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

Summary of Proposed Rule

[CMS-9070-P]

Introduction

On October 18, 2011 the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule addressing unnecessary, obsolete, or excessively burdensome Medicare or Medicaid regulations. The proposed regulatory changes would affect a broad array of providers, including physicians, other practitioners, end-stage renal disease (ESRD) facilities, and ambulatory surgical centers (ASCs); none of the changes would directly affect hospitals. 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 proposed rule would create overall cost savings to regulated entities and to patients that may approach $200 million in the first year.

The proposed rule is scheduled to be published in the October 24, 2011 issue of the *Federal Register*. Public comments are due by December 23, 2011. **CMS notes in several places that it welcomes comments on its proposed changes as well as additional suggestions from stakeholders.**

Provisions of the Proposed Rule

The proposed changes are 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). Note that the preamble says that "14 specific reforms" are included in the proposed rule but 15 issues are actually addressed and separately listed in an accompanying table giving section-by-section economic impact estimates. For each issue, a CMS subject matter contact is listed in the proposed rule and shown 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 proposes 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 proposes to use the NFPA definition of "high hazard occupancy."*

In proposing this change, CMS notes the following:

- While the risks of fire are very low in an outpatient dialysis facility, the costs of complying with the Federal LSC requirements in dialysis facilities are high and profoundly exceed the original government estimate of $1,960.
- In dialysis facilities, the evacuation process from fire is rapid disconnection from the dialysis machine and a quick exit.
- Complying with three requirements of NFPA 101 (smoke compartments, occupancy separation, and hazardous areas separation) would require an average cost of $77,659 per dialysis facility.
- As of June 2011, about 50 percent of existing dialysis facilities had not been renovated to comply with the February 2009 implementation date of NFPA 101.
- The resulting, total one-time savings to dialysis facilities that would no longer be subject to NFPA 101 would range from about $47.5 million to about $217 million.
- All ESRD facilities would continue to be required to comply with State and local fire codes and safety standards.

CMS also proposes 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. CMS notes 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 State law so permits.

CMS says it welcomes comments on other possible changes to the conditions for coverage or other regulations affecting dialysis facilities.

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* 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.

2. ASC Emergency Equipment (§416.44)

CMS proposes 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 current regulatory list of emergency equipment has not been revised since 1982 and CMS believes that its proposed policy better recognizes the diversity of ASCs. CMS also proposes that the emergency equipment identified by the ASC meet the current acceptable standards of practice in the ASC industry.

CMS estimates that this proposed change would impose a one-time burden of two hours of registered nurse time (at $45 per hour, including fringe benefits) to revise each ASC's policies and procedures relating to emergency equipment.

CMS acknowledges that its proposed policy could increase variation in emergency preparedness between different ASCs and invites comments on its proposal and on possible alternatives, such as having CMS categorize ASCs according to the major services they provide and then specify a minimum array of equipment tailored to the various categories of risk.

Contact: Jacqueline Morgan, 410-786-4282

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

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 proposes 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 current re-enrollment bar to involve "unnecessarily harsh consequences."

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. Under this policy, CMS estimates that about 12,000 physicians and non-physician practitioners have been deactivated each year. CMS proposes to continue to apply this policy only to providers and suppliers who do <u>not</u> submit a Form CMS-855I (the enrollment

form for individual physicians and non-physician practitioners). CMS believes 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. Further, CMS notes 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 estimates that the "per application" burden of completing a Medicare enrollment application is 5 hours, at a per hour cost of $50, meaning that the proposed change would result in a total savings to physicians and non-physician practitioners of about $2.7 million per year if one assumes that 90 percent of the 12,000 physicians and non-physician practitioners whose billing privileges would previously have been deactivated each year (that is, 10,800 physicians and non-physician practitioners) would have elected to submit a Medicare enrollment application in order to reactivate their billing privileges.

CMS also proposes to add a new §424.540(a)(3) that would 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.

Contact: Morgan Burns, 202-690-5145

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

CMS proposes to replace the current time-limited provider agreements under Medicaid for intermediate care facilities for the mentally retarded (renamed intermediate care facilities for the intellectually disabled (ICFs/ID) by another provision of the proposed rule) with an open ended agreement that would remain in effect until the Secretary or a State determines that the ICF/ID no longer meets the applicable conditions of participation. CMS also proposes to specify that ICFs/ID must be surveyed on average every 12 months with a maximum 15-month survey interval (rather than the current fixed 12-month requirement). Although CMS trumpets this new flexibility, note that survey intervals greater than 12 months would need to be offset by survey intervals of less than 12 months in order to meet the average 12-month requirement.

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 proposes to delete a current regulatory listing of Office of Management and Budget (OMB) control numbers for information collections, found at §400.310, since 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 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.

