

**Medicare and Medicaid Program;
Regulatory Provisions to Promote Program Efficiency,
Transparency, and Burden Reduction**

Summary of Final Rule

[CMS-9070-F]

Introduction

On May 10, 2012, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule addressing unnecessary, obsolete, or excessively burdensome Medicare or Medicaid regulations (the proposed rule was published on October 24, 2011). The regulatory changes will affect a broad array of providers, including physicians, other practitioners, end-stage renal disease (ESRD) facilities, and ambulatory surgical centers (ASCs). The changes are being made in response to Executive Order 13563, "Improving Regulations and Regulatory Review," issued by President Barack Obama in January 2011.

CMS estimates that the final rule will create overall cost savings to regulated entities and to patients that will exceed \$200 million in the first year.

The final rule is scheduled to be published in the May 16, 2012 issue of the *Federal Register*. Its effective date is July 16, 2012.

The final rule observes that the Department of Health and Human Services will continue to assess its existing significant regulations and welcomes public suggestions about appropriate reforms to streamline requirements and reduce existing burdens.

Provisions of the Final Rule

CMS had proposed a total of 15 policy changes grouped into three categories: (1) removes unnecessarily burdensome requirements (five issues); (2) removes obsolete regulations (eight issues); and (3) responds to stakeholder concerns (two issues). The final disposition of these issues, only one of which is not finalized, is summarized below. In addition, a CMS subject matter contact for each issue is identified below.

A. Removes Unnecessarily Burdensome Requirements

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

Rather than requiring all ESRD facilities to meet the National Fire Protection Agency's (NFPA's) 101 Life Safety Code (LSC), 2000 Edition, CMS proposed to restrict mandatory compliance 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. For this purpose, CMS proposed to use the NFPA definition of “high hazard occupancy.”* CMS finalizes these proposals without change.

In responding to comments on the proposed rule, CMS:

- Does not accept suggestions to also exempt ESRD facilities that do not have exits at grade level and those providing only home dialysis training and support services;
- Indicates that Americans with Disabilities Act (ADA)-compliant accessibility ramps in the exit area of an ESRD facility that provide ease of access between the patient treatment level and the outside street level (for example, where the ESRD facility is slightly above grade level and provides such ramps from patient treatment areas to grade level) would not be considered stairways or passageways, thus making the ESRD facility eligible for exemption from the LSC; and
- Clarifies that the term “adjacent” (in the context of high hazard occupancies) means sharing a common wall, floor, or ceiling.

CMS also adopts as final its proposal 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 and constructed after January 1, 2008 (in the proposed rule, the construction date aspect of the “high rise” provision had not been clearly stated).

In response to comments, CMS:

- Notes that the date of building construction is “the date the structural permit approvals and plan reviews were completed by the authority having jurisdiction”; and
- Rejects comments requesting a new effective date for compliance, with CMS observing 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 the date will still be used to determine whether a building housing an ESRD facility that must comply with the LSC requirement is considered “new” or “existing”.

CMS also received 3 public comments suggesting areas of ESRD policy for possible future reform. First, concerns were expressed regarding mandatory

* 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.

reporting of infection data for the Centers for Disease Control and Prevention (CDC) system, the National Healthcare Safety Network (NHSN), and CMS says it is currently working with the CDC to explore methods for facilitating the use of NHSN as a reliable national system for ESRD infection data. Second, a commenter expressed concern about the 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; CMS responds that it considers the paperwork requirements to be appropriate since the relevant payments are elective and not mandatory. Finally, one commenter urged revisions to the ESRD Conditions for Coverage to clarify expectations for educating ESRD patients on their options for dialysis modalities and settings, and CMS responds that it will take this suggestion into consideration for possible future reform.

Contact: Lauren Oviatt, 410-786-4683

2. ASC Emergency Equipment (§416.44)

CMS adopts without change its proposal to remove a list of emergency equipment at §416.44(c)(1) through (c)(9), including mechanical ventilator assistance equipment, tracheotomy set, and laryngoscopes and endotracheal tubes, and instead require ASCs, in conjunction with their governing body and the medical staff, to develop policies and procedures which specify the types of emergency equipment that would be appropriate for the facility's patient population, and make the items immediately available at the ASC to handle inter- or post-operative emergencies. The emergency equipment identified by the ASC must also meet the current acceptable standards of practice in the ASC industry. CMS notes that it 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.

