

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 434, 438, and 447

[CMS-2400-P]

RIN 0938-AQ34

**Medicaid Program; Payment Adjustment for
Provider-Preventable Conditions Including Health
Care-Acquired Conditions**

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement section 2702 of the Patient Protection and Affordable Care Act of 2010 which directs the Secretary of Health and Human Services to issue Medicaid regulations effective as of July 1, 2011 prohibiting Federal payments to States under section 1903 of the Social Security Act for any amounts expended for providing medical assistance for health care-acquired conditions. It would also authorize States to identify other provider-preventable conditions for which Medicaid payment would be prohibited.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[OFR insert date 30 days after the date of filing for public inspection at OFR]**.

ADDRESSES: In commenting, please refer to file code CMS-2400-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2400-P,
P.O. Box 8016,
Baltimore, MD 21244-1850.

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

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2400-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close

of the comment period to either of the following addresses:

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

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

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

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT:

Venesa Day, (410)786-8281, or Gary Jackson, (410)786-1218.

SUPPLEMENTARY INFORMATION:

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

<http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

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

Acronyms

To assist the reader, the following is list of the acronyms used in this proposed rule:

AHRQ Agency for Healthcare Research and Quality

BPM	Benefit Policy Manual
CABG	Coronary artery bypass graft
CBO	Congressional Budget Office
CDC	Centers for Disease Control and Prevention
DVT	Deep vein thrombosis
ESRD	End-stage renal disease
DRA	Deficit Reduction Act of 2005 (Pub. L. 109-171, enacted on February 8, 2006)
FFP	Federal financial participation
FY	Fiscal year
HAC	Hospital-acquired condition
HCAC	Health care-acquired condition
ICR	Information collection requirement
IPPS	Inpatient prospective payment system
MS-DRG	Diagnosis-related group
NCA	National coverage analysis
NDC	National coverage determination
NQF	National Quality Forum
OACT	[CMS] Office of the Actuary
OIG	Office of Inspector General
OMB	Office of Management and Budget
OPPC	Other provider-preventable condition
PE	Pulmonary embolism
POA	Present on admission
PPC	Provider-preventable condition
PRA	Paperwork Reduction Act

RFA Regulatory Flexibility Act (September 19, 1980,
Pub. L. 96-354)

RIA Regulatory impact analysis

SMDL State Medicaid Director Letter

SPA State plan amendment

UMRA Unfunded Mandates Reform Act of 1995
(Pub. L. 104-04, enacted on March 22, 1995)

UTI Urinary tract infection

I. Background

Title XIX of the Social Security Act (the Act) authorizes Federal grants to the States for Medicaid programs to provide medical assistance to persons with limited income and resources. While Medicaid programs are administered by the States, they are jointly financed by the Federal and State governments. Each State establishes its own eligibility standards, benefits packages, payment rates, and program administration for Medicaid in accordance with Federal statutory and regulatory requirements. Operating within broad Federal parameters, States select eligibility groups, types, and range of services, payment levels for services, and administrative and operating procedures. Each State Medicaid program must be described and administered in accordance with a Federally-approved "State plan." This comprehensive document describes the nature and scope of the State's Medicaid program, and provides assurances that it will be administered in conformity with all Federal requirements.

The Federal government pays its share of medical assistance expenditures to the State on a quarterly basis according to a formula described in sections 1903 and 1905(b) of the Act. Specifically, section 1903 of the Act requires that the Secretary (except as otherwise provided) pay to each State which has a plan approved under this title, for each quarter, an amount equal to the Federal medical assistance percentage of the total amount expended during such quarter as medical assistance under the State plan.

Among the statutory requirements for Medicaid State plans, section 1902(a)(4) of the Act requires that State plans provide for methods of administration as are found to be necessary by the Secretary for the proper and efficient operation of the plan. Section 1902(a)(6) of the Act requires that a State plan for medical assistance provide that the State agency will make such reports, in such form and containing such information, as the Secretary may from time-to-time require, and comply with such provisions as the Secretary may from time-to-time find necessary to assure the correctness and verification of such reports. In addition, section 1902(a)(19) of the Act requires that a State plan for medical assistance provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with

simplicity of administration and the best interests of the recipients.

A. The Medicare Program and Quality Improvements Made in the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171)

Title XVIII of the Act provides authority for the Secretary to operate the Medicare program, which provides payment for certain medical expenses for persons 65 years of age or older, certain disabled individuals, and persons with end-stage renal disease (ESRD). Medicare benefits include inpatient care, a wide range of medical services, and outpatient prescription drugs.

The Medicare statute authorizes the Secretary, in the course of operating the Medicare program, to develop, implement, and monitor quality measures, as well as take other actions, to ensure the quality of the care and services received by Medicare beneficiaries.

Payment under the Medicare program for inpatient hospital benefits is generally based on the "inpatient prospective payment system" (IPPS) described in section 1886(d) of the Act. Hospitals receive a payment for each inpatient discharge based on diagnosis codes that identify a "diagnosis-related group" (MS-DRG). Assignment of an MS-DRG can take into account the presence of secondary diagnoses, and payment levels are also adjusted to account for a number of hospital-specific factors.

Section 5001(a) of the Deficit Reduction Act of 2005 (Pub. L. 109-171, enacted on February 8, 2006) (DRA) amended

section 1886(b)(3)(B) of the Act to expand the set of hospital quality measures collected by Medicare. In particular, this provision directed the Secretary to start collecting baseline measures set forth by the Institute of Medicine in its November 2005 report in fiscal year (FY) 2007. These measures include 22 Hospital Quality Alliance measures and 3 process measures. In FY 2008 and subsequent years, the Secretary was required to add other measures that reflect consensus among affected parties. The provision also allowed the Secretary to replace and update existing quality measures. The statute mandates that the Secretary establish a process for hospitals to review data that will be made public and, after that process is complete, requires the Secretary to post measures on the Hospital Compare Internet Web site. The quality measures required under section 5001(a) of the DRA were integral to the direction under section 5001(b) of the DRA for the Secretary to develop a plan to implement value-based purchasing commencing FY 2009 for most Medicare hospital services. We are currently developing a hospital value-based purchasing system as required by the Patient Protection and Affordable Care Act (Pub. L. 111-148, enacted on March 23, 2010) (Affordable Care Act).

Section 5001(c) of the DRA amended section 1886(d)(4) of the Act to prohibit payment to hospitals for certain preventable hospital-acquired conditions (HACs) identified by the Secretary. Specifically, under section

1886(d)(4)(D)(iv) of the Act, the Secretary is required to identify HACs for which no payment for hospital services would be made. These conditions are required to have the following characteristics: (a) High cost or high volume or both; (b) result in the assignment of a case to a MS-DRG that has a higher payment when present as a secondary diagnosis; and (c) could reasonably have been prevented through the application of evidence-based guidelines.

