is more appropriate for providers and suppliers that intentionally break laws and violate the trust of their patients.

Response: We appreciate the commenters' support for our proposal. We are finalizing our proposed change to § 424.535(c), which we believe will help reduce the administrative burden on providers and suppliers whose revocations are based solely on a failure to respond timely to a revalidation or other request for information. As commenters pointed out and as we explained above, some legitimate providers and suppliers were barred from being able to treat and bill for Medicare patients because of the wide scope of this reenrollment bar.

Comment: Several commenters, while expressing support for our proposed change to § 424.535(c), sought clarification as to: (1) When this change would become effective, and (2) whether it would apply to providers and suppliers that were mailed a revalidation notice in September 2011 but unintentionally missed the 60-day deadline for revalidating their enrollment.

Response: The revision to § 424.535(c) will become effective upon the effective date of this final rule. It will not be applied retroactively.

Comment: Several commenters opposed our proposed change to § 424.535(c). One commenter stated that under § 424.535(a), CMS may—but is not required to—revoke and establish a

re-enrollment bar if a provider or supplier has not responded timely to a revalidation or other informational request. Hence, CMS should not remove its discretionary authority to impose a re-enrollment bar in these instances. The commenter also recommended that CMS provide data regarding the number of times that Medicare contractors have revoked Medicare billing privileges and established a re-enrollment bar in such cases. Another commenter asked how our proposed revision to § 424.535(c) would reduce fraud, waste and abuse and how CMS would deal with providers and suppliers that repeatedly fail to respond to revalidation or other informational requests; the commenter asked, for instance, whether a site visit would be performed and whether the provider's ownership would be verified.

Response: While CMS has the discretion to revoke a provider or supplier's Medicare billing privileges under § 424.535(a) for a provider or supplier's failure to respond to a revalidation or other informational request, the imposition of a re-enrollment bar under § 424.535(c) is not discretionary. If the provider or supplier is revoked, a re-enrollment bar must follow. As explained above, we believe that an automatic re-enrollment bar for a revocation based on a failure to respond to a revalidation or other informational request is overly punitive. The most appropriate remedy, therefore, is to remove the re-enrollment bar in such situations.

With respect to the commenter's request that CMS furnish data regarding the number of revocations and associated re-enrollment bars that have been imposed, we do not believe that such information is necessary for our analysis. We proposed this change in an effort to reduce the administrative burden on any provider or supplier subject to the bar, regardless of how often CMS or its contractors have imposed re-enrollment bars.

We do not believe that the finalization of our proposed revision to § 424.535(c) will impact our ability to prevent or combat fraudulent activity in our programs. Providers and suppliers that fail to respond once or repeatedly to a revalidation or other informational request will still be subject to adverse consequences, including—as explained below—the deactivation of their Medicare billing privileges. CMS does—and will continue to—closely scrutinize every provider and supplier that seeks to reactivate its billing privileges or re-enroll in Medicare after a revocation. In fact, in the latter case, the provider or supplier would be subject to the ''high'' level of categorical screening under § 424.518(c)(3), which would include additional screening tools. In sum, the aforementioned safeguards should alleviate any program integrity concerns regarding our proposed change—which, as already noted, focuses on reducing the unfair burden to providers and suppliers that inadvertently fail to respond to revalidation or other informational requests.

The above summarizes this provision in our proposed rule and the comments received. We are finalizing our changes to § 424.535(c) as proposed.

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) titled ''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 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 attempts to submit a claim after the date of deactivation, the claim would be denied. To reactivate its Medicare billing privileges, a provider or supplier is required to recertify—generally via the submission of a complete CMS–855 enrollment application—that the provider or supplier's enrollment information currently on file with Medicare is accurate. Physicians and non-physician practitioners are deactivated most often due to billing inactivity.

In our October 24, 2011 proposed rule, we proposed to revise § 424.540(a)(1) to apply only to those providers and suppliers that do not submit a Form CMS–855I (the enrollment form for individual physicians and non-physician practitioners) to enroll in the Medicare program. As we explained in the proposed rule, we were mostly 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. We felt, on the other hand, that there are instances in which individual practitioners had valid reasons for not filing claims within a 12-month period. These included, but were not limited to, cases where the practitioner: (1) Was enrolled in Medicare, but generally only treated non-Medicare patients, or (2) had multiple, separately-enumerated practice locations, yet typically only performed services at one of them. We also believed that the 12-month deactivation and reactivation processes increased the workload and administrative costs of Medicare contractors. For these reasons, we proposed the above-mentioned revision to § 424.540(a)(1)

We received 27 separately submitted public comments on our proposed change to § 424.540(a)(1). The comments, which we have summarized, and our responses, are as follows:

Comment: A significant number of commenters either opposed or expressed concerns about our proposed revision to § 424.540(a)(1). One commenter, for instance, stated that by allowing unused Medicare billing numbers to remain active, CMS is fundamentally increasing the risk of fraud, waste and abuse (for example, identity theft) in Medicare. Other commenters cited a number of Health and Human Services Office of Inspector General (OIG) reports, including OEI–03–01–00270 and OEI–04–08–4470, in support of OIG's contention that CMS should retain its existing discretionary authority to deactivate physicians and non-physician practitioners for 12 months of non-billing. Commenters also stated that these reports identified, among other things, the risks involved in allowing unused billing numbers to remain active.

Response: We understand the commenters' concerns and have elected not to finalize our proposed change to § 424.540(a)(1) at this time. The commenters are correct that our current deactivation authority for non-billing is discretionary. Upon further analysis, and based on the input we received from several commenters voicing reservations about our proposal, we do not believe it is necessary to revise this authority at this time. As commenters pointed out, a provider or supplier's failure to bill Medicare for an extended period of time raises numerous questions, such as whether the provider is still operational and meets the standards for his or her provider type. We believe that deactivation can protect the agency from risks associated with

misused provider numbers by (1) allowing CMS to confirm whether the provider or supplier continues to meet all Medicare requirements based on the provider or supplier's submission of a complete CMS–855 application; and (2) preventing others from misusing the provider or supplier's billing number, which was a concern that several commenters expressed.

CMS intends to study this issue further, as we believe that an appropriate balance between protecting the Medicare Trust Fund and reducing the burden on provider and suppliers is achievable. For example, CMS implemented in December 2011 a system for Automated Provider Screening that both simplifies enrollment into Medicare for providers and suppliers while increasing the ability of CMS to identify potentially ineligible or fraudulent providers and suppliers.

Our decisions not to finalize the proposed change to § 424.540(a)(1) and finalize our proposed change to § 424.535(c) are both grounded in efforts to weigh the potential benefits and costs to our program and providers. In the former case, we concluded that the program integrity risks associated with removing our discretionary deactivation authority in § 424.540(a)(1) outweighed the potential benefits of a reduced burden on providers and suppliers. However, as explained, we believe our proposed changes to § 424.535(c) will result in a decrease in provider and supplier burden without adversely impacting our ability to prevent and combat fraudulent activity in our programs. In the latter case, we do not see any increased program integrity risks that could potentially outweigh the benefits of reduced provider burden.

Comment: One commenter stated that almost all State Medicaid agencies deactivate physician and non-physician practitioner billing numbers based on a lack of claim submissions over a given time. The commenter asked CMS to explain—(1) Whether the Federal Employee Health Benefit Program (FEHBP) also deactivates billing privileges based on claim non-submissions, and; (2) why CMS will forgo deactivation in its proposed revision to § 424.540(a)(1) while most State Medicaid agencies will continue deactivations.

Response: Approximately 200 private plans participate in the FEHBP. In the FEHBP, providers bill plans, not the Federal government. Hence, there is no federal deactivation authority as such in the FEHBP. Other management approaches, most notably private plan decisions on participating providers and program-wide debarment, are used to deal with provider billing problems related to program integrity. Regardless, as explained above, we have decided not to finalize our proposed revision to § 424.540(a)(1).

Comment: Several commenters requested that CMS explain why it will continue its deactivation process for Medicare-enrolled provider and supplier organizations, yet did not fully implement the deactivation process for Medicaid and Children's Health Insurance Program providers that was proposed in the February 2, 2011 final rule titled ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers.'' The commenter believes that this represents an inconsistency in CMS's approach to deactivation.

Response: As we stated in the February 2, 2011 final rule, we decided not to finalize the 12-month deactivation provision in proposed § 455.418 based on the comments received and certain operational considerations. However, we also stated in that rule that while States should have the discretion ''to police their own provider enrollment,'' we recommended that States ''deactivate provider numbers that have not been used for an extended period of time.'' This recommendation, in our view, is consistent with our decision not to finalize our proposed change to § 424.540(a)(1).

Comment: One commenter agreed with CMS' policy to continue to deactivate billing privileges associated with physicians and non-physician practitioners who complete and submit the ''Medicare Enrollment Application—For Eligible Ordering and Referring Physicians and Non-Physician Practitioners (CMS–855O).''

Response: While we appreciate the commenter's support, we note that physicians and non-physician practitioners who complete the Form CMS–855O are not granted Medicare billing privileges. They do not and cannot send claims to Medicare for services they provide. They submit the form for the sole purpose of ordering or referring Medicare-covered items and services.

Comment: One commenter recommended that CMS continue to deactivate Medicare billing numbers for physicians and non-physician practitioners who submit the CMS–855O and the CMS–855R and who do not bill the Medicare program for 12 consecutive months. The commenter added that since CMS did not consider the impact of deactivation on physicians and other practitioners in the proposed rule's preamble or regulation text, the inclusion of our proposed change in final rulemaking without adequate public notice would violate the Administrative Procedures Act.