In response to comments, CMS:

- Emphasizes 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;
- Rejects a comment recommending a revised standard list of emergency equipment, saying this would only create the same problems that the agency is trying to eliminate; and
- Rejects a comment requesting that all ASCs stock a minimum of 36 vials of dantrolene sodium for injection if they administer malignant hyperthermia-triggering anesthetics, saying that it would expect that ASCs that perform procedures using anesthetics that involve a risk of malignant hyperthermia would stock appropriate supplies, including medications, to handle such emergencies.

Contact: Jacqueline Morgan, 410-786-4282

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

Under current CMS policy, a provider, supplier, delegated official, or authorizing official whose billing privileges are revoked is barred from participating in the Medicare program for a period of 1 to 3 years. CMS adopts without change its proposal to eliminate this re-enrollment bar in instances when providers and suppliers have not responded timely to requests for revalidation of enrollment or to other requests for information initiated by CMS. Under such circumstances, CMS considers the automatic re-enrollment bar “overly punitive.”

In response to comments, CMS:

- Says the policy change will become effective upon the effective date of the final rule and will not be applied retroactively;
- Declines to furnish data regarding the number of revocations and associated re-enrollment bars that have been imposed, saying the agency does not consider such information necessary for its analysis; and
- Argues that the policy change will not impact the agency’s ability to prevent or combat fraudulent activity in the programs it administers.

Contact: Morgan Burns, 202-690-5145

4. Deactivation of Medicare Billing Privileges (§424.540)

Under current policy, Medicare billing privileges may be deactivated if Medicare claims are not submitted for 12 consecutive months. CMS had proposed to continue to apply this policy only to providers and suppliers who do not submit a Form CMS-855I (the enrollment form for individual physicians and non-physician practitioners). CMS believed that individual physicians and non-physician practitioners may have valid reasons for not submitting claims (e.g., if they generally treat only non-Medicare patients), and that deactivating their Medicare billing privileges and thereby requiring them to re-enroll in the Medicare program is unnecessarily burdensome. In the proposed rule, CMS had also noted that Medicare contractors are conducting verification activities to guard against identity theft, thus lessening the concern that unused billing numbers might end up being used by others to submit false claims.

CMS notes that a significant number of commenters either opposed or expressed concerns regarding this proposed policy change (fearing it would expose the Medicare program to fraud, waste and abuse). As a result, CMS elects not to finalize the proposal at this time, saying that it intends to study the issue further and possibly address the matter in future rulemaking “or another suitable vehicle.” CMS adds that it may 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.

In response to a comment, CMS notes that physicians and non-physician practitioners who complete the CMS-855O Medicare enrollment form do not receive Medicare billing privileges and are thus not subject to deactivation (such practitioners use this form solely to permit them to order or certify certain Medicare covered items and services, including: durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); imaging; laboratory services; and home health services).

CMS does finalize its proposal to add a new §424.540(a)(3) that will allow the agency 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. A deactivated provider or supplier would still have to submit a complete enrollment application to reactivate its billing privileges but would not be subject to other, ancillary consequences that a revocation entails.