Section 5001(c) of the DRA provides for revision of the list of conditions from time to time, as long as it contains at least two conditions.

B. Previously Specified Medicare HACs

As amended by section 5001(c) of the DRA, section 1886(d)(4) of the Act provides that the Secretary must ensure that additional payment under the IPPS is not made to hospitals for identified HACs including infections. By October 1, 2007, the Secretary was required under section 1886(d)(4)(D) of the Act to select, in consultation with the Centers for Disease Control and Prevention (CDC), diagnosis codes associated with at least two HACs that: (a) Are high cost, high volume, or both; (b) are assigned to a higher paying MS-DRG when present as a secondary diagnosis (that is, conditions under the MS-DRG system that are complications or co-morbidities or major complications or co-morbidities); and (c) could reasonably have been prevented through the application of evidence based guidelines. The list of

conditions can be revised from time-to-time as long as the list contains at least two conditions.

Under the provisions of section 1886(d)(4)(D)(ii) of the Act, when an HAC is not present on admission (POA), but is reported as a secondary diagnosis associated with the hospitalization, the Medicare payment under IPPS to the hospital may be reduced to reflect that the condition was hospital-acquired. More specifically, the hospital discharge cannot be assigned to a higher paying MS-DRG if the secondary diagnosis associated with the HAC would otherwise have caused this assignment. If an HAC were POA, then the Medicare payment under IPPS to the hospital would not be reduced. Since October 1, 2007, hospitals subject to the IPPS have been required to submit information on Medicare claims specifying whether diagnoses were POA. The POA indicator reporting requirement and the HAC payment provision apply to IPPS hospitals only. This requirement does not apply to hospitals exempt from the IPPS.

The following is a list of the current Medicare HACs (75 FR 50084 through 50085):

- Foreign Object Retained After Surgery.
- Air Embolism.
- Blood Incompatibility.
- Stage III and IV Pressure Ulcers.
- Falls and Trauma.
 - + Fractures.
 - + Dislocations.

- + Intracranial Injuries.
- + Crushing Injuries.
- + Burns.
- + Electric Shock.
- Manifestations of Poor Glycemic Control.
 - + Diabetic Ketoacidosis.
 - + Nonketotic Hyperosmolar Coma.
 - + Hypoglycemic Coma.
 - + Secondary Diabetes with Ketoacidosis.
 - + Secondary Diabetes with Hyperosmolarity.
- Catheter-Associated Urinary Tract Infection (UTI).
- Vascular Catheter-Associated Infection.
- Surgical Site Infection Following:
 - + Coronary Artery Bypass Graft (CABG) -
Mediastinitis.
 - + Bariatric Surgery.
 - Laparoscopic Gastric Bypass.
 - Gastroenterostomy.
 - Laparoscopic Gastric Restrictive Surgery.
 - + Orthopedic Procedures.
 - Spine.
 - Neck.
 - Shoulder.
 - Elbow.
- Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE).
 - + Total Knee Replacement.
 - + Hip Replacement.

The Secretary may revise this list upon review.

C. Previously Specified Medicare National Coverage
Determinations (NCD)

In 2002, the National Quality Forum (NQF) published "Serious Reportable Events in Healthcare: A Consensus Report", which listed 27 adverse events that were "serious, largely preventable and of concern to both the public and health care providers." These events and subsequent revisions to the list became known as "never events." This concept and need for the proposed reporting led to NQF's "Consensus Standards Maintenance Committee on Serious Reportable Events," which maintains and updates the list which currently contains 28 items.

The Medicare program has addressed certain "never events" through national coverage determinations (NCDs). Similar to any other patient population, Medicare beneficiaries may experience serious injury and/or death if they undergo erroneous surgical or other invasive procedures and may require additional healthcare in order to correct adverse outcomes that may result from such errors. In order to address and reduce the occurrence of these surgeries, Medicare issued three NCDs. Under these NCDs, Medicare does not cover a particular surgical or other invasive procedure to treat a particular medical condition when the practitioner erroneously performs: (1) a different procedure altogether; (2) the correct procedure but on the wrong body part; or (3) the correct procedure but on the wrong patient. Medicare will

also not cover hospitalizations and other services related to these non-covered procedures.

D. Prior Guidance on Medicaid HACs and NCDs in Response to Medicare's Policy

Section 5001(c) of the DRA addressed only the Medicare program and did not require that Medicaid implement nonpayment policies for HACs. However, in light of the Medicare requirements, we encouraged States to adopt payment prohibitions on provider claims for HACs to coordinate with the Medicare prohibitions under section 1886(d)(4)(D) of the Act. To accomplish this task, we issued State Medicaid Director Letter (SMDL) #08-004 on July 31, 2008. In the July 31, 2008 SMDL, we noted that there was variation in how State Medicaid programs had addressed such claims in the past. The letter noted that nearly 20 States already had, or were considering, eliminating payment for some or all of the 28 conditions on the NQF's list of Serious Reported Events. Other States had more limited efforts to deny payment for services related to such conditions because the services were "medically unnecessary" in light of the primary diagnosis.

Recognizing this variation and addressing the immediate concern of the States over Federal cost-shifting that could result from the Medicare HAC policy as applied to those who are dually-eligible for Medicare and Medicaid, we took a flexible position in the July 31, 2008 SMDL guidance on State Medicaid handling of the issue. The SMDL indicated that States seeking to implement HAC nonpayment policies could do

so by amending their Medicaid State plans to specify the extent to which they would deny payment for an HAC. Those interested only in avoiding secondary liability for Federal Medicare denials of HACs and NCDs in the case of dual-eligibles could do so by amending their State Plan to indicate that payment would not be available for HACs and the procedures described in the 3 NCDs that are not paid by Medicare. States that wanted broader payment prohibitions could indicate that payment would not be available for conditions specified in the State plan amendment (SPA), or that meet criteria identified in the SPA.

E. Section 2702 of the Affordable Care Act

Section 2702 of the Affordable Care Act requires that the Secretary implement Medicaid payment adjustments for health care-acquired conditions (HCACs). Section 2702 of the Affordable Care Act did not grant the Secretary new authorities, indicating that existing statutory authorities are sufficient to fulfill the obligation. Section 2702(a) of the Affordable Care Act sets out a general framework for application of Medicare prohibitions on payment for HCACs to the Medicaid program. Section 2702(a) of the Affordable Care Act first directs the Secretary to identify current State practices that prohibit payment for HCACs and to incorporate the practices identified, or elements of such practices, which the Secretary determines appropriate for application to the Medicaid program in regulations. Section 2702(a) of the Affordable Care Act then requires that,

effective as of July 1, 2011, the Secretary prohibit payments to States under section 1903 of the Act for any amounts expended for providing medical assistance for HCACs specified in regulations. Such regulations must ensure that the prohibition on payment for HCACs shall not result in a loss of access to care or services for Medicaid beneficiaries.