Response: As stated above, physicians and non-physician practitioners who complete the CMS–855O do not receive Medicare billing privileges and are thus not subject to deactivation under § 424.540(a)(1). In addition, we did not predicate our proposed change based on whether the physician or non-physician practitioner completed the CMS–855R. Deactivation for non-billing, in our view, should not be based solely on whether the physician or non-physician practitioner reassigns his or her benefits. Finally, we disagree with the commenter's assertion regarding CMS's consideration of the impact of deactivation on physicians and non-physician practitioners. We expressly outlined in the preamble to the proposed rule the burden imposed on such individuals because of the deactivation process. Indeed, it was this burden that encouraged us to propose our change to § 424.540(a)(1).

Comment: One commenter noted our statement in the proposed rule: ''We have issued guidance that requires our contractors to conduct certain verification activities to guard against physician and non-physician practitioner identity theft.'' The commenter asked CMS to furnish additional information about the techniques being used to prevent physician and non-physician practitioner identity theft.

Response: Since January 2010, Medicare contractors have been required to perform additional verification activities to confirm the identity of a physician or non-physician practitioner who is reporting, for instance, a change in his or her practice location address, special payment address, or correspondence address. Specifically, the contractor is required to compare the signature on the submitted Form CMS–855 change request with the signature on file. If they do not match, the provider must submit proper identification, such as a copy of a driver's license or passport. These and other verification procedures are outlined in Chapter 15 of CMS's Program Integrity Manual.

Comment: A commenter cited our statement in the proposed rule: ''Currently Medicare provider and supplier enrollment billing privileges are deactivated (made ineligible for

Medicare billing purposes) for providers and suppliers that have not submitted a Medicare claim for 12 consecutive months.'' The commenter believed that this statement was incorrect, arguing that CMS discontinued the automatic deactivation process in late 2010 or early 2011. The commenter requested that CMS explain why it: (1) Discontinued the automatic deactivation process for physicians, non-physician practitioners, medical groups and other suppliers, and (2) has not implemented an automatic deactivation process for Part A providers.

Response: To clarify, the statement the commenter quotes was meant to describe CMS' existing deactivation authority at § 424.540(a)(1). Insofar as the automatic deactivation process, we believed that a case-by-case approach was more appropriate, in part for reasons which we have discussed in this final rule. Indeed, the burdens posed by automatic deactivations—both on our contractors and on those providers and suppliers that have legitimate reasons for not billing Medicare for 12 months—did not at that time justify the continuation of such a ''one-size-fits-all'' process. It is primarily for this reason, moreover, that an automatic deactivation mechanism has not been initiated for Part A providers.

Comment: One commenter recommended that CMS explain the linkage, if any, between the current deactivation policy and the maximum period for claim submissions. The commenter also asked CMS to explain why a physician or non-physician practitioner should remain enrolled in Medicare if he/she cannot bill for services within 12 months from the date of service.

Response: We do not see a significant linkage between deactivation and the timeframe in which a provider must submit a claim for payment. Rather, the deactivation policy, as already explained, was based largely on the need to prevent others from accessing unused billing numbers and to ensure—via the deactivated provider's submission of a complete Form CMS–855—that the provider and supplier continues to meet Medicare enrollment requirements. With respect to the commenter's second statement, we do not believe that a failure to submit claims justified the revocation of a provider or supplier's billing privileges so long as the provider or supplier is still in compliance with all Medicare requirements.

Comment: Several commenters stated that CMS did not fully explain its rationale for its proposed change to § 424.540(a)(1). They requested that CMS do so or otherwise withdraw the proposal. They also recommended that CMS explain how this change will affect CMS's efforts to reduce fraud, waste and abuse. One commenter requested that CMS outline the benefits that have accrued from the annual deactivation process. Another commenter urged CMS to explain how it will ensure that physician billing numbers are not misused by clearinghouses, billing agents, or former employees.

Response: We believe that we provided sufficient rationale for the proposed change to § 424.540(a)(1) in the proposed rule. However, based on the concerns that commenters have expressed, we will not be finalizing our proposed change.

Comment: A commenter stated that CMS should have explained the impact that our proposed change would have on fraud, waste and abuse by physicians and practitioners who only order and refer services to Medicare beneficiaries.

Response: We assume that the commenter is referring to physicians and non-physician practitioners who complete the Form CMS–855O. As stated above, such individuals do not have Medicare billing privileges. They are therefore unaffected by the deactivation provisions in § 424.540(a)(1).

Comment: A commenter requested that CMS explain: (1) Why it did not include information regarding the supplier notification aspect of the deactivation process in the proposed rule, and (2) whether the post-deactivation process allowed physicians and non-physician practitioners to update their re-enrollment in the Medicare program.

Response: We did not include information about the supplier notification process in the proposed rule because we believed it was immaterial to the larger question of the burden that the deactivation process poses as a whole. As for the commenter's reference to a ''post-deactivation process,'' we are unclear as to what the commenter means. If the commenter is asking whether a reactivation application can always be simultaneously used as a revalidation application, CMS does not generally hold that position; reactivation and revalidation applications are for separate purposes and are governed by separate rules.

Comment: One commenter cited a Government Accountability Office (GAO) report (GAO–04–707) stating that out-of-date information increases the risk that Medicaid will pay individuals who are not eligible to bill Medicaid. The commenter asked CMS to explain why it disagrees with this statement and why its proposed change will decrease the risk to the Medicare program.

Response: We agree that out-of-date enrollment information poses a risk to all of our programs. Our ongoing effort, in fact, to revalidate all providers and suppliers reflects the importance we place on the need for Medicare to have accurate and up-to-date information on all enrolled individuals and entities. As explained above, we are not finalizing our proposed change due to the program integrity concerns raised by comments such as this one.

Comment: One commenter cited a December 1995 OIG report (OEI–01–94–00231) that: (1) Generally stated that CMS should require carriers to deactivate unused provider numbers, (2) recommended that a 1-year non-billing period be used, and (3) pointed out certain risks involved with unused numbers. The commenter asked why CMS did not discuss the history and background of the deactivation process in the proposed rule. The commenter also asked why CMS, through its proposal to eliminate non-billing deactivations for physicians and non-physician practitioners, is disregarding the OIG's above-referenced recommendation.

Response: We did not and do not believe that a detailed history of the deactivation process is necessary, as many providers and suppliers are already familiar with the concept of deactivation. We add that, as explained earlier, we are not finalizing our proposed change to § 424.540(a)(1).

Comment: Several commenters supported our proposed revision to § 424.540(a)(1). They generally stated that it would reduce the burden on providers, suppliers and Medicare contractors, and would ensure better access to care for beneficiaries. They added that there are indeed valid reasons for a physician or non-physician practitioner not to submit a Medicare claim for 12 consecutive months; for instance, he or she may: (1) Simply not have many Medicare patients, (2) have been ill, or (3) have been working outside the country. Another commenter stated that the reimbursement delays associated with deactivations can be devastating to some providers.

Response: We appreciate these supportive comments. However, for reasons already discussed, we will not be finalizing our proposed change.

Comment: One commenter urged CMS to expand our proposed change to § 424.540(a)(1) to include physician group practices.

Response: As already stated, we are not finalizing our proposed change.

Based on the comments received and for the reasons expressed above, we have decided not to finalize our proposed change to § 424.540(a)(1). We may, however, seek other approaches—including future rulemaking—to address the concerns of providers and suppliers regarding the deactivation of providers and suppliers for 12 consecutive months of non-billing.

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 the provider or supplier 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 did not propose 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.

We did not receive any comments with respect to § 424.540(a)(2).

c. Section 424.540(a)(3)

We proposed 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. While the deactivated provider or supplier would still need to submit a complete enrollment application to reactivate its billing privileges, it 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. Indeed, it is for this reason that we believed our proposal would reduce the burden on the provider and supplier communities.

We received 5 public comments on proposed § 424.540(a)(3), all of which supported our proposed addition of § 424.540(a)(3). The comments stated that revocation is often too harsh a penalty and that deactivation is a more suitable remedy. They added that our proposal would reduce the burden on providers and suppliers that inadvertently miss the 90-day deadline. We appreciate the support of these commenters and are finalizing the policy as proposed.

We note that we received several comments in response to our request for feedback regarding additional ways to reduce the burden on providers and suppliers. The comments below pertain to the provider enrollment process:

Comment: A commenter suggested that CMS allow providers and suppliers 120 days—rather than the 90 days referred to in § 424.540(a)(2)—to report a change of information. The commenter believed that such an extension would be beneficial in light of CMS's ongoing revalidation effort and would reduce the burden on Medicare providers and suppliers.

Response: While we appreciate this suggestion, we believe that 90 days constitutes more than sufficient time for a provider or supplier to submit a change of information. We have repeatedly stressed to the provider community how important it is for CMS to have accurate information on individuals and entities that bill Medicare. Erroneous data can lead to improper payments, thereby endangering the Medicare Trust Fund.

Comment: A commenter recommended that CMS extend the timeframe for reporting a change in ownership or control from 30 days to 90 days. The commenter felt that 30 days is too short a timeframe for compliance. A 90-day period would: (1) Make this reporting requirement consistent with that applied to other types of informational changes that must be reported, and (2) ease the burden on the provider community.

Response: We recognize that 30 days is a significantly shorter period than that given for reporting most types of changes of information. Given, however, the relative importance of information regarding the provider's ownership, we believe that a 30-day period is appropriate.

Comment: A commenter urged CMS to implement safeguards designed to avoid contractor application processing errors, which can lead to delays in payment to providers and, in turn, interruptions in patient access to care. The commenter also recommended that CMS implement a clearer and more direct process for streamlining Medicare enrollment; this includes identifying and resolving application processing errors and issues related to the customer service hotlines.

Response: We appreciate these recommendations. We can assure the commenter that CMS is currently undertaking a number of initiatives designed to streamline and improve the provider enrollment process, such as the ongoing enhancement of the Provider Enrollment, Chain and Ownership System (PECOS) Internet-based enrollment mechanism.