Despite the unlikelihood of discovering pre-BIPA appeals in the future, the proposed rule includes two tables, reproduced below, specifying how such appeals would be handled (that is, how a pre-BIPA appeal relating to a Medicare Part A or Part B claim at one level of review would be handled under subpart I) in order to ensure an orderly and proper handling of the matter.

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

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

CMS also proposes to retain §405.706 in subpart G, "Decisions of utilization review committees" but to redesignate 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 proposes to retain (with minor technical edits) and redesignate 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 proposes to remove "obsolete" provisions in §405.753 and §405.877 ("Appeal of a categorization of a device"). CMS notes that the agency's decision (acting on the Food and Drug Administration's categorization) to deny a claim for a category A device is an initial determination that is subject to review through the claims appeals process.

Contact: Flosetta Rowry, 410-786-8492

3. ASC Infection Control Program (§416.44)

CMS proposes 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.

Contact: Jacqueline Morgan, 410-786-4282

4. E-prescribing (§423.160)

CMS proposes 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 proposes to revise §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. The effective date would be January 1, 2012.

Contact: Andrew Morgan, 410-786-2543

5. Physical and Occupational Therapist Qualifications (§440.110)

CMS proposes 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 asserts that 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." CMS further notes that the current Medicaid requirements do not address individuals who have been trained outside of the United States.

Contact: Adrienne Delozier, 410-786-0278

6. Definition of Donor Document (§486.302)

CMS proposes 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 notes that this new definition would cover documents or other ways for individuals to express their wishes more specifically (e.g., on an organ by organ basis, for organs but not tissues, etc.). CMS goes on to add that in the absence of a valid donor document, the donation decisions would continue to rest with the individual who is legally responsible for making these decisions, usually the person's next of kin.

Contact: Jacqueline Morgan, 410-786-4282

7. Administration and Governing Body (§486.324)

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

Contact: Jacqueline Morgan, 410-786-4282

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

CMS proposes 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 proposes 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 would be 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 the Terms "Mental Retardation" and "Mentally Retarded" with "Intellectual Disability" and "Intellectually Disabled" throughout 42 CFR title IV

CMS proposes 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 would 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. CMS notes that current forms CMS-3070G (ICF/MR Survey Report) and CMS-3070H (ICF/MR Deficiencies Report), which would need to be revised to reflect the change in nomenclature, may be used by State survey agencies until current supplies are exhausted.

Contact: Peggye Wilkerson, 410-786-4857

Regulatory Impact Analysis

CMS considers the proposed rule to be economically significant. However, the agency also states that all of the economic effects of the proposed rule are positive. Table 3 of the proposed rule, reproduced below, provides CMS' estimates of likely savings or benefits for each of the proposed changes.

Table 3. Section-by-Section Economic Impact Estimates

Section	Frequency	Likely Savings or Benefits (millions)
A. Removes Unnecessarily Burdensome Requirements		
1. End-Stage Renal Disease (ESRD) Facilities (§494.60)	One-Time	$108.7
2. ASC Emergency Equipment (§416.44)	One-Time	$18.5
3. Revocation of Enrollment/Billing Privileges (§424.535)	Recurring	$10.0
4. Deactivation of Medicare Billing Privileges (§424.540)	Recurring	$26.7
5. Duration of Agreement for ICFs/ID (§442.15-§442.109)	Recurring	<$1
B. Removes Obsolete or Duplicative Regulations		
1. OMB Control Numbers for Information Collection (§400.300 and §400.310)	Recurring	<$1
2. Removal of Obsolete Provisions Related to Processing Part A and Part B Claims and Entitlement Determinations (§405.701 through §405.877)	Recurring	<$1
3. ASC Infection Control Program (§416.44)	Recurring	<$1
4. E-prescribing (§423.160)	Recurring	<$1
5. Physical and Occupational Therapist Qualifications (§440.110)	Recurring	<$1
6. Definition of Donor Document (§486.302)	Recurring	See below
7. Administration and Governing Body §486.324)	Recurring	<$1
8. Requirement for Enrolling in the Medicare Program (§424.510)	Recurring	<$1
C. Responds to Stakeholder Concerns		
Nomenclature Changes		
1. Redefining the Term “Beneficiary” (§400.200 through §400.23)	Recurring	<$1
2. Replace “Mental Retardation” terminology with “Intellectual Disability” (throughout 42 CFR title IV)	Recurring	See below

CMS notes that the proposed reforms affecting reenrollment and billing processes would allow physicians and other providers to avoid business and payment losses that are difficult to estimate but likely to be in the tens of millions of dollars annually.

With respect to the definition of donor document, **CMS welcomes comments on the extent to which this policy change may increase organ donation and any information that would assist in quantifying these impacts.** 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.”

Finally, with respect to the changes estimated to produce “minor costs savings,” **CMS welcomes comments on whether they may create larger savings that the agency has failed to identify.**