Section 2702(b) of the Affordable Care Act defines the term "health care-acquired condition" as "a medical condition for which an individual was diagnosed that could be identified by a secondary diagnostic code described in section 1886(d)(4)(D)(iv) of the Act."

Section 2702(c) of the Affordable Care Act specifically requires that the Secretary, in carrying out section 2702 of the Affordable Care Act, apply the regulations issued under section 1886(d)(4)(D) of the Act relating to the prohibition of payments based on the presence of a secondary diagnosis code specified by the Secretary in such regulations, as appropriate for the Medicaid program. The Secretary may exclude certain conditions identified under title XVIII of the Act for nonpayment under title XIX of the Act when the Secretary finds the inclusion of such conditions to be inapplicable to beneficiaries under title XIX.

F. Requirement to Review Existing State Practices Prohibiting Nonpayment Policies for HCACs

Section 2702 of the Affordable Care Act requires that the Secretary identify current State practices that prohibit

payment for HCACs and incorporate those practices, as appropriate, into Medicaid regulations.

To fulfill the statutory direction, we reviewed existing SPAs originally submitted in response to the July 31, 2008 SMDL (#08-004). We also researched State HCAC-related nonpayment policies that had been implemented outside of Medicaid State plans. We reviewed State quality assurance programs, pay-for-performance programs, reporting requirements and procedures, and payment systems.

We reviewed various articles, reports, summaries, and data bases pertaining to States' existing practices concerning hospital and HCACs and infections including, but not limited to:

- Nonpayment for Preventable Events And Conditions: Aligning State and Federal Policies to Drive Health System Improvement, Jill Rosenthal and Carrie Hanlon, December 2009.
- "Estimating the Costs of Potentially Preventable Hospital Acquired Complications," Richard L. Fuller M.S et al, Health Care Financing Review, Summer 2009, Volume 30, Number 4.
- "Identifying Potential Preventable Complications Using a Present on Admission Indicator," John S. Hughes, M.D., et al, Health Care Financing Review, Spring 2006, Volume 27, Number 3.
- State Government Tracking of Hospital-Acquired Conditions, Nathan West, MPA et al, April 2010.

- "The Triple Aim: Care, Health, And Cost," Donald Berwick, et al, Health Affairs, Volume 27, Number 3 (2008).
- "Lessons from the Pioneers: Reporting Healthcare-Associated Infections," Anna Spencer, et al. National Conference of State Legislatures, July 2010.
- "OIG Report: Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries," OEI-06-09-00090, November 2010.
- "OIG Report: Adverse Events in Hospitals: Public Disclosure of Information About Events," OEI-06-09-00360, January 2010.
- "OIG Report: Adverse Events in Hospitals: State Reporting Systems," OEI-06-07-00471, December 2008.
- To Err is Human: Building a Safer Health System, A report of the Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, 2000, L.T. Kohn, J.M. Corrigan, and M.S. Donaldson, eds.

We discussed internally within CMS, as well as with interagency partners at the Agency for Healthcare Research and Quality (AHRQ) and the CDC to ensure that the proposed regulations are consistent with other regulations, policies, and procedures currently in existence surrounding this issue. We also met with them to gain information on areas where we could mirror existing processes to eliminate undue burdens on States or providers.

We issued a State survey to capture data from all related payment policies regardless of whether they were

implemented as a result of the July 31, 2008 SMDL or whether such practices are currently detailed in the State plan. The survey is still undergoing the Paperwork Reduction Act (PRA) process and has not been made mandatory. However, we have received information from a few States through the survey and have reviewed other information that has been helpful in explaining current State processes for making payment adjustments for HCACs. Subsequent to the publication of the survey, we held all-State calls where we answered questions in response to the survey, had States with existing policies talk about their experiences, and listened to discussion regarding the implementation of the HCAC policy.

We met with nongovernmental partners including the NQF, the National Academy for State Health Policy, the National Association of Children's Hospitals, the Joint Commission, and State Medicaid Medical Directors. Most of these organizations are primarily focused on State program development and/or quality issues. We reached out to them to ensure that the proposed policies would be consistent with current industry understanding of both State payment and quality improvement goals. In our discussions with these organizations, we were able to discuss State experiences on a broad, national level that had been gained from working with States. During these meetings, we discussed a number of issues related to the proposed rule and State concerns in implementing this provision. For

instance, it was clear from many of our discussions that States hoped to be able to look to this provision to provide additional definition regarding the types of conditions to identify for nonpayment, as well as to provide some support in working with provider communities to which these policies would be applied.

G. Current State Practices Prohibiting Payment for HACs, HCACs, and Other Similar Events

We found that 29 States do not have existing HCAC-related nonpayment policies. Most of the 21 States that currently have HCAC-related nonpayment policies identify at least Medicare's HACs for nonpayment in hospitals. However, it is important to note that at least half of the existing policies we reviewed exceeded Medicare's current HAC requirements and policies, either in the conditions identified, the systems used to indicate the conditions, or the settings to which the nonpayment policies applied. These policies vary tremendously from State to State in the authority used to enact the policies, the terminology used, the conditions identified, State's utilization of the current Medicare HAC list, the service settings to which nonpayment policies are applied, reporting requirements, and the claims processing of the nonpayment policies.

All of the States with HCAC-related nonpayment policies have implemented provisions that would protect the State from dual-eligible liability either by directly prohibiting

payment for Medicare crossover claims or by relying on existing State plan authority to deny payment for claims previously denied by Medicare.

We found that 17 of the States implemented Medicaid specific policies that reduce payment for services provided to Medicaid beneficiaries. Most of the States implementing Medicaid specific policies identify at least Medicare's current list of HAC, and nearly half of those States defined a list that was different from Medicare's current list of HACs for nonpayment.

Similar variation exists in States' plan language identifying Medicare's NCD for nonpayment ranging from mirroring Medicare to completely breaking from Medicare. We do note, however, that the nature of the NQF serious reportable events, like surgery on the wrong body part, proper surgery wrong patient, and wrong surgery, is so severe that States were likely to have relied on State coverage provisions and appropriate care requirements to deny payment for these events.

We also found that States use different general terminology for HCAC-related nonpayment policies even though many of the conditions identified overlap, are from the same sources, and do not generally vary in medical definition from one list to the other. For example, 3 States identify "air embolism" as a condition for nonpayment under its plans with the condition understood to be consistently defined for medical purposes. However, one State includes air embolisms

on its list of "HACs"; another includes the same condition as a "Serious Adverse Event"; and the third includes it on a list of "Medical Errors."

We also found that at least 7 of the States with HCAC-related nonpayment policies apply those policies to settings other than the inpatient hospital setting required by Medicare, including both physicians and ambulatory surgical centers.