Comment: One commenter recommended that CMS reduce the risk categorization—as described in CMS final rule, published in the **Federal Register** on February 2, 2011, titled ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers''—for certain types of DMEPOS suppliers. Specifically, the commenter suggested that the risk category for ''non-commercial'' DMEPOS suppliers—that is, physicians and non-physician practitioners who furnish DMEPOS items to their own patients—be changed from ''high'' to ''limited.'' The commenter argued that such suppliers would have to undergo fingerprinting and a criminal background check each time they enrolled in Medicare or opened a new location. This could spur many physicians to opt-out of Medicare, rather than be subjected to these burdens.

Response: We understand the commenter's concerns. As we stated in the February 2, 2011 final rule, however, we predicated our screening level assignments on the collective experience of provider and supplier categories. Based on the continued problem of fraud and abuse in the DMEPOS arena, we believe that all newly enrolling DMEPOS suppliers—irrespective of subcategory—should be in the ''high'' level of categorical screening. We will, nonetheless, continue to monitor this issue and may make adjustments to the risk categories when appropriate.

Comment: One commenter suggested that hospital-based physician groups be permitted to submit enrollment applications more than 30 days before the effective date listed on the application. This would allow such groups to begin billing Medicare sooner.

Response: We appreciate this suggestion. We will study the issue further and, if needed, furnish clarifying guidance to the public.

Comment: A commenter urged CMS to reduce the period in which contractors must process enrollment applications to no later than 60 days for paper applications and 45 days for Web-based applications. The commenter asked CMS to modify the proposed deadlines in the re-designated § 405.818 in accordance therewith.

Response: Medicare contractors must process enrollment applications in accordance with the timeframes outlined in CMS Publication 100–08,

chapter 15, and as specified in their respective Statements of Work. We note that the vast majority of initial enrollment applications today must be processed within 60 days (paper) and 45 days (Web-based).

Comment: Several commenters requested that CMS reduce all unnecessary paperwork from the enrollment process.

Response: We appreciate this comment and are working towards making the enrollment process as paperless as possible, in part through enhancements to the Internet-based PECOS enrollment mechanism.

Comment: A commenter requested that CMS: (1) Exempt federally qualified health centers (FQHCs) from the provider enrollment application fee described in § 424.514; (2) have each Medicare Administrative Contractor assign an FQHC subject matter expert and customer service representative who can help better facilitate the processing of FQHC applications; and (3) no longer require each individual FQHC site to separately enroll, but to allow the parent to enroll with the individual sites listed as practice locations. The commenter believed that these changes would greatly reduce the burden on FQHCs.

Response: Section 1866(j) of the Act requires the Secretary to impose a fee on each ''institutional provider of medical or other items or services or supplier.'' The term ''institutional provider'' is defined in § 424.502 as ''any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and non-physician practitioner organizations), CMS–855S or associated Internet-based PECOS enrollment application.'' Since FQHCs complete the Form CMS–855A to enroll in Medicare, they are subject to the application fee.

We appreciate the commenter's suggestion regarding the assignment of designated contacts at Medicare contractor sites to handle FQHC enrollment applications. While we are not adopting the commenter's recommendation at this time, we will take it under advisement.

Although we understand the commenter's concern about the FQHC ''site-by-site'' process, we intend to retain the policy at 42 CFR 491.5(a)(3)(iii) which states: ''If clinic or center services are furnished at permanent units in more than one location, each unit is independently considered for approval as * * * an FQHC.'' We believe it is important that each individual FQHC site be able—on its own merits—to meet all CMS requirements. Since we did not propose to change this requirement, it is considered outside the scope of the regulation, though we may take this comment into consideration for future rulemaking.

Comment: A commenter recommended that CMS eliminate PECOS—which the commenter believes is a redundant system—and instead standardize the Medicare enrollment process with other public and private payers via the adoption of the Council for Affordable Quality Healthcare Universal Provider Datasource.

Response: We do not believe that PECOS should be eliminated. It has proven to be an extremely valuable tool in capturing provider enrollment information that is unique to the Medicare program.

Comment: A commenter requested that CMS standardize its fraud and abuse regulations, arguing that such changes would reduce physicians' burden of complying with multiple inconsistent regulatory schemes.

Response: As the commenter has not specifically identified any inconsistencies within CMS's program integrity regulations, we unfortunately are not in a position to address this comment further.

We also received several comments not clearly related to regulatory matters:

Comment: One commenter recommended that CMS consider civil monetary penalties for physicians and other providers and suppliers who fail to report changes in a timely manner.

Response: We believe that this comment is out-of-scope, as it pertains neither to the issue of burden reduction nor the provisions of the proposed rule; nonetheless, we believe that the remedies we have outlined in this final rule, as well as those which already exist, are the most appropriate ones.

Comment: One commenter recommended that CMS remove the ordering and referring file from the CMS Web site. The commenter argued that providing the names of physicians and non-physician practitioners and their active National Provider Identifiers to the public increases the likelihood of fraud, waste and abuse. The commenter also: (1) Contended that CMS has no statutory or regulatory requirement mandating the issuance of ordering and referring information to the public, and (2) requested that CMS explain why it is posting the ordering and referring file when it has not yet implemented any ordering and referring claims edits.

Response: We believe that this comment, too, is out-of-scope, as it is unrelated to the issue of burden reduction and the provisions of the proposed rule. We note, however, that making NPIs available online is important for the processing of many standard health care transactions, for Medicare and other payers.

The above summarizes this proposal and the comments we received. As noted above, we are not finalizing our proposed changes to § 424.540(a)(1) and intend to study this issue further and possibly address in future rulemaking or another suitable vehicle. However, we are finalizing our provision to add a new § 424.540(a)(3) as proposed.

Contact: Morgan Burns, 202–690–5145.

5. Duration of Agreement for Intermediate Care Facilities for Individuals With Intellectual Disabilities (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 ''individuals with intellectual disabilities'' as described in this program, so we have used the new term in these final provisions.

Section 1910 of the Act provides for the certification and approval of Intermediate Care Facilities for the Individuals with Intellectual Disabilities (ICF/IIDs). These facilities were formerly known as Intermediate Care Facilities for the Mentally Retarded (ICF–MRs) and are renamed through the change in nomenclature described below in this rule. Current regulations at § 442.109 and § 442.110 address ICFs-IIDs provider agreements and limit the ICFs-IIDs provider agreements under Medicaid to annual time limits. We proposed to remove the time limited agreements for ICF/IIDs at § 442.16. We also proposed to eliminate this requirement at § 442.15, § 442.109, and § 442.110. In order to give more flexibility to States, we proposed 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/IID no longer meets the conditions of participation for ICF/IIDs at subpart I part 483.

Also, we proposed to add a requirement that a certified ICF/IID must be surveyed on average every 12 months with a maximum 15 month survey interval. Current regulations at 42 CFR part 442 require that ICF/IIDs 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 change in the certification period will have positive impacts on the care provided in these facilities because the new process will be less predictable and will require facilities to be more proactive in maintaining high standards of care. The new process will also improve the efficient and effective operation of State survey agencies responsible for regulating ICF/IIDs.

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.

We received three public comments on our proposed changes to the duration of agreement for ICF/IID.

Comment: One commenter representing a state survey agency agreed with CMS's belief that the change will provide opportunities to increase operational efficiency at the state level by enabling more flexible scheduling and by reducing duplication when complaint survey timing may coincide with annual recertification. The commenter noted that with the proposed changes survey times would be less predictable and the expanded interval range will improve the quality improvement impact of surveys. The commenter also noted that the changes will provide a reduction in paperwork at the survey agency, the state Medicaid agency, and certified facilities, and that the additional flexibility afforded by the change will allow resources to be focused on problematic facilities and validation processes.

The commenter requested the survey time for ICF/IIDs be expanded to 24 months to provide States opportunities to focus resources on poor performing facilities.

The commenter also requested that CMS consider relaxing the requirement that surveys be unannounced. The state has recently implemented a system of announced state surveys and believes the practice contributes to improved quality improvement efforts by encouraging state agency cooperation.

Response: The commenter's observations regarding the efficiencies and process improvements afforded by this change reinforce the rationale for revising the duration of the agreement.

The change to the survey time will make ICF/IID's consistent with certified nursing facilities regarding survey scheduling. At this time CMS has not found that extending the survey time for ICF/IID's beyond 12 months on average could be accomplished without negative impacts on the quality of care delivered by these facilities. Therefore, the same standard survey time period for nursing facilities has been applied to ICF/IID's. However, the proposed change will allow states greater latitude to survey poor performing facilities more frequently and high quality facilities less frequently, as long as the overall time-frames are observed. The requirement that surveys be unannounced is intended to assure that facilities provide a consistent quality of services and care required under the conditions of participation. While announced surveys may improve state and facility cooperation, CMS has not determined that overall program performance or the quality of care for residents would benefit by announcing survey visits.

Comment: One commenter requested that CMS allow states, through the State Performance Standards, as much flexibility as possible during the first year of implementation to modify survey schedules and thereby produce a higher level of survey unpredictability.

Response: CMS seeks to eliminate the administrative burden of the completion of forms which extend the provider agreement in cases where the survey activity has not been completed within the required 12 month period. These forms, currently exchanged between two units of State government and the provider, require administrative work without adding value or increasing the survey frequency. They also serve, to some extent, in alerting ICF/IID facilities to the prospect of an imminent survey. Therefore, in addition to reducing administrative burden the regulatory change also provides an increased opportunity for the State Survey Agencies to more greatly vary their survey schedules and to decrease the predictability of the survey visits by the provider. We agree with the commenter with regard to State performance expectations, and will ensure that the State Performance Standards for this measure will be listed as ''developmental'' to encourage the State Survey Agencies to make significant changes to their survey schedules for ICF/IID and thus enhance the unpredictability of surveys

Comment: Another commenter from a state agency expressed the concern that the 12 month average survey interval is inconsistent with the 15 month maximum time interval allowed. The commenter also expressed concern that the rule does not specify whether the state or CMS will determine the statewide average interval, nor how the state may appeal a determination of compliance with the interval if the state disagrees.