CMS acknowledges receipt of several comments regarding additional ways to reduce the burden on providers and suppliers. CMS rejects a recommendation that providers and suppliers be given 120 days (rather than 90 days) to report a change of information, saying that 90 days “constitutes more than sufficient time.” Similarly, CMS rejects a recommendation that the timeframe for reporting a change in ownership or control be extended from 30 to 90 days, noting that 30 days is appropriate given “the relative importance of information regarding the provider’s ownership.” CMS also rejects a comment requesting that non-commercial DMEPOS suppliers (that is, physicians and non-physician practitioners who furnish DMEPOS items to their own patients) be considered “limited” rather than “high” risks for Medicare enrollment purposes, arguing that the continued problem of fraud and abuse in the DMEPOS arena warrants considering all new DMEPOS suppliers as “high” risk. Nonetheless, CMS adds that it will “continue to monitor this issue and may make adjustments to the risk categories when appropriate.” In response to a comment addressing Medicare enrollment issues relating to federally qualified health centers (FQHCs), CMS says it does not have the authority to exempt FQHCs from the provider enrollment application fee, nor is it persuaded that the “parent” of a multi-site FQHC should be allowed to enroll once for all sites, arguing that it is important that each site meet all CMS requirements. CMS does take “under advisement” the suggestion that each Medicare Administrative Contractor assign an FQHC subject matter expert and customer service representative who can help better facilitate the processing of FQHC enrollment applications. Lastly, CMS rejects a comment recommending elimination of the Provider Enrollment, Chain and Ownership System (PECOS) and adoption instead of the Council for Affordable Quality Healthcare Universal Provider Datasource.

Contact: Morgan Burns, 202-690-5145

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

CMS adopts as final its proposal to replace the current time-limited provider agreements under Medicaid for intermediate care facilities for the mentally retarded (renamed intermediate care facilities for individuals with intellectual disabilities (ICF/IIDs) by another provision of the final rule) with an open-ended agreement that would remain in effect until the Secretary or a State determines that the ICF/IID no longer meets the applicable conditions of participation. CMS also finalizes its proposal to specify that ICF/IIDs must be surveyed on average every 12 months with a maximum 15-month survey interval (rather than the current fixed 12-month requirement).

In response to comments on the proposed rule, CMS:

- Rejects a comment recommending that the survey time for ICF/IIDs be expanded to 24 months to provide States opportunities to focus resources on poor performing facilities, saying that it “has not found that extending the survey time beyond 12 months on average could be accomplished without negative impacts on the quality of care delivered in these facilities”;
- Rejects a comment recommending relaxation of the requirement that ICF/IID surveys be unannounced, stating that CMS “has not determined that overall program performance or the quality of care for residents would benefit by announcing survey visits”; and
- Notes that it plans to publish in the agency’s Mission and Priority Document (MPD) the methodology to be applied in computing the maximum and average survey intervals for ICF/IIDs, and adds that while there is no formal appeals 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’ calculation of the average survey interval (the regulation text states that 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”).

Contact: Thomas Hamilton, 410-786-9493

B. Removes Obsolete or Duplicative Regulations or Provides Clarifying Information

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

CMS finalizes without change its proposal to delete a current regulatory listing of Office of Management and Budget (OMB) control numbers for information collections, found at §400.310, because the list has not been updated since 1995

and an accurate inventory of currently approved CMS information collections, including OMB control numbers, can be accessed at <http://www.reginfo.gov/public/do/PRAMain>.

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)

Part 405 subparts G and H contain policies for initial determinations, appeals, and reopenings of Medicare Part A and Part B claims, before the effective date of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), referred to as “pre-BIPA appeals”). Part 405 subpart I contains provisions governing all aspects of all other Part A and Part B claims. Given the passage of time, CMS believes that maintaining a separate pre-BIPA claim appeals process in the unlikely event such an appeal is discovered is inefficient, impracticable, and even confusing. Further, even if such a claim were to be discovered, CMS believes that the reduced timeframes and other process improvements offered through subpart I would provide a more appropriate means for handling the matter. CMS adopts as final its proposal to channel all appeals through the current process in subpart I.

As originally proposed, CMS also retains §405.706 in subpart G, “Decisions of utilization review committees” but redesignates it as §405.925 in subpart I. This provision ensures that beneficiaries and providers understand that utilization review committee decisions are not appealable. CMS also retains (with minor technical edits) and redesignates provisions in subpart G relating to denials of provider or supplier enrollment applications, revocations of Medicare provider or supplier billing privileges, and the appeal rights afforded to the parties to those determinations. Finally, CMS removes “obsolete” provisions in §405.753 and §405.877 (“Appeal of a categorization of a device”).