Variation across States is not surprising given the States have been permitted broad flexibility in defining their HCAC policies and programs. However, we attribute some of the variety on this issue to the wealth of information and evidence-based guidelines available to States, either through their own experiences and resources or through industry researched and developed resources related to health system quality. Data gathered on the conditions identified, reporting strategies, and implementation guidelines indicate that States have relied heavily on existing health system quality improvement research to define requirements while tailoring policies appropriate to their own systems. In addition, our research indicates that States' HCAC-related nonpayment policies are mainly intended to drive broader health system agendas to promote quality outcomes. We believe the use of evidence-based measures and the push for health system quality are an appropriate foundation for the proposed regulation. We propose to implement Medicaid HCAC

regulations that would provide some consistency across health care payers (Medicare and Medicaid). At the same time, we also propose to accommodate State flexibility to design individual HCAC policies for nonpayment, quality-related programs suitable for their own Medicaid program and health marketplace to the extent such policies go beyond Federally-established minimum standards. We request comment on this issue.

The July 31, 2008 SMDL (#08-004) instructed States to submit SPAs to enact nonpayment provisions. Thirteen States complied with this requirement. Other States that implemented these policies through some other authority like State law or administrative procedures will be required to submit new SPAs for review and work with CMS to ensure their policies, effective July 1, 2011, are in line with the final provisions of this rule.

H. Provider Preventable Conditions

We are proposing to exercise our authority under sections 1902(a)(4), 1902(a)(19), and 1902(a)(30)(A) of the Act to provide for identification of Provider Preventable Conditions (PPCs) as an umbrella term for hospital and nonhospital conditions identified by the State for nonpayment to ensure the high quality of Medicaid services. These statutory provisions authorize requirements that States use methods and procedures determined by the Secretary to be necessary for the proper and efficient administration of the State plan, to provide care and

services in the best interests of beneficiaries, and to provide for payment that is consistent with efficiency, economy, and quality of care.

With the introduction of this term, we propose to include two categories of PPCs-- HCACs and OPPCs. HCACs would apply as required under the statute. OPPCs would be applicable to other conditions that States identify and have approved through their Medicaid State plans.

The inclusion of the new terms, PPCs and OPPCs, is consistent with the implementation of a broader application of this policy which allows us to appropriately incorporate existing State practices. The adoption of a new term is necessary because the term, "health care-acquired condition" is very narrowly defined in the Statute and does not provide for the inclusion of conditions other than those identified as HACs for Medicare, even excluding the 3 Medicare NCDs. Additionally, the statutory definition of HCACs only applies to the inpatient hospital service setting.

We considered a broader definition of the term, "health care-acquired conditions," attempting to isolate the idea of the actual condition from the setting in which it occurred, however after conferring with Medicare to clearly understand the statute at section 1886(d)(4)(D)(iv) of the Act, we came to understand that it applies specifically to conditions applicable to inpatient hospitals as defined in that section and reimbursed by diagnosis related groups. For example, section 1886 of the Act is titled, "Payment to Hospitals for

Inpatient Hospital Services.” Section 1886(d) of the Act applies specifically to “the amount of the payment with respect to the operating costs of inpatient hospital services.” Section 1886(d)(4) of the Act requires that, “The Secretary shall establish a classification of inpatient hospital discharges...” Section 1886(d)(4)(D) of the Act is specific to the assignment of diagnosis-related groups which apply solely to Medicare payment for inpatient hospital services.

We did look to the Affordable Care Act in creating these terms. Section 3008(b) of the Affordable Care Act, “Study And Report On Expansion Of Healthcare Acquired Conditions Policy To Other Providers,” requires that Medicare study the effects of expanding its existing policy to other providers. We adopted the “Other Providers” term to remain consistent with Medicare in the expansion of its policy.

In looking to expand the overall policy, we considered a number of other terms but determined that many of them like “adverse events” or “serious reportable events” would generate confusion because they had existing industry definitions that did not necessarily overlap with our policy aims. We adopted the term “Provider Preventable Condition” after discussion with Medicare because it appropriately identified the scope of the conditions and could act as a “catch-all.” Also, the term had not been narrowly defined by use in Medicare, Medicaid, or in the industry at-large.

I. Reporting of Results

After researching State, industry, and Federal information related to the importance of reporting of quality data in driving improved health outcomes, we propose that a simplified level of reporting is essential to creating a successful nonpayment policy both from the payment and quality perspectives. We believe that any requirements for provider reporting should provide a consistent format for States to report State-specific measures; require that providers report conditions identified for nonpayment when they occur regardless of a provider's intention to bill; and not cause undue burden on States or providers.

Quality reporting across States is inconsistent. There are 27 States that require reporting of either hospital-acquired infections, conditions, or some combination of both. Some of those States require quality reporting but have not implemented associated HCAC-related nonpayment policies. Others have HCAC-related nonpayment policies, but have not implemented quality reporting requirements.

Existing national quality reporting formats do not support the collection of data on HCACs and OPPCs for Medicaid beneficiaries. Providers, mainly hospitals, are subject to reporting requirements in addition to those imposed by States. For instance, most hospitals report some quality measures to CMS, the Joint Commission, or the CDC.

We considered requiring reporting to Hospital Compare and the National Health Safety Network, but decided against these formats because: we do not believe they currently have the capacity to allow State specific reporting of varied measures; their existing collections may not be consistent with what most States are currently requiring providers report; and the reporting formats may impose undue significant burden for providers - particularly those that do not have full-time quality staffs or resources.

Without direct reporting requirements, providers have no incentive to report conditions or adverse events for nonpayment or otherwise. HACs, HCACs, and related policies represent liabilities for providers beyond nonpayment provisions. In fact, Medicare and the industry-at-large, have experienced nonclaiming or nonbilling on the part of providers seeking to escape the liability that could come with any type of notification of a particular event or avoid negative health outcome indicators.

In consideration of our research, we propose a requirement that existing claims systems be used as a platform for provider self-reporting. We also propose to include reporting provisions that would require provider reporting in instances when there is no associated bill. For instance, States could employ the widely used POA system in combination with including edits in their Medicaid claims systems that would indicate an associated claim and flag it for medical review.

J. States' Use of Payment Systems other than MS-DRG

We also found that States' payment systems will dictate the manner in which States are able to operationalize PPCs related nonpayment policies. For instance, some States reimburse using MS-DRG or some other type of grouper software to price claims. As with Medicare, these States may use the POA indicator system to identify claims and reduce payments by programming the grouper to reduce payment through the grouper. We note that a considerable number of States do not use grouper systems to reimburse providers. These States may identify and reduce payment for HCACs using methods appropriate to the specific reimbursement system used within that State. For instance, at least one State has elected to carve out a portion of the total system reimbursements for redistribution based on its own historical quality measures. We believe that the proposed provision allows States this type of flexibility in designing methodologies that would isolate amounts for nonpayment and allow provider payment to be reduced based on a CMS-approved State plan methodology that is prospective in nature. We would welcome comment on this issue.