Response: As discussed above, the proposed change in the rule will make the timing of ICF/IID surveys consistent with the requirements for surveys of certified nursing facilities. Each facility will be surveyed at least once every 15 months, and facilities must be surveyed an average of every 12 months. Necessarily, this means that if some facilities are surveyed only after 12 months but before the end of 15 months from the last survey, other facilities in the state must be surveyed more frequently than 12 months. We will publish in our Mission and Priority Document (MPD) the methodology to be applied in computing the maximum and average survey intervals for ICF/IID's. While there is no formal appeal process for States to dispute the calculations included in the MPD, this methodology will be available to the states which can use it to verify CMS's calculation of the average survey interval.

The above summarizes this provision as proposed in our proposed rule and the comments we received. We are finalizing the policy above as proposed.

Contact: Thomas Hamilton, 410–786–9493.

B. Removes Obsolete or Duplicative Regulations or Provides Clarifying Information

The following provisions 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 Web site at *http://www.reginfo.gov/public/do/PRAMain.* The Web site 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 proposed 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 Web site.

We did not receive any public comments on our proposed changes to remove the list of OMB control and approval numbers in subpart C. Therefore, we are finalizing the policy as proposed.

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 the proposed rule, we proposed to remove obsolete provisions contained in 42 CFR part 405 subparts G and H governing initial determinations, appeals, and reopenings of Medicare Part A and Part B claims, and determinations and appeals regarding an individual's entitlement to benefits under Medicare Part A and Part B. See 76 FR 65913, October 24, 2011. Currently, initial determinations, appeals and reopenings of Medicare Part A and B claims are governed by the provisions in section 1869 of the Act and in 42 CFR part 405 subpart I. Initial determinations and reconsiderations of an individual's entitlement to Medicare Parts A and B are governed by the provisions in 20 CFR part 404, subpart J, and entitlement appeals beyond the reconsideration level are governed by part 405 subpart I. The part 405 subpart I regulations implemented pertinent sections of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). (For more detail see 76 FR 65913–65914).

Part 405 subparts G and H contain policies that applied to initial determinations, appeals, and reopenings of Medicare Part A and Part B claims, as well as determinations and appeals regarding an individual's entitlement to benefits under Medicare Part A and Part B, prior to the implementation of the part 405 subpart I provisions (collectively referred to as ''pre-BIPA'' actions). Although we phased in the implementation of the part 405 subpart I regulations, these regulations were effective for all claims processed on or after January 1, 2006 (See 70 FR 11425, March 8, 2005). Once all pre-BIPA claims appeals were completed, the provisions in part 405 subparts G and H would be considered obsolete and replaced by the provisions in part 405 subpart I.

As explained in the proposed rule (76 FR 65914), we believe that all pre-BIPA claims appeals have been processed. Therefore, we proposed to remove the obsolete provisions in part 405 subparts G and H. However, since we cannot be completely certain that there are no pending pre-BIPA claims appeals, we also proposed that any newly identified pre-BIPA claims appeals would be handled under the current appeals provisions set forth in the part 405 subpart I regulations to ensure that parties would have due process for their disputes (See 76 FR 65914). We believe 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 provisions in part 405 subpart I for all claim appeal requests filed on or after the effective date of this final rule, reduces potential confusion about applicable appeal procedures, and enables parties to take advantage of the reduced decision-making timeframes and other process improvements offered throughout the part 405 subpart I regulations.

We proposed that parties who demonstrate that they requested an appeal of a pre-BIPA claim but did not receive a decision would be entitled to refile their appeal request, and would have their appeal processed under the part 405 subpart I regulations in the manner set forth below. Any pre-BIPA claims appeals identified on or after the effective date of this final rule (''newly identified pre-BIPA appeals'') that are still pending at the first level of appeal (a reconsideration for Part A claims (42 CFR 405.710) and review of the initial determination for Part B claims (42 CFR 405.807)) would be processed beginning at the redetermination level under the part 405 subpart I regulations (see 42 CFR 405.940–405.958). Any newly identified pre-BIPA appeals that are still pending at the second level of appeal (ALJ hearing for Part A claims (42 CFR 405.720) and carrier hearing for Part B claims (42 CFR 405.821)) would be processed beginning at the QIC reconsideration level under the part 405 subpart I regulations (see 42 CFR 405.960–405.978). In addition, any newly identified pre-BIPA appeals of Part B claims that are pending at the ALJ hearing level (42 CFR 405.855) would be processed as QIC reconsiderations under the part 405 subpart I regulations. Any newly identified pre-BIPA appeals that are still pending at the final level of administrative appeal, Departmental Appeals Board review (42 CFR 405.724 for Part A claims and 42 CFR 405.856 for Part B claims) would be processed at the Medicare Appeals Council review level under the part 405 subpart I regulations (see 42 CFR 405.1100–405.1134). See 76 FR 65914–65915 for additional information.

We also explained that several sections in part 405 subparts G and H were either unrelated to claims or entitlement appeals and were still in effect, or were inadvertently not included in part 405 subpart I. See 76 FR 65915. We proposed to retain § 405.874, ''Appeals of CMS or a CMS contractor'' and redesignate it as §§ 405.800–405.818 in part 405 subpart H, and to retain § 405.706, ''Decisions of utilization review committees'' and redesignate it as § 405.925 in part 405 subpart I. Finally, we proposed to remove § 405.753 and § 405.877 (''Appeal of a categorization of a device.'') because these sections are obsolete and no longer comport with the definition of ''national coverage determination'' in section 1869(f) of the Act, as amended by section 522 of BIPA. See 76 FR 65915.

We received one public comment regarding several of the appeals proposals described above. A summary of the commenter's concerns regarding these proposals and our responses are included below.

Comment: The commenter stated that the proposed changes do not afford appeal rights to all initial determinations, and expressed concern that the complexity and length of the appeals process requires legal counsel to navigate, is expensive, and does not provide physicians a meaningful opportunity to challenge claim determinations.

Response: In this rule, we are not changing existing policy with respect to appeal rights under part 405 subpart I. Rather, we are removing obsolete provisions in part 405 subparts G and H, and redesignating existing policy that is not obsolete. We are also finalizing our proposal that any newly identified pre-BIPA appeals that are still pending in

the administrative process will be handled under the current appeals regulations in 42 CFR part 405 subpart I. As discussed previously, these regulations were effective for all claims processed on or after January 1, 2006 (See 70 FR 11425, March 8, 2005).

The appeals process for claim determinations set forth in the 42 CFR part 405 subpart I regulations implements the statutory requirements found in section 1869 of the Act. In this rule, we are not changing what we consider to be initial determinations under part 405 subpart I (42 CFR 405.924). When contractors make initial determinations, as defined in 42 CFR 405.924, those determinations may be appealed by the parties to the determination. However, some actions taken by CMS or its contractors are not initial determinations and, therefore, do not trigger appeal rights. See 42 CFR 405.926. For example, there is no initial determination and, therefore, no right to appeal when there is no valid claim or request for payment for which a determination is made (such as when claims are returned to providers as incomplete or invalid, in which case they must be resubmitted rather than appealed), or when administrative review is precluded by statute (such as for coinsurance amounts prescribed by regulation for outpatient services under the prospective payment system, see § 1833(t)(12)(B) of the Act).

We respectfully disagree with the commenter's characterization of the administrative appeals process as overly complex, expensive and lengthy, and the commenter's assertion that it does not provide physicians a meaningful opportunity to challenge claim determinations and requires legal counsel to navigate. As we explain above, the appeals process for claim determinations set forth in the 42 CFR part 405 subpart I regulations implements the statutory requirements found in section 1869 of the Act. Although there are four levels of administrative claims appeals, an overwhelming majority of disputes are resolved at the first level of appeal through informal proceedings with the claims processing contractor. In addition, we offer parties the opportunity to correct minor claims errors through the reopening process set forth in 42 CFR 405.980, *et seq.* For disputes that are not resolved at the first level of appeal, parties have an opportunity for review by a Qualified Independent Contractor, a hearing before an Administrative Law Judge, and review by the Medicare Appeals Council prior to commencing litigation in federal district court. Furthermore, adjudicators have relatively short timeframes for issuing decisions (60 days at the first and second levels and 90 days at the third and fourth levels). In most cases, these administrative proceedings are non-adversarial, and less formal than proceedings in federal or state court. We believe the administrative process crafted by the Congress under section 1869 of the Act adequately balances the need to develop a full and complete administrative record should a case result in a civil action in federal district court, with the ability for parties to obtain quick, informal and independent review of claim determinations.

Comment: The commenter also expressed concern that adequate time may not have elapsed for the resolution of all pre-BIPA claims, and that channeling pre-BIPA appeals through the procedures in 42 CFR part 405 subpart I does not streamline the process for such appeals. The commenter also urged CMS to develop materials that are widely available to explain the claims appeals process.