CMS also calls attention to sources of information relating to the various levels of Medicare appeal:

- <http://www.cms.gov/OrgMedFFSAppeals> or <http://www.medicare.gov/navigation/medicare-basics/understanding-claims/medicare-appeals-and-grievances.aspx> for the first and second levels of claims appeals; and
- <http://www.hhs.gov/omha> for hearings before administrative law judges; and
- <http://www.hhs.gov/dab> for proceedings before the Medicare Appeals Council.

CMS also notes that shortly after the final rule becomes effective, it will update the CMS online manuals and website to provide instructions on how requests for

newly identified pre-BIPA claims appeals should be made, and how such appeals will be processed.

In response to public comments, CMS:

- Disagrees with a 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; and
- Reaffirms that decisions of utilization review committees are decisions made by health care professionals at hospitals, not initial determinations made by the Secretary, and thus are not appealable under Medicare appeals processes.

Contact: David Danek, 617-565-2682

3. ASC Infection Control Program (§416.44)

CMS finalizes its proposal to remove a “duplicative...unnecessary and obsolete” requirement relating to ASC infection control at §416.44(a)(3), located in the Environment condition for coverage, since the issue has been elevated from a standard level under the Environment condition to a separate Infection Control condition level requirement located at §416.51. In response to a comment opposing the change, CMS emphasizes that it has not changed the normal procedures that ASCs must follow in order to meet State infection reporting requirements and that there is sufficient authority in the infection control Condition for Coverage at 42 CFR 416.51(b)(3) that will continue to support CMS requirements for such reporting.

Contact: Jacqueline Morgan, 410-786-4282

4. E-prescribing (§423.160)

CMS finalizes its proposal to revise §423.160 relating to standards for electronic prescribing under the Voluntary Medicare Prescription Drug Benefit to make these standards consistent with previously adopted transaction standards under the Health Insurance Portability and Accountability Act (HIPAA). More specifically, CMS revises §423.160(b)(3) to: (1) update Version 4010/4010A of the electronic transaction standards with Version 5010; (2) adopt the National Council for Prescription Drug Programs (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.

CMS acknowledges receiving a comment expressing disappointment that the agency has not yet finalized more e-prescribing-related standards, including those for clinical drug terminology, electronic prior authorization (ePA), and Structured and Codified Sig Format (SIG) (instructions on the prescription label). In response, CMS says it is not currently in a position to propose additional standards because it would be “premature...to propose the adoption of standards that have not been fully developed and tested.”

Contact: Andrew Morgan, 410-786-2543

5. Physical and Occupational Therapist Qualifications (§440.110)

CMS finalizes its proposal to remove “outdated” personnel qualifications language for physical and occupational therapists (PTs and OTs) in §440.110 of the current Medicaid regulations and instead cross reference the previously updated Medicare personnel qualifications under §484.4.

CMS acknowledges receipt of a comment suggesting incorporation by reference into 42 CFR §440.110 of the Medicaid regulations the Medicare definition of Occupational Therapy Assistant found at 42 CFR §484.4. In response, CMS says it does not believe that such action is necessary at this time but does agree “that States utilizing PT or OT assistants would be well served to follow the Medicare definition...to ensure consistency across programs.”

Contact: Adrienne Delozier, 410-786-0278

6. Definition of Donor Document (§486.302)

CMS had proposed to update the regulatory definition of “donor document” (at §486.302) to read as follows: “[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.” CMS received three comments on this proposal, all of which suggested changes to the proposed definition in order to make it more consistent with the Uniform Anatomical Gift Act (UAGA) and avoid implying that a non-written communication cannot be a valid expression of a donor’s wishes. The final definition adopted by CMS reads 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.”

In response to comments, CMS argues that the definition being adopted will allow individuals to express their wishes concerning organ and/or tissue donation, including their wishes regarding any specific organ.

Contact: Diane Corning, 410-786-8486

7. Administration and Governing Body (§486.324)

CMS finalizes its proposal to remove a duplicate paragraph (§486.324(e)) in the conditions for coverage for organ procurement organizations.

Contact: Diane Corning, 410-786-8486

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

CMS finalizes its proposal to correct an incorrect reference in §424.510(a) due to a typographical error. This section addresses requirements that providers and suppliers must meet to enroll in the Medicare program.