II. Provisions of the Proposed Regulations

A. General Discussion

We propose to codify provisions that would allow States flexibility in identifying PPCs that include, at a minimum, the HAC identified by Medicare, but may also include other State-identified conditions. This flexibility would extend

to applying nonpayment provisions to service settings beyond the inpatient hospital setting. We believe that establishing Medicare as the minimum for the application of this policy is appropriate at this point. Many States that have implemented HCAC-related policies have adhered to Medicare because the conditions have been researched and are generally accepted by the provider community. In addition, provider familiarity with Medicare's HACs and identification processes limits the States' implementation burden.

We also recognize that Medicare's own policy is evolving. The Affordable Care Act requires that Medicare attach new payment incentives to its HAC provisions, as well as to study the implications of applying HCACs policy to providers other than inpatient hospital providers. We encourage States to consider the benefits and quality implications of expanding HCAC quality and nonpayment policies as more information becomes available from Medicare and State Medicaid programs. We invite comment on the topic of expanding HCAC-related policies in State Medicaid programs.

We propose that PPCs are defined under two categories: HCACs; and OPPCs. We are proposing to define the category of PPCs that would be referred to using the term "health care-acquired conditions" (HCACs) based on the definition of that term in section 2702(b) of the Affordable Care Act. That definition provides that an HCAC must be a condition that "could" be identified in the Medicare program by a

secondary ICD-9-CM OR ICD-10-CM code as an HAC under section 1886(d)(4)(D)(iv) of the Act for Medicare purposes. Section 2702(c) of the Affordable Care Act specifically requires that the Secretary shall apply to State plans (or waivers) under title XIX of the Act the regulations issued under section 1886(d)(4)(D) of the Act relating to the prohibition of payments based on the presence of a secondary diagnosis code specified by the Secretary in such regulations, as appropriate for the Medicaid program. This means States must, at a minimum, identify conditions as HACs in accordance with section 1886(d)(4)(D) of the Act. Consistent with this identification, we propose that every State must, at a minimum, identify as an HCAC, those secondary diagnosis codes that have been identified as Medicare HACs when not present on hospital admission. We note that the Secretary has authority to update the Medicare HAC list as appropriate. As such, States are required to comply with subsequent updates or revisions in accordance with section 1886(d)(4)(D) of the Act.

States will be responsible for ensuring that the conditions identified under their Medicaid State plans are, at a minimum, consistent with those identified in Medicare's final annual hospital IPPS rule. Medicare is required to display its final IPPS rule 60 days prior to the beginning of the Federal fiscal year to which the update applies. If Medicare revises its HAC list, we believe States will have sufficient time to update their corresponding policies.

Therefore, we propose that States' policies will be effective consistent with Medicare's revisions to its list of HACs. We are soliciting comments on this issue.

Because the definition does not require that HCACs must be limited to Medicare HAC, we propose a definition for an HCAC that would not be limited to those specifically identified for the Medicare program, but can include conditions identified by States for nonpayment under their State plans, as approved by CMS through the State plan review process, that the State has determined meet the statutory criteria outlined at section 1886(d)(4)(D)(iv) of the Act. We believe this is appropriate at this point in time, considering where many States are in development of their programs but we are seeking comment on this proposed policy. This proposed definition would establish Medicare as the floor, but allow further State innovation as determined by each State. However, even if a State chooses to go beyond Medicare, it will still have to be implemented through SPAs, and we will publish such policies on the CMS Web site on an annual basis to encourage States to learn from each other. With respect to those statutory criteria for identification of an HCAC, section 1886(d)(4)(D)(iv) of the Act sets forth the following criteria:

- Cases described by such code have a high cost or high volume, or both, under this title.

- The code results in the assignment of a case to a MS-DRG that has a higher payment when the code is present as a secondary diagnosis.

- The code describes such conditions that could reasonably have been prevented through the application of evidence-based guidelines.

In applying these criteria to identify HCACs, we propose that the term "code" would refer to ICD-9-CM OR ICD-10-CM codes assigned in the International Classification of Diseases coding system, 9th (or 10th) Revision, Clinical Modification or a State-specified alternative method of identifying conditions for purposes of payment.

In addition, we propose that when analyzing the payment impact of an inpatient hospital HCAC, the State may consider the nature of its particular payment methodology. For instance, when a State reimburses hospitals on a per diem basis and determines that there was an HCAC that was not POA, the State may need to isolate the increased cost of the services (possibly through a utilization review) and reduce the per diem reimbursement accordingly.

While we believe that the broad use of ICD-9-CM OR ICD-10-CM codes in inpatient hospital payment, as well as the POA indicator system currently used by Medicare to indicate conditions for nonpayment is the most consistent methodology for States in identifying HCACs, we are interested in hearing about other methods of identifying HCACs. We recognize that there is considerable variation

among State hospital payment methodologies. In addition, we recognize that there is considerable variation among States in the availability of data necessary to identify HCACs and related quality issues. We are proposing to require that States implement requirements for provider self-reporting of HCACs in the Medicaid claims payment process.

The rule proposes that States would identify an HCAC similar to the way Medicare identifies an HAC. However, as the OIG points out in its report evaluating the usefulness of selected methods for identifying events that harm hospitalized Medicare beneficiaries, Adverse Events in Hospitals: Methods for Identifying Events (OEI-06-08-00221), tools like the Institute for Healthcare Improvement's Global Trigger Tool that require standardized medical record reviews are considered much more effective in detection than the POA system. This is significant because one cannot prevent what one cannot detect. Accurate measurement is the necessary antecedent of quality improvement. We are soliciting comments on the efficiency of POA indicators for purposes of this provision.

We are also proposing to provide that States may identify similar OPPCs related to services furnished in settings other than inpatient hospitals, which would also be subject to a payment prohibition.

Preventable conditions that are caused or related to the provision of health care are not limited to inpatient hospital settings. These conditions can occur in outpatient

hospital, nursing facility, and ambulatory care settings, and other healthcare settings.

We are proposing that the treatment of these OPPCs will be similar to the treatment of HCACs. State plans must provide for nonpayment for care and services related to these OPPCs, and Federal financial participation (FFP) will not be available in State expenditures for such care and services related to OPPCs.

To establish a base of an OPPC, we propose to define OPPC to include, at a minimum, wrong surgical or other invasive procedure performed on a patient; a surgical or other invasive procedure performed on the wrong body part; and a surgical or other invasive procedure performed on the wrong patient.

These three conditions were addressed by Medicare in three national coverage analyses (NCAs) to establish NCDs.

Effective January 15, 2009, Medicare does not cover a particular surgical or other invasive procedure to treat a particular medical condition when the practitioner erroneously performs: (1) a different procedure altogether; (2) the correct procedure but on the wrong body part; or (3) the correct procedure but on the wrong patient. Medicare will also not cover hospitalizations and other services related to these non-covered procedures as defined in the Medicare Pub. 100-02, Benefit Policy Manual (BPM), chapter 1, sections 10 and 120 and chapter 16, section 180. We propose to adopt these 3 for purposes of this regulation.