Response: It has been over six years since we began to transition from the claims appeals process in 42 CFR part 405 subparts G and H to the current process in 42 CFR part 405 subpart I. As explained in the preamble to the proposed rule, it is our expectation that in the 6 years since implementation began for the part 405 subpart I appeals process, any party with a pending pre-BIPA claims appeal would have received a decision or would have brought the pending matter to our attention (see 76 FR 65914). We proposed, and are finalizing in this rule, that parties who demonstrate that they requested an appeal of a pre-BIPA claim but did not receive a decision would be entitled to refile their appeal request, and would have their appeal processed under the part 405 subpart I regulations (see 76 FR 65914–65915). We believe that channeling appeals of pre-BIPA claims through the current process in part 405 subpart I will eliminate confusion and uncertainty by having parties and adjudicators follow a single set of rules that have been in place for over six years. In addition, as explained in the proposed rule (76 FR 65914), using the current appeals process under part 405 subpart I for all claims appeal requests filed on or after the effective date of this final rule, will enable parties to take advantage of reduced decision-making timeframes and other process improvements offered throughout part 405 subpart I. For example, pre-BIPA claims appeals did not have timeframes within which decisions must be issued. Applying the decision making timeframes for current claims appeals to pre-BIPA claims appeals will likely result in quicker turnaround times for pre-BIPA claims appeals, and a more streamlined process in comparison to the pre-BIPA appeals process. Thus, we believe our proposal to channel all claims appeals through the current process in part 405 subpart I will be more efficient and effective than maintaining separate appeals processes.

Materials that explain the steps in the first and second levels of the claims appeals process are currently available at: *http://www.cms.gov/OrgMedFFSAppeals/* and also at: *http://www.medicare.gov/navigation/medicare-basics/understanding-claims/medicare-appeals-and-grievances.aspx.* Information about hearings before an ALJ is available at: *http://www.hhs.gov/omha,* and information about the proceedings before the Medicare Appeals Council is available at: *http://www.hhs.gov/dab.* In addition, shortly after this rule becomes effective, we will update the CMS online manuals and CMS' Web site to provide instructions on how requests for newly identified pre-BIPA claims appeals should be made, and how such appeals will be processed.

Comment: The commenter raised additional concerns about existing policies regarding effective dates of revocation actions and enrollment determinations and existing policies regarding submission of claims during the appeal of an enrollment determination (see, 42 CFR 405.800–818).

Response: The commenter's concerns regarding existing policies for enrollment appeals are outside the scope of this rule. In this rule, we are not changing existing policy with respect to enrollment appeals or the submission of claims while appeals of enrollment determinations are pending. Rather, we are removing obsolete provisions in part 405 subparts G and H, and redesignating existing policy that is not obsolete. The technical corrections proposed with respect to enrollment appeals are purely editorial in nature. We are maintaining existing policies in 42 CFR 405.874 that were previously subject to formal notice and comment rulemaking (see 73 FR 36460, June 27, 2008) and redesignating them as 42 CFR 405.800–818. However, we will consider the concerns raised by the commenter. Should we determine that changes to current enrollment appeals policy are necessary, we will conduct separate rulemaking.

Comment: Finally, the commenter disagreed with our policy that decisions of utilization review committees are not

''initial determinations'' and may not be appealed under the part 405 subpart I regulations. The commenter stated that such decisions have an impact on substantive rights.

Response: Decisions of utilization review committees (URC) are decisions made by health care professionals at hospitals. They are not initial determinations made by the Secretary within the meaning given in section 1869 of the Act. It has been our longstanding policy that URC decisions are not initial determinations, and thus, are not appealable; however, the decision of a URC may be considered by CMS along with other pertinent medical evidence in determining whether or not an individual has the right to have payment made under Medicare Part A (42 CFR 405.706). In this rule, we are not changing existing policy with respect to URC decisions. We are simply redesignating the existing provisions in § 405.706 as § 405.925.

Accordingly, we are finalizing our proposed policies without modification.

Contact: David Danek (617) 565–2682.

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. The revised CfC final rule published in the **Federal Register** November 2008 (73 FR 68502) 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 section of the CFR duplicative. The Infection Control CfC located at 42 CFR 416.51 expands and broadens the infection control requirements that were part of the original ASC requirements in the Environment CfC section. Therefore, we proposed to remove the requirement at § 416.44(a)(3), located in the Environment CfC section, as it is unnecessary and obsolete. We believe this change will alleviate any duplicative efforts and confusion regarding the infection control requirements.

We received two public comments on our proposed changes to the ASC Environment CfC section.

Comment: One commenter supported our proposal to remove the unnecessary and redundant requirement regarding infection control. In addition, the commenter supported the elevation of the infection control requirements from a standard level under the Environment CfC section to a separate condition level requirement.

Response: We thank the commenter for the comment and appreciate the commenter's support for the proposed changes.

Comment: We received one comment that opposed the removal of a particular section of the requirement that states ASCs must report the results of any identified infections to the appropriate authorities. In addition, the commenter stated it was ill-advised to remove the reporting requirement and that the Centers for Disease Control recently published studies analyzing infection rates in ASCs.

Response: The Federal regulations for ASCs do not have specific infection control reporting requirements. The language we have proposed to delete states that ''ASCs must report the results to the appropriate authorities''. We have not changed the normal procedures that ASCs must follow in order to meet their State reporting requirements. Currently, there is sufficient authority in the infection control CfC at 42 CFR 416.51(b)(3) that will continue to support CMS requirements for such reporting. In addition, CMS has similar hospital infection control regulations and the guidance includes complying with reportable disease requirements of the local health authorities.

The above summarizes this provision made in our proposed rule and the comments we received. We are finalizing the policy above as proposed.

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), titled ''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 and equivalent NCPDP Batch Standard Batch Implementation Guide version 1.,1 (NCPDP Telecom 5.1) which provides for communication 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. Additional discussion on the updating of the Medicare Part D e-Prescribing standards can be found in the October 24, 2011 proposed rule (76 FR 65909).

For consistency with the current HIPAA transaction standards, and the need for covered entities (prescribers

and dispensers) to comply with HIPAA, we proposed to revise § 423.160(b)(3), to—(1) Update Version 4010/4010A with the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279, (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. As noted above, this change will promote consistency and ensure that covered entities are compliant with the most current transaction standards.

We received three public comments on our proposed changes to the Medicare Part D e-prescribing foundation standards (§ 423.160). One commenter was from a standards development organization (SDO) and two were from professional medical organizations.

Comment: All commenters agreed with our proposal to adopt the above-referenced standards and guide for transmitting eligibility inquiries and responses between dispensers and Part D sponsors.

Response: For consistency with the current HIPAA transaction standards, and the need for covered entities (prescribers and dispensers) to comply with HIPAA, we agree with the commenters and we are finalizing what we proposed for § 423.160.

Comment: One commenter supports finalizing what was proposed, but noted disappointment that CMS has not yet finalized a comprehensive set of standards that would fully support the Medicare Part D e-prescribing program. They commented that, although CMS has finalized the formulary and benefits, medication history, and fill status notification e-prescribing standards, it has not addressed the National Committee on Vital and Health Statistics' (NCVHS) recommendations about the adoption of standards for a clinical drug terminology, electronic prior authorization (ePA), and Structured and Codified Sig Format (SIG) (instructions on the prescription label). They suggested that CMS should propose and finalize such standards.

Response: We appreciate the commenter's support of our proposed changes, and appreciate their interest in the adoption of a comprehensive set of e-prescribing standards. While several of the necessary standards are still under development, we are not currently in a position to propose additional standards that, if finalized, would more fully support the Medicare Part D e-prescribing Program. Some of the standards that the commenter mentioned as having support from NCVHS, such as ePA and SIG are still in the development stage and have not yet been pilot tested by industry. Thus, it would be premature for us to propose the adoption of standards that have not been fully developed and tested.

Since all commenters agreed with our proposal 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) and to adopt the NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 as a replacement to NCPDP Telecommunication Standard Version 5.1, we are finalizing the proposals in this final rule. We note that we updated the regulatory text at § 423.160(c) to adopt the updated standards and retire the old standards as discussed above. Compliance with these new adopted standards will be 60 days after the publication of this final rule.

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). Current regulations detail provider qualification for a ''qualified occupational therapist'' under Medicaid at 42 U.S.C. 440.110(b)(2). These current regulations contain outdated terminology referencing several professional organizations. Additionally, 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 we revised multiple regulations to cross-reference the personnel qualifications for therapists in § 484.4 to the personnel requirements in many other sections.

We proposed 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.

We received 12 public comments on this proposed change.

Comment: We received several comments in support of the proposed revisions.

Response: We appreciate the expressions of support.

Comment: We received several comments requesting that we also allow individuals who meet State licensure requirements to be recognized in the Medicaid program as a qualified physical or occupational therapist.

Response: State licensure is already taken into account in existing Medicare requirements found at 42 CFR 484.4. Aligning Medicaid provider qualifications with Medicare will continue this practice. Adopting these qualifications for the Medicaid program will ensure consistency among programs and enhance the scope of individuals qualified to deliver Medicaid services. If practices at the State level are prohibiting individuals from meeting Medicaid qualifications, we suggest addressing those concerns with the State Medicaid Agency.

Comment: We received one comment requesting retroactive applicability of these revised provider qualifications.

Response: The effective date of these changes must be prospective, rather than retrospective, as it would be impractical to do otherwise.

Comment: One commenter urged HHS to review the ''therapy incident-to'' rule contained in the 2005 physician fee schedule regulation, which disallowed Medicare Part B payments for outpatient rehabilitative therapy services provided as incident to services furnished by other practitioners.

Response: We appreciate this comment, but it is outside the scope of this regulation.

Comment: We received two comments in opposition to the proposed revisions, as they would exclude other health care professionals from providing PT and OT services, even when they are under the direct supervision of a physician.

Response: We disagree with these commenters. Aligning Medicare and Medicaid provider qualifications will increase the number of individuals eligible to furnish PT and OT services under the Medicaid program. We also point out that current regulations for PT and OT at § 440.110 require therapy providers to either meet the specified qualifications themselves, or furnish services under the direction of a qualified therapist. Individuals not meeting these qualifications could potentially still be qualified providers of Medicaid services, however, these services could not be billed to CMS as PT or OT services.