Contact: Morgan Burns, 202-690-5145

C. Responds to Stakeholder Concerns

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

CMS finalizes its proposal to add a definition of “beneficiary” in §400.200 that applies to individuals under both the Medicare and Medicaid programs (that is, “Beneficiary means a person who is entitled to Medicare benefits and/or has been determined to be eligible for Medicaid.” This is consistent with CMS’ intent to discontinue use of the term “recipient” under Medicaid, in response to comments from the public.

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”

CMS had proposed to change the regulatory terminology used in the program currently called Intermediate Care Facilities for the Mentally Retarded (ICFs/MR), which would be referred to as Intermediate Care Facilities for the Intellectually Disabled (ICFs/ID). This was intended to be consistent with Rosa’s Law (P.L. 111-256), which made similar changes in terminology in several health and education statutes (but not the Social Security Act) in 2010 and directed that corresponding regulations also be updated. In response to a comment recommending use of “person first” language (that is, “individuals with intellectual disabilities” rather than “intellectually disabled”), CMS modifies its proposal to

adopt the term Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID).

Contact: Peggye Wilkerson, 410-786-4857

Information Collection Requirements

CMS is soliciting public comment for 30 days regarding the information collection requirements associated with provisions of the final rule.

As was the case for the proposed rule, CMS estimates that the change in ASC emergency equipment requirements will impose a one-time burden of two hours of registered nurse time per ASC (at an hourly labor cost of \$45) associated with revising the policies and procedures pertaining to the list of emergency equipment and supplies maintained and commonly used by the ASC during emergency responses to the ASC's specific patient population.

CMS also notes that the removal of time limited agreements for ICF/IIDs will reduce the need for State agencies to process requests for temporary extensions of provider agreements. CMS estimates that such extensions have been made for about 5,900 of the current 6,500 facilities, and that each extension requires one hour of State survey agency Medicaid staff time. Based on CMS' FY 2012 rate for such staff of \$77.23 per hour, this translates into an annual national savings of about \$455,700 ($\$77.23 \times 5,900$ facilities), of which 75 percent consists of Federal funds and 25 percent of State funds.

CMS believes that the other policies adopted in the final rule do not produce any reduction or increase in information collection burden or do not impact any information collections.

Comments on the information collection issues can be submitted 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.

Regulatory Impact Analysis

CMS considers the final rule to be economically significant since the agency estimates that it will reduce costs to regulated entities and to patients by more than \$100 million annually. CMS estimates that over 5 years, the final rule will save about \$600 million. Table 3 of the final rule, reproduced below, provides CMS' estimates of likely savings or benefits for each of the changes being adopted.

Table 3. Section-by-Section Economic Impact Estimates for 2012

Section	Frequency	Likely Savings or Benefits (millions)	Likely 5 Year Savings or Benefits (rounded to the nearest 10 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
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 below	See below
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 \$400.23)	Recurring	<\$1	<\$1
2. Replace "Mental Retardation" terminology with "Intellectual Disability" (throughout 42 CFR title IV)	Recurring	See below	See below

The estimate of savings relating to the change in ESRD life safety code requirements (\$108.7 million) assumes 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 (\$77,659 x 1,400 facilities).

Elimination of the automatic, Medicare re-enrollment bar in certain cases affects provider and supplier billing privileges under Medicare. CMS estimates that this change will help between 1,000 and 2,000 providers and suppliers avert Medicare billing losses of roughly \$100 million annually. This is substantially more than the \$10 million estimate in the proposed rule, which CMS now labels an “unnecessarily conservative figure.”

With respect to the definition of donor document, CMS invited comments on the extent to which this policy change may increase organ donation but did not receive any. With respect to the proposed replacement of the pejorative term “mental retardation,” CMS says this reform “undoubtedly has substantial value to millions of Americans” but acknowledges that it has no data “that would enable a precise calculation of this value.”

During the public comment period on the proposed rule, CMS received requests for data regarding Medicare provider enrollment deactivations and reactivations. However, since CMS is not finalizing its proposal to eliminate deactivations due to failure to submit claims for 12 consecutive months, it does not “believe that furnishing the requested statistics is necessary.”