In addition to these Federally-identified OPPCs, we propose to authorize States to identify other OPPCs and apply payment prohibitions the same as those applied to HCACs. The criteria that we are proposing for such other OPPCs would be similar to the criteria for HCACs. We propose the following criteria for States to use in identifying additional OPPCs:

- A condition or event identified by a State for inclusion under this provision must be a discrete, auditable, quantifiable, and clearly defined occurrence.
- A condition or event must be clearly adverse, resulting in a negative consequence of care that results in unintended injury or illness.
- A condition or event identified must be reasonably preventable, meaning an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure.

In designating additional OPPCs, we recommend that States consider the 2002 NQF report entitled "Serious Reportable Events in Healthcare: A Consensus Report." In that report, NQF listed 27 events that were "serious, largely preventable and of concern to both the public and health care providers." NQF's "Consensus Standards Maintenance Committee on Serious Reportable Events" maintains and updates the list which currently contains 28 items.

In order to implement the requirements of this new payment prohibition, we recognize that States may need additional information to properly process claims and determine the availability of FFP. We propose requiring States to establish provider self-reporting procedures for PPCs related to claims for Medicaid payment or courses of treatment that otherwise would be payable under Medicaid. We solicit comments on this issue.

We will continue to gather information from States to further inform our policies and facilitate information sharing across States. We note that the Secretary may update this regulation over time to require additional nonpayment by States as we learn more from State practices.

B. Access To Care

Section 2702(a) of the Affordable Care Act requires that the Secretary ensure that adjustments to payment rates under this section do not result in a loss of access to care for beneficiaries. To this end, we propose that any reduction in payment would be limited to the amounts directly identifiable as related to the PPC and the resulting treatment. We are proposing this method of protecting access because it limits States' ability to unduly reduce provider rates. For instance, if a patient develops mediastinitis after a CABG, the State would be allowed to deny payment for the treatment of the mediastinitis, but not the CABG.

Additionally, we do not believe that beneficiaries would be best served by this policy if the focus was shifted from quality to system cost containment. We note further that nothing in this rule prevents a State from reinvesting any savings it may achieve from nonpayment of PPCs into rate improvements aimed at achieving improved access to care, as appropriate. We solicit comments on this issue.

C. Effective Date of the Proposed Provisions

Consistent with the provisions of section 2702(a) of the Affordable Care Act, we would make these requirements effective July 1, 2011. We will be requesting that States submit conforming SPAs to implement these provisions prior to that date. To be in compliance with the July 1, 2011 proposed effective date, under 42 CFR 430.20, the last date a SPA may be submitted would be September 30, 2011, which is the last day of the quarter in which the amendment would be effective.

D. Specific Revisions to Regulations Text

The provisions of this rule would deny FFP for Medicaid expenditures made for PPCs, including HCACs and OPPCs identified in the State plan; and ensure that related payment adjustments do not limit beneficiary access to care. These provisions would apply to payments as specified under States' approved Medicaid State plans, effective no later than July 1, 2011. We are proposing to modify the regulations at 42 CFR parts 434, 438, and 447 following general provider payment rules and preceding other

provisions concerning reductions in provider payments. In addition, to ensure that these provisions apply to contracts that States use to provide Medicaid benefits using a managed care delivery system, we are also proposing to modify the regulations at 42 CFR part 438. Because the basic rule is set forth in part 447, we discuss that proposed modification first.

Currently the general rules regarding Medicaid State plan payments for Medicaid are provided at part 447 subpart A. We propose to add a new §447.26 to indicate that FFP will not be available for expenditures made for PPCs. We have included in §447.26(a) a statement of the basis and purpose for the regulation, and in §447.26(b), the definitions for the umbrella term PPCs, and the included terms HCACs, and other PPCs. These proposed provisions will establish Medicare as the floor that all States must adopt, but allow flexibility for States to move beyond the Medicare definitions and settings. As States' programs evolve and they make additional requirements, we would require that necessary SPAs be submitted for implementation purposes.

In §447.26(c), we are proposing to set forth the general rule that State plans must preclude payment to providers for PPCs, and that FFP is not available for State expenditures for PPCs. To ensure beneficiary access to care, we specify that any reductions may be limited to the added cost resulting from the PPC.

In §447.26(d), we have included a provision that would require States to require provider reporting of PPCs associated with Medicaid claims, or with courses of treatment for Medicaid beneficiaries that would otherwise be payable under Medicaid.

In addition to these changes in part 447, we are proposing to include a requirement in §434.6(a)(12) for contracts for medical or administrative services that contractors do not make payment for PPCs, and require that providers comply with the reporting requirements in §447.26(d) as a condition of receiving payment. Likewise, to ensure that these provisions are included as required elements in Medicaid managed care contracts, we are proposing to include a requirement in §438.6(f)(2) that contracts must comply with both §434.6(a)(12) and §447.26.

We have proposed these particular provisions because the information gathered in preparation for issuing these proposed rules indicate the need for a consistent authority under which States can implement PPC nonpayment policies; a consistent approach to identifying conditions for nonpayment; a streamlined terminology to indicate Medicaid HCAC payment policies; State flexibility to implement provisions suitable to their own systems; and a consistent provider reporting platform.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register**

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

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

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

Effective July 1, 2011, proposed §447.26 would require States to submit SPAs for CMS approval that would reduce payments to providers by amounts related to PPCs. The burden associated with this proposed requirement would be the time and effort necessary for a State to submit its SPA and the associated pre-print. We estimate that 50 States would be required to comply with this requirement. We

further estimate that it will take each State 7 hours to submit the aforementioned documentation to CMS. The total estimated burden associated with this requirement would be 350 hours at a cost of \$20.67 per hour per State.

We estimate that it will take each State 7 hours because we intend to issue a template to States to simplify the process of making the related amendment to the Medicaid State plan.

Proposed §447.26 would also require States to implement provider reporting requirements to ensure that PPCs are identified in claims for Medicaid payment. The burden associated with this requirement is the time and effort necessary to develop and implement provider reporting requirements that are effective with the provisions of this regulation. We estimate that 50 States would be required to comply with this requirement. Similarly, we estimate that it will take 24 hours for each State to develop and implement the provider reporting requirements as specified above. The total estimated burden associated with this requirement would be 1200 hours at a cost of \$20.67 per hour per State. We believe that this estimate is reasonable because we are requiring that States have providers use their existing claims processes to report identified events.