Comment: We received one comment suggesting that HHS modify policies set forth in the final provider enrollment rule.

Response: We appreciate this comment, but it is outside the scope of this regulation.

Comment: We received one comment suggesting that we also incorporate by reference into 42 CFR 440.110 the Medicare definition of Occupational Therapy Assistant found at 42 CFR 484.4.

Response: We do not believe that such action is necessary at this time. As the commenter noted, Medicaid regulations are silent as to the qualifications of a PT or OT assistant. This is partly due to the fact that individuals other than a PT or OT assistant could furnish PT or OT services under the direction of a qualified therapist. However, we do agree that States utilizing PT or OT assistants would be well served to follow the Medicare definition found at 42 CFR 484.4, to ensure consistency across programs.

The above summarizes this provision made in our proposed rule and the comments we received. We are finalizing the policy above as proposed.

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 titled, ''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 proposed 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.'' The definition as finalized in this rule modifies the previous 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 that the definition as finalized 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.

We received three public comments on our proposed changes to the donor document definition located in § 486.302. The commenters represented a major patient advocacy organization, a major industry organization, and a state health and human services commission. All three commenters suggested changes to the proposed definition of donor document.

Comment: Two of the commenters were opposed to the new definition for donor document because the proposed definition does not appear to be consistent with the Uniform Anatomical Gift Act (UAGA). The commenters suggested that under the UAGA, there are other individuals who can make a legally binding gift on behalf of the donor before his or her death. In addition, they felt the new definition did not fully address alternatives, such as a situation where people may choose to be an organ donor but not a tissue donor, or may only want to consent to the donation of specific organs. The commenters noted that the UAGA does allow for such alternatives.

Response: We agree that the proposed definition does not acknowledge that the UAGA allows other individuals to make a legally binding anatomical gift during the donor's lifetime. Section 4 of the 2006 revision of the UAGA allows for ''an agent of the donor, unless the power of attorney for health care or other record prohibits the agent from making an anatomical gift; a parent of the donor, if the donor is an unemancipated minor; or the donor's guardian'' to make an anatomical gift for the donor while he or she is still alive. We believe this is an unusual circumstance; however, we want to avoid any confusion. If another individual is authorized to make an anatomical gift and documents his or her decision to do so in accordance with any applicable state law, we believe that constitutes a valid donor document under the OPO CfCs. Therefore, we have modified the definition of donor document to include that circumstance.

We agree that the proposed definition does not fully address alternatives. One commenter noted the use of the word ''executed'' implied that donor documents must be in writing and noted

that under Texas law (citing Tex. Health & Safety Code Ann. § 692A.005(West), a valid donation can be made if a terminally ill or injured donor communicates in any way his or her desire to donate to at least two adult witnesses. One of these individuals must be a disinterested witness. We believe that a non-written communication can be a valid expression of the donor's wishes, as long as it is made in accordance with any applicable state law. However, there must be some documentation of that non-written communication. For example, if a terminally ill or injured patient communicates to his or her next of kin and a nurse that he or she wants to donate his or her organs in a non-written communication and that satisfies any applicable state law, we would agree that was a valid consent to donate from the patient. The next-of-kin or the nurse should then document the patient's consent consistent with requirements under state law, if applicable, and hospital policy. That documentation of the patient's consent to donate would then become the donor document. Therefore, we have modified the definition of ''donor document''. We have removed the word ''executed'' and inserted the word ''made.''

We disagree that the definition does not allow for individuals to indicate consent to donation of specific organs. The proposed definition allows for individuals to indicate ''his or her wishes regarding organ and/or tissue donation.'' We believe this allows individuals to express their wishes concerning organ and/or tissue donation, including their wishes regarding any specific organs.

Comment: One commenter asked for clarification whether, under the amendment to the definition of ''donor document'', an organ procurement organization may continue to recognize a donation made by a communication between the patient and at least two witnesses.

Response: Yes, if the communication between the patient or potential donor and the two witnesses is in accordance with any applicable state law.

The above summarizes our proposal in this rule and the comments we received. After consideration of the public comments, we are finalizing the definition of ''donor document'' as follows: ''Donor document means any documented indication of an individual's choice regarding his or her wishes concerning organ and/or tissue donation that was made by that individual or another authorized individual in accordance with any applicable State law.''

Contact: Diane Corning, 410–786–8486.

7. Administration and Governing Body (§ 486.324)

On May 31, 2006, we published a final rule in the **Federal Register** (71 FR 30982) titled, ''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).

In the proposed rule (76 FR 65917), we proposed to remove the duplicate paragraph (e), which appears immediately after § 486.324(d). We stated that this deletion will not alter or change the legal requirement, nor will it create a change in information collection requirements or other regulatory burden.

We received no comments on this proposed change and are therefore finalizing it as proposed.

Contact: Diane Corning, 410–786–8486.

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).

We received no comments on this proposed change and are therefore finalizing it as proposed.

Contact: Morgan Burns, 202–690–5145.

C. Responds to Stakeholder Concerns

The following provisions responded to some of the concerns and feedback that we have received from the public. We have identified nomenclature and definition changes that will 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 proposed to add a definition of ''beneficiary'' in § 400.200 that applies to patients under the Medicare and Medicaid programs. We will remove the terms ''beneficiary'' and ''recipient'' from § 400.202 and § 400.203, respectively, and we will 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 sought comments on whether this definition could be improved to attain that objective.

We received no comments on this proposed change and are therefore finalizing it as proposed.

Contact: Ronisha Davis, 410–786–6882.

2. Replace All the Terms: ''the Mentally Retarded; ''Mentally Retarded Persons;'' and ''Mentally Retarded Individuals'' With ''Individuals With Intellectual Disabilities'' and Replace ''Mentally Retarded or Developmentally Disabled'' With ''Individuals With Intellectual Disabilities or Developmental Disabilities''

We proposed 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 proposed to adopt the term ''intellectual disability'' (as used under Rosa's Law) in our regulations at § 400.203. We proposed to define the term ''individuals with intellectual disabilities'' to mean the condition 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 will require revision of forms CMS–3070G and CMS–3070H, as discussed below.

We received four public comments on our proposed nomenclature change, changing ''mental retardation'' to ''intellectual disability.''

Comment: One commenter expressed appreciation for the effort to change the term. He recommends that person-first terminology ''individuals with intellectual disabilities'' be substituted for ''intellectually disabled.''

Response: We appreciate and agree with the comment that the term ''individuals with intellectual disabilities'' is preferable to ''intellectually disabled'' and CMS will use ''person first'' language in our agency policies and our internal and external communications. The nomenclature changes included in the NPRM were, by design, intended to make the current nomenclature in the regulation consistent with the language of Rosa's Law (Pub. L. 111–256). After due consideration of the commenter's suggestion, we believe that reasonable consistency with Rosa's law can be maintained with the adoption, in this final rule, of ''person first'' language, and have made the change accordingly. In the rule itself, we therefore use the term Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) in place of Intermediate Care Facilities for the Mentally Retarded (ICF/MR).

Comment: Two commenters ask for clarification of the definition of Intellectual Disability. The commenters suggest that CMS is unclear when it defines Intellectual Disability to be equivalent to the term Mental Retardation. They point out that the definition of Mental Retardation at 42 CFR 483.102(b)(3) is from 1983 and is no longer in use. Furthermore, the definition in the Social Security Act still references Mental Retardation and the rule has no effect on that definition. In addition, one commenter notes that in medical usage the terms mental retardation and intellectual disability are not equivalent.

Response: The rule's intent is to extend the intent of Rosa's Law, 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'' to include those regulations that implement the Social Security Act. While the term ''mental retardation'' has various definitions in a variety of contexts, and those definitions may have varied over time, within 42 CFR chapter IV the term has uses in determining benefit eligibility and describing provider types. The change simply makes the terms mental retardation and mentally retarded equivalent to intellectual disability and individuals with intellectual disabilities, respectively, for the purposes of the regulations.

Comment: One commenter notes that the term Mental Retardation also appears in Chapter V at 42 CFR 1001.1301.

Response: We thank the commenter for finding this omission and will review the Chapter V reference for future action.

Comment: One commenter correctly notes that the rule has no effect on the language in section 1919(e)(7)(G)(ii) of the Act.

Response: Making this change to the Act will require legislation. We believe that the Congress will consider doing so in the future. Meanwhile, cross-references can be changed as necessary.

Comment: One commenter correctly notes the incorrect use of ''title'' for ''chapter'' in the discussion.

Response: This error has been corrected.

Comment: One commenter notes that the change might have unintended consequences if applied to historical references.

Response: We will review the suggested sections and make changes if necessary to avoid confusion regarding the meaning of the term as used in the regulations.

The above summarizes this provision made in our proposed rule and the comments we received. We are finalizing the policy above as proposed, while adopting a commenter's suggestion of using person-first terminology.

Contact: Peggye Wilkerson, 410–786–4857.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule without changes. Those provisions of this final rule that differ from the proposed rule are as follows:

- In section II.A.4.a, and for reasons stated in that section, we have decided not to finalize our proposed revisions to § 424.540(a)(1).
- In section II. B. 6, we have revised our proposed definition of ''donor document'' to be defined as ''any documented indication of an individual's choice regarding his or her wishes concerning organ and/or tissue donation that was made by that individual or another authorized individual in accordance with any applicable State law.''
- In the regulatory text, we have revised the proposed language to clarify that the requirement for sprinklers in facilities housed in high rise buildings was intended to be applicable to those buildings constructed after January 1, 2008.
- Also in the regulatory text, we are changing what we proposed to clarify that the term ''Individuals with Intellectual Disabilities'' will replace all of the following terms: ''the mentally retarded''; ''mentally retarded persons''; and ''mentally retarded individuals''. Also we clarify that ''individuals with intellectual disabilities or developmental disabilities'' will replace ''mentally retarded or developmentally disabled.''