Proposed §438.6(f)(2) would also require States which provide medical assistance using a managed care delivery system to modify their managed care contracts to reflect the PPCs payment adjustment policies as applied through these

regulations. The burden associated with this requirement is the time and effort necessary for a State to amend its managed care contracts to reflect these policies. We estimate that 48 States would be required to comply with this requirement. We also estimate that it would take 8 hours for each State to revise its contracts to comply with this requirement and submit the amended contract to CMS for review and approval. The total estimated annual burden associated with this requirement is 384 hours at a cost of \$20.67 per hour per State.

The total estimated burden associated with this requirement is 1934 hours at a cost of \$806.13 per State.

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

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

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

Attention: CMS Desk Officer, [CMS-2400-P]

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

IV. Response to Comments

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

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

V. Regulatory Impact Statement

A. Statement of Need

This proposed rule implements section 2702 of the Affordable Care Act of 2010 which directs the Secretary to issue Medicaid regulations effective as of July 2011, prohibiting Federal payments to States (under section 1903 of the Act) for any amounts expended for providing medical assistance for HCACs. It would also authorize States to identify other PPCs for which Medicaid payment would be prohibited. We view this regulation as one step of a larger approach to address the problem of HCACs.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (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 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and,

if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule under the Congressional Review Act. We request comments on our economic analysis.

It is difficult to estimate the amount which will be withheld from providers under this regulation, as not all of these events will be billed. However, it is instructive to note that the total dollar amount of Medicare claims denied under its HAC policy is approximately \$20 million per year (see 75 FR 23895, May 4, 2010). The original regulation creating the Medicare HACs was published in the August 19, 2008 **Federal Register** (73 FR 48433). In addition, estimates were conducted by the Congressional Budget Office (CBO) and the CMS Office of the Actuary (OACT) on the impact of section 2702 of the Affordable Care Act. The CBO estimate concluded there would be no impact associated with section 2702 of the Act (CBO and JCT, 2010 Estimate). The CMS OACT estimate (Estimated Financial Effects of the "Patient Protection and Affordable Care Act," as Amended, 2010) projected an impact from section 2702 on the Medicaid program of cost savings of \$2 million for FY

2011 (\$1 million for the Federal share and \$1 million for the State share), with an aggregate cost savings of \$35 million (\$20 million for the Federal share and \$15 million for the State share) for FYs 2011 through 2015. The Federal and State share cost savings, as result of denied payments, are represented by the reduction in transfers from Medicaid to hospitals.

Table 1: Medicaid Impacts for FYs 2011 through 2015

Medicaid Impacts	FY Impact (\$ Millions)					
	2011	2012	2013	2014	2015	Total
Federal Share	-1	-4	-5	-5	-5	-20
State Share	-1	-3	-3	-4	-4	-15
Total	-2	-7	-8	-9	-9	-35

There are administrative cost impacts on States to modify their systems to meet reporting requirements, but we believe these are not significant. As noted above, the reporting system in this proposed regulation relies on an existing billing system currently in place. Both States and providers already have billing, claiming, and payment systems in place to act upon the information obtained. The costs reported in section III. of this proposed rule, Collection of Information Requirements, amount to an additional \$39,976 dollars aggregate across all States.

Hospitals may incur additional costs to reduce HCACs. Such costs include hiring additional nurses to ensure enforcement of the infection prevention policies. In turn, preventing or reducing HCACs will lead to a reduction in direct health spending, which is a benefit realized by

Medicaid, hospitals and other payers.

The Joint Commission requires hospitals to have established programs for Quality Improvement, Risk Management, Safety, and Infection Control. As a result, a majority of hospitals already have in place programs to avert Medicare HACs and thus would not incur new costs to implement parallel programs to avert Medicaid HACs. Furthermore, we anticipate a public benefit to all providers and payers since programs that hospitals develop to avoid Medicaid HCACs will likely benefit all patients and reduce health care costs. Patient benefits resulting from a reduction in HCAC may include an increase in healthy years of life. However, this public benefit will derive from possible responses by hospitals and not from this regulation itself.

We realize that the overall problem of HCACs cannot be completely addressed in this regulation, as this proposed regulation is one step of an overall approach. Consequently, the estimated economic impacts from all HHS initiatives to address HCACs may result in much higher savings impact than presented in this analysis. However, such economic savings, for example, will not derive from this regulation alone, but will in part come from the knowledge that State and Federal governments gain from the reporting requirements created by this regulation. That knowledge will in turn inform future HHS initiatives to reduce excess morbidity and mortality attributable to HCACs.

The RFA requires agencies to analyze options for regulatory relief for small entities, if a rule has a significant impact on a substantial number of small entities. Most hospitals, other 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. Guidance issued by the Department of Health and Human Services interpreting the RFA considers effects to be economically significant if they reach a threshold of 3 to 5 percent or more of total revenue or total costs. As illustrated in Table 1, any decrease in payments, as a result of this regulation, to small entities should be significantly less than this threshold. Therefore, we are not preparing an analysis for the RFA because the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because

the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately \$136 million. This rule will have no consequential effect on State, local, or tribal governments in the aggregate or on the private sector.

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. While this regulation does not impose substantial costs on State or local governments, it does preempt some State laws. The requirements of Executive Order 13132 are applicable.

Executive Order 13132 sets forth a process to be followed by the Federal government whenever Federal regulatory processes may affect or preempt State regulations or laws. We are aware that many States do have regulations for Medicaid nonpayment in the event that specified adverse events occur during provider care. This proposed rule is intended to create a Federal legal minimum for such State regulations. States could continue to enact more stringent

laws or regulations upon approval of a Medicaid SPA by CMS to assure that there is no adverse impact on Medicaid beneficiary access to care.

This proposed rule derives from section 2702 of the Affordable Care Act and other CMS regulatory authority. Like the Affordable Care Act, it is derived from Federal authority under the Commerce Clause of the US Constitution. Under the requirements of Executive Order 13132 and the requirements of section 2702 of the Affordable Care Act, we have consulted with the States before issuing this proposed rule. Major portions of the regulation are, in fact, derived from comparable State regulations. Significant regulatory authority in this area would remain with the States should the proposed regulation become final. As stated, the proposed rule does not completely preempt State law, but merely sets a Federal minimum standard.

Moreover, we solicit comments from States as part of this proposed rule and will consider such State comments in drafting the final rule. While there will be some additional administrative costs to States to administer this regulation, it is expected that State Medicaid savings will largely offset such costs.

The requirements of Executive Order 13132 will be met in the final rule to be issued 30 days prior to the effective date of July 1, 2011, set forth in the Affordable Care Act.

C. Anticipated Effects

1. Effects on State Medicaid Programs

The effects on State Medicaid programs as a result of this provision will depend on various factors. For instance, as we state in the preamble, there are 21 States that have already implemented similar policies. While we have reviewed existing State policies and incorporated those policies that we believe would best apply on a national level, these States will have to make changes to comply with the minimums set in this proposed rule. In addition, States will have to work through the SPA review process to ensure that their existing policies do not serve to limit beneficiaries' access to healthcare.