We are implementing all other provisions as proposed.

V. Collection of Information Requirements

In the proposed rule, pursuant to the Paperwork Reduction Act, we solicited public comments for 60 days on each of the following issues regarding information collection requirements (ICRs). No comments were received. For the purpose of this final rule, we are soliciting public comment for 30 days for the following sections of this rule regarding ICRs:

A. Removes Unnecessarily Burdensome Requirements

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

This rule limits the number of ESRD facilities that must meet the LSC

requirements found in chapters 20 and 21 of NFPA 101. This action will reduce burden on ESRD facilities in terms of costly structural modifications and will not impact any information collections under the Paperwork Reduction Act.

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

Section 416.44(c) requires that ASCs coordinate, develop, and revise ASC policies and procedures to 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 are subject to these requirements. We estimate that § 416.44(c) imposes 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 is estimated to be 10,400 (5,200 ASCs x 2 hours) hours. The cost associated with this requirement is estimated to be $90 per ASC ($45.00—based on an hourly nurse's salary—x 2 hours) or $468,000 total (10,400 x $45), including fringe benefits, as specified by the Bureau of Labor Statistics for 2009).

Consistent with this provision, we are submitting a revision to CMS–10279 (OMB control number 0938–1071; expiration date October 31, 2012) to the Office of Management and Budget for review/approval.

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

This rule eliminates 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 will 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 (OMB control number 0938–0685) initial enrollment application—will not change and, therefore, will neither increase nor decrease the existing information collection burden related to this requirement.

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

This rule removes 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 will 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 will no longer face the uncertainty created by the issuance of the multiple temporary extensions due to the provider agreements. Extensions may be made for a maximum of 60 days. We estimate that an extension is made for most ICF/IID facilities (about 5900 of the current 6500 facilities). We further estimate that each extension requires approximately one hour of staff time to complete. Based on CMS' FY 2012 rate for State survey agency Medicaid staff of $77.23 per hour, we project an annual national savings of State Medicaid administrative expenditures totaling $455,700 ($77.23 x 5900 ICF/IID facilities), of which 75 percent consists of Federal funds and 25 percent of State funds. Consistent with this change, we are submitting a revision to OMB control number 0938–0062 (CMS–3070G).

B. Removes Obsolete or Duplicative Regulations or Provides Clarifying Information

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

This rule removes the chart that displays OMB control numbers since that information has become obsolete. This action does not produce any reduction or increase in burden, but will ensure that the public is viewing the most current information regarding OMB control numbers.

2. ICRs Regarding 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)

This rule, removes obsolete provisions from part 405 subparts G and H, and channels any remaining pre-BIPA claims appeals through the current appeals process under part 405 subpart I. In addition, we are redesignating certain sections of part 405 subparts G and H that are still in effect. We do not expect an increase or reduction in burden and believe that using the current appeals process under part 405 subpart I for all claims appeals will be beneficial for appellants and other parties.

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

This rule removes the requirement at § 416.44(a)(3) regarding infection control that substantially duplicates the requirements of § 416.51. The removal of this requirement will not result in any additional burden on ASCs, but will alleviate any duplicative efforts and confusion regarding the infection control requirements.

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

This rule updates the current e-prescribing standards to mirror the HIPAA standards that will become effective after publication of this final rule. There is no burden (addition or reduction) associated with this action.

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

This rule updates and aligns provider qualifications for PT and OT professionals. This action 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 change does not impact any information collections under the Paperwork Reduction Act.

6. ICRs Regarding Definitions (§ 486.302)

This rule modifies the definition of ''donor document'' to acknowledge that there are multiple ways for patients or potential donors to indicate their wishes regarding the donation of organs and tissues, while also emphasizing that the

patient's decision is voluntary. We do not expect that there will be any changes in the collection of information requirements for OPOs. We anticipate that the enhanced ability individuals initially will have to more specifically identify their wishes will reduce burden associated with vague and unclear designations.

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

This rule removes the duplicate paragraph (e). This action will not result in any change in information collection or other regulatory burden.

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

This rule corrects a typographical error found in § 424.510(a). This action will create no change in information collection or other regulatory burden.

C. Responds to Stakeholder Concerns

Nomenclature Changes

1. ICRs Regarding General Definitions (§ 400.200)

This rule adds a definition of ''beneficiary'' that applies to patients under the Medicare and Medicaid programs. This action will create no change in information collection or other regulatory burden.

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

This rule adds to a definition of ''individuals with intellectual disabilities'' 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 replaces all references in CMS regulations to, ''mental retardation'' with ''intellectual disability.'' Furthermore, we are replacing the term ''the mentally retarded,'' as defined in section 1919(e)(7)(G)(ii) of the Act, with ''individuals with intellectual disabilities.'' This action creates no change in information collection or other regulatory burden. The change will require the revision of forms CMS–3070G and CMS–3070H, which are approved under OMB control number 0938–0062 (expiration date April 30, 2013). CMS is submitting this revised ICR to OMB for their review/approval.

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–9070–F], Fax: (202) 395–5806; or Email: *OIRA_submission@omb.eop.gov.*

VI. 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 final rule will reduce costs to regulated entities and to patients by more than $100 million annually and by more than $200 million in the first year. Accordingly, over five years this rule will save about $600 million dollars. It will also create significant life saving 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 final rule responds directly to the President's instructions in Executive Order 13563 by reducing outmoded or unnecessarily burdensome rules, and thereby increasing the ability of health care entities to devote resources to providing high quality patient care.

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, but we are using $108.7 million as our point estimate. Second, we also estimate a one-time savings of $18.5 million to ASCs through reduced emergency equipment requirements. Both of these estimates are conservative and total savings could be significantly higher. The many types of recurring savings that these provisions will create include avoidance of business and payment losses for physicians and other providers 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 FOR 2012

Section	Frequency	Likely savings or benefits (millions)	Likely five year saving or benefits (rounded to nearest ten million)
A. Removes Unnecessarily Burdensome Requirements			
1. End-Stage Renal Disease (ESRD) Facilities (§ 494.60)	One-Time	$108.7	$110.
2. ASC Emergency Equipment (§ 416.44)	One-Time	$18.5	$20.
3. Revocation of Enrollment/Billing Privileges (§ 424.535)	Recurring	$100.0	$500.

TABLE 3—SECTION-BY-SECTION ECONOMIC IMPACT ESTIMATES FOR 2012—Continued

Section	Frequency	Likely savings or benefits (millions)	Likely five year saving or benefits (rounded to nearest ten million)
4. Duration of Agreement for ICFs/ID (§ 442.15–§ 442.109)	Recurring	<$1.	<$1.
B. Removes Obsolete or Duplicative Regulations			
1. OMB Control Numbers for Information Collection (§ 400.300 and § 400.310).	Recurring	<$1.	<$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.	<$1.
3. ASC Infection Control Program (§ 416.44)	Recurring	<$1.	<$1.
4. E-prescribing (§ 423.160)	Recurring	<$1.	<$1.
5. Physical and Occupational Therapist Qualifications (§ 440.110)	Recurring	<$1.	<$1.
6. Definition of Donor Document (§ 486.302)	Recurring	See Text	See Text.
7. Administration and Governing Body (§ 486.324)	Recurring	<$1.	<$1.
8. Requirement for Enrolling in the Medicare Program (§ 424.510)	Recurring	<$1.	<$1.
C. Responds to Stakeholder Concerns			
Nomenclature Changes:			
1. Redefining the Term ''Beneficiary'' (§ 400.200 through § 400.203).	Recurring	<$1	<$1.
2. Replace ''Mental Retardation'' terminology with ''Intellectual Disability'' (throughout 42 CFR chapter IV).	Recurring	See Text	See Text.

There are two areas of potentially significant benefits, beyond the cost savings to providers. First, the rule acknowledges that individuals can specifically express their wishes and not simply make the choice to donate or not donate. We believe this will encourage individuals to be clearer and more specific concerning their wishes or intentions regarding donation. We also believe that families will be more willing to accept the potential donor's decision if it is a clear and specific statement of his or her wishes concerning 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 clear and specific decision concerning donation, and on the willingness of families to honor that decision, can turn on personal preference. We believe that the change we are making could and likely will tip that decision in some cases. However, we do not have a basis for quantifying this potential increase in donations. We requested comment on the extent to which this policy change may increase organ donation, but received no comments on this issue.

In addition, while Rosa's Law began the elimination of official Federal government use of the pejorative term ''mental retardation,'' our final rule will complete this step for CMS regulations. The reform undoubtedly has substantial value to millions of Americans, not only to individuals with intellectual disabilities, 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 reforms together, we estimate that the overall cost savings that this rule will create will exceed $200 million in the first year. This includes the one-time savings related to ESRD and ASC reforms, as well as the savings to providers in reductions 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. Although total cost estimates range from about $47.5 to $217 million, 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 these investments, total savings will be $108.7 million (2,800 × ($77,659/2)). We received no specific comments on these savings estimates and have not reestimated them.

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 will 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 × $12,300 = total savings of about $18.5 million). We received no specific comments on these savings estimates and have not reestimated them.

With respect to our revision to § 424.535(c), the number of affected providers is certainly very small as a proportion of the total universe of over 1.4 million Medicare providers, of whom over 800,000 are physicians and over 300,000 are non-physician practitioners. Based on administrative data, we estimate that the number of providers and suppliers that will be affected by this reform is between 1,000

and 2,000, a fraction of one percent of these.

We have no concrete statistical data on the resultant economic effects. We have, however, re-estimated billing losses from the unnecessarily conservative figure of $10 million (or $10,000 per each of the aforementioned 1,000 providers/suppliers) used in the proposed rule. We instead believe that our revision to § 424.535(c) could result in total savings of roughly $100 million annually.