The States that have used State plan authority to implement their nonpayment policies will need to review their policies and ensure that they comply with any finally implemented provisions of these rules. These States will likely have to submit revisions to their State plans. In addition, the States that implemented these policies through some other authority like State law or administrative procedures will have to submit new SPAs for review and work with CMS to ensure that their policies effective July 1, 2011, are in line with the final provisions of these rules. States that have elected not to implement Medicaid specific policies or that do not have related policies at all will need to submit new SPAs. Further, States which use a managed care delivery system to provide Medicaid benefits to beneficiaries will have to amend and submit for CMS

review and approval managed care contracts that reflect these new requirements. While this regulation is effective on July 1, 2011, most States will already have their managed care contracts for the fiscal year in place by that time and there may be some delay in incorporating new language in their managed care contracts. We will issue subregulatory guidance to States requiring that appropriate changes be made to managed care contracts to comply with the regulation.

All States will need to incorporate the reporting requirements into their claims systems. In addition, States will need to evaluate the best ways in which to identify and reduce payment for PPCs under their respective Medicaid plans.

We anticipate that this provision will prompt programmatic changes for States regarding quality improvement considerations within health care systems. This provision, while it is a payment provision, is primarily targeted at preventing medical errors.

2. Effects on Other Providers

We anticipate that these provisions will prompt health care providers to adopt quality programs that would limit the risk of providing services or using resources, in error, that will not be reimbursed.

We anticipate that the reporting requirements will ultimately be a catalyst for providers in developing quality practices to reduce the risks associated with receiving care

at their facilities and promote overall quality improvements.

3. Effects on the Medicaid Program.

Medicare's and States' experience has demonstrated that related policies often do not produce substantial short-term financial savings within health care systems. Medicare estimated that the policy will reduce its spending by an aggregate amount of about \$80,000,000 from FY 2009 through FY 2013, or by less than 0.01 percent of total annual spending on inpatient hospital services (75 FR 50661). States report similar short-term savings. However, there are more significant gains to be realized when considering the broader impact of increased quality on the health system overall, or more exactly the savings created when preventable conditions and related treatment are measured.

The anticipated public benefit to all providers and payers from programs that hospitals develop to avoid Medicaid HCACs will likely benefit all patients and reduce health care costs. This includes, for example, Medicaid beneficiaries realizing an increase in healthy years of life as a result of the reduction in HCACs. However, this public benefit will derive from possible responses by hospitals and not from this regulation itself.

D. Alternatives Considered: Conditions Identified as Provider-Preventable Conditions

The Statute requires that Medicaid, at a minimum, recognize Medicare's current list of HACs. We considered

proposing regulatory action that included only the conditions listed as Medicare HACs. However, when considering current State practices our research concluded that many States' policies included conditions not identified by Medicare as HACs. We concluded that such limited action would not serve the program purposes of ensuring high quality care and would potentially limit State flexibility to protect beneficiaries and program integrity. Similarly, we considered proposing regulatory action that included only the inpatient hospital setting. Again, after assessing current State practices, as well as industry-based research, there is clear indication that data is available to States that will allow them to employ evidence based policy practices beyond the inpatient hospital setting. In order to provide States full flexibility to protect beneficiaries and the program, we elected the more comprehensive approach proposed. We are seeking comment on both issues.

We considered defining OPPC as, "a condition occurring in any health care setting that could have reasonably been prevented through the ordinary provision of high quality care during the course of treatment..." We believed that this terminology would limit additional requirements on States to produce evidence of preventability. However, after discussing the terminology and scientific parameters that exist in relation to this issue, we propose that the term be defined as, "a condition that could have reasonably been

prevented through the application of evidence based guidelines." We are seeking comment on the use of both definitions.

E. Conclusion

For the reasons outlined in the RIA, we are not preparing an analysis for either the RFA or section 1102(b) of the Act because we have determined that this proposed rule would not have a direct significant economic impact on a substantial number of small entities or a direct significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 434

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

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 447

Grant programs-health, Medicaid.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR parts 434, 438, and 447, as set forth below:

PART 434--CONTRACTS

1. The authority citation for part 434 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart A--General Provisions

2. Section 434.6 is amended by--

A. Revising the introductory text of paragraph (a).

B. Removing the semicolons from the end of paragraphs (a)(1) through (a)(9), and the semicolon and the word "and" from the end of paragraph (a)(10), and adding in their place a period.

C Adding a new paragraph (a)(12).

The revision and addition read as follows:

§434.6 General requirements for all contracts and subcontracts.

(a) Contracts. All contracts under this part must include all of the following:

* * *

(12) Specify the following:

(i) No payment will be made by the contractor to a provider for provider-preventable conditions, as identified in the State plan.

(ii) The contractor will require that all providers agree to comply with the reporting requirements in §447.26(d) of this subchapter as a condition of payment from the contractor.

(iii) The contractor will comply with such reporting requirements to the extent the contractor directly furnishes services.

* * * * *

PART 438--MANAGED CARE

3. The authority citation for part 438 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart A--General Provisions

4. Section 438.6 is amended by revising paragraph (f) to read as follows:

§438.6 Contract requirements.

* * * * *

(f) Compliance with contracting rules. All contracts must meet the following provisions:

(1) Comply with all applicable Federal and State laws and regulations including title VI of the Civil Rights Act of 1964; title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act of 1990 as amended.

(2) Provide for compliance with the requirements prohibiting payment for provider-preventable conditions as set forth in §434.6(a)(12) and §447.26 of this subchapter.

(3) Meet all the requirements of this section.

* * * * *

PART 447--PAYMENTS FOR SERVICES

5. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart A--Payments: General Provisions

6. Section 447.26 is added to read as follows:

§447.26 Prohibition on payment for provider-preventable conditions.

(a) Basis and purpose. The purpose of this section is to protect Medicaid beneficiaries and the Medicaid program by prohibiting payments by States for services related to provider-preventable conditions.

(1) Section 2702 of the Patient Protection Act and Affordable Care Act of 2010, P.L. 111-148 requires that the Secretary exercise authority to prohibit Federal payment for certain provider preventable conditions (PPCs) and health care-acquired conditions (HCACs).

(2) Section 1902(a)(19) of the Act requires that States provide care and services consistent with the best interests of the recipients.

(3) Section 1902(a)(30) of the Social Security Act requires that State payment methods must be consistent with efficiency, economy, and quality of care.

(b) Definitions. As used in this section--

Health care-acquired condition means a condition identified as a HAC by the Secretary under section 1886(d)(4)(D)(iv) of the Act for purposes of the Medicare program and other HACs identified in the State plan that the State determines meet the requirements described in section 1886(d)(4)(D)(ii) and (iv) of the Act.

Other provider-preventable condition means a condition occurring in any health care setting that meets the following criteria:

(i) Could have