We note that gross annual physician practice revenue in America often exceeds $1 million a year (see, for example, *http://www.merritthawkins.com/pdf/2010_revenuesurvey.pdf).*

(We chose physician revenue as the basis for our estimate because the majority of Medicare providers/suppliers are physicians.) Though it varies widely by physician type and geographic locality, roughly one-third of physician practice revenue is Medicare-related. While, on paper, this could result in up to $333 million in projected savings (1,000 providers × $1 million × ⅓), we believe that a $100 million figure is more appropriate for two reasons. First, non-physician practitioners are likely to be affected by our revision. Their annual revenue, on average, is significantly less than that of physicians. Second, a fair proportion of potentially affected physicians will be those who infrequently bill Medicare, as they may have limited involvement with Medicare and, in turn, may be less familiar with revalidation and other Medicare enrollment requirements. These smaller billers, in our view, bring down the projected savings to closer to $100 million. Although we unfortunately do not, as explained above, have concrete data regarding the actual projected savings, we believe that $100 million is a reasonable estimate.

Of the remaining reforms, most have minor cost savings as shown in Table 1 through entries of $1 million or less.

We received several comments on our cost and burden estimates related to our proposed revisions to § 424.540(a)(1) and § 424.535(c), but none of these comments addressed the average billings estimates we decided to revise.

Comment: Several commenters requested that CMS explain its estimate that only 12,000 physicians and non-physician practitioners per year would have their Medicare billing privileges deactivated pursuant to § 424.540(a)(1). One commenter stated that CMS previously announced that it had deactivated 20,000 Part B billing numbers each month beginning in January 2007—which, the commenter states would have resulted in 240,000 Part B deactivations per year. The commenter requested that CMS recalculate the regulatory impact analysis using the 240,000-figure minus the 12,000-estimate used in the proposed rule.

Response: CMS indeed deactivated approximately 20,000 Provider Transaction Identification Numbers (PTANs) per month between 2007 and 2010. This does not mean, however, that 20,000 physicians and non-physician practitioners had their billing privileges deactivated, as the vast majority of these suppliers had multiple PTANs. We based our estimate on the number of physicians and non-physician practitioners who would be affected, not the number of PTANs. Nonetheless, the issue is largely moot, as we are not finalizing our proposed revision to § 424.540(a)(1).

Comment: Several commenters requested that CMS explain why it did not consider any alternatives to its proposed change to § 424.540(a)(1). They suggested that CMS contemplate alternatives, such as: (1) Having the Medicare contractor attempt to contact the provider by telephone or email prior to deactivating their Medicare billing privileges, or (2) utilizing a 2-year or 3-year deactivation period for non-billing physicians and non-physician practitioners, rather than eliminating deactivation altogether.

Response: CMS did, in fact, explore various ways to reduce the burden of the deactivation process on physicians and non-physicians. Although we are not finalizing our proposed revision to § 424.540(a)(1), we intend, as explained earlier, to examine other possibilities for burden reduction.

Comment: A commenter asked why CMS did not consider alternatives to its proposal to revise § 424.535(c) to eliminate the re-enrollment bar in situations where the provider or supplier has failed to respond to a revalidation or other informational request.

Response: As stated earlier, the goal of the October 24, 2011 proposed rule was to set forth approaches to alleviate unnecessary burdens on providers and suppliers. With respect to provider enrollment, the issue of the re-enrollment bar in cases where the provider or supplier failed to respond to a revalidation or other informational request was one of the two principal concerns expressed by the provider and supplier communities, the other being the deactivation of billing privileges for 12 consecutive months of non-billing. We therefore focused our primary efforts on these two approaches.

Comment: One commenter recommended that CMS provide the number of provider enrollment reactivations that were entered into PECOS in FY 2009, FY 2010 and FY 2011. The commenter also recommended that CMS estimate the annual costs in FY 2009, FY 2010 and FY 2011 associated with: (1) The systematic deactivation process, and (2) reactivation.

Response: As we are not finalizing our proposed revision to § 424.540(a)(1), we do not believe that the requested statistics would be material to our discussion.

Comment: To gauge the impact of the proposed change to § 424.540(a)(1), several commenters recommended that CMS provide information regarding: (a) The number of physicians, non-physician practitioners, and Part B organizations whose billing privileges were deactivated each year from 2006 through 2011, (b) the number of physicians, non-physician practitioners and Part B organizational entities whose billing privileges were reactivated in 2008, 2009, 2010 and 2011, and (c) the number of Medicare contractor-initiated deactivations that have occurred based on the provider or supplier's failure to respond to revalidation or other informational requests.

Response: Again, since we are not finalizing our proposed revision to § 424.540(a)(1), we do not believe that furnishing the requested statistics is necessary.

The above is a summary of all the comments that we received on our impact analysis section.

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 will yield substantial net benefits. In this analysis we have provided estimates to suggest the potential savings these reforms could achieve under certain assumptions. We appreciate that those assumptions are simplified, and that actual results could be substantially higher or lower. We plan to evaluate these reforms over time, and welcome independent external evaluations of their effects by professional societies, individual providers, provider associations, academics, and others.

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 will create will exceed $200 million in the first year, and will be approximately $100 million per year thereafter. 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 (percent)	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).	$100	2012	7	2012–16
	$100	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 final rule will reduce costs to tens of thousands of physicians, ASCs, ESRD facilities, and other small entities. Provisions in this final rule will 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 will 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 will be economically significant. The purpose of the RFA is to reduce burdens on regulated entities, and HHS interprets the RFA as requiring a Final Regulatory Flexibility Analysis (FRFA) only when a rule creates an adverse economic impact. Accordingly, we certify that this final rule will not have a significant economic impact on a substantial number of small entities. HHS nonetheless voluntarily prepares a FRFA for final 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 final rule are positive, and some are economically significant.

Substantial savings will 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 will benefit from more sensible emergency equipment policies. In addition, while we cannot estimate the number of positively affected entities for every provision we proposed, these reforms will 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 final 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 will have increased resources to devote to improving patient care, increasing accessibility to care and reducing associated health care costs. We invited and welcomed 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 604 of the RFA. For purposes of

section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. 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 final rule will 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 $139 million. This proposed rule mandates no new expenditures by either State, local, or tribal governments, or by 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, and under the authority of sections 1102(a), 1871(a)(1), and 1871(a)(4) of the Social Security Act, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

Chapter IV

Nomenclature Changes

■ 1–2. In 42 CFR chapter IV:

■ a. Remove ''Recipient'' and ''Recipients'' wherever they appear and add in their place ''Beneficiary'' and ''Beneficiaries,'' respectively; and

■ b. Remove ''Mental Retardation,'' ''the Mentally Retarded'' and the abbreviated form ''MR'' wherever they appear and add in their place ''Intellectual Disability,'' ''Individuals with Intellectual Disabilities'' and ''IID,'' respectively.

PART 400—INTRODUCTION; DEFINITIONS

■ 3. 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

■ 4. 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]

■ 5. Section 400.202 is amended by removing the definition of ''beneficiary.''

■ 6. 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]

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

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 8. 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).

§ 405.706 [Redesignated as § 405.925]

■ 9. Redesignate § 405.706 in subpart G as § 405.925 in subpart I.

Subpart G—[Removed and Reserved]

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

■ 11. Subpart H is revised to read as follows:

Subpart H—Appeals Under the Medicare Part B Program

Sec.

Subpart H—Appeals Under the Medicare Part B Program

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

§ 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

■ 12. 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

■ 13. Section 416.44 is amended by removing paragraph (a)(3) and revising paragraph (c) to 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

■ 14. 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

■ 15. In § 423.160, paragraphs (b)(3)(i) and (ii) and (c)(1)(iii) and (c)(2)(i) are revised 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.

* * * * *

(c) * * *

(1) * * *

(iii) National Council for Prescription Drug Programs Telecommunication Standard Specification, Version D, Release 0 (Version D.0), August 2007 and equivalent National Council for Prescription Drug Programs (NCPDP) Batch Standard Batch Implementation Guide, Version 1, Release 2 (Version 1.2), August 2007 supporting Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) for the NCPDP Data Record in the Detail Data Record.

* * * * *

(2) * * *

(i) Accredited Standards Committee (ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279.

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PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 16. 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

■ 17. 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.

* * * * *

■ 18. 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.

* * * * *

■ 19. Section 424.540 is amended by:

■ a. Revising paragraph (a) introductory text;

■ b. Revising paragraph (a)(2);

■ c. Adding paragraph (a)(3).

The revisions and addition 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:

* * * * *

(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

■ 20. 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

■ 21. 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 INDIVIDUALS WITH INTELLECTUAL DISABILITIES

■ 22. 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

■ 23. Section 442.15 is revised to read as follows:

§ 442.15 Duration of agreement for ICF/IIDs.

(a) The agreement for an ICF/IID 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]

■ 24. Section 442.16 is removed and reserved.

Subpart C—Certification of ICF/IIDs

■ 25. Section 442.109 is revised to read as follows:

§ 442.109 Certification period for ICF/IIDs: 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/IID 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.

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

§ 442.110 Certification period for ICF/IID 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.

* * * * *

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

■ 27. 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

■ 28. 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 regarding his or her wishes concerning organ and/or tissue donation that was made by that individual or another authorized individual in accordance with any applicable State law.''

* * * * *

§ 486.324 [Amended]

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

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

■ 30. 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. l302 and l395hh).

Subpart B—Patient Safety

■ 31. In § 494.60, paragraphs (e)(1) and (2) are revised to read as follows:

§ 494.60 Condition: Physical environment.

* * * * *

(e) * * *

(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 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, which were constructed after January 1, 2008.

* * * * *

(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: February 2, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 2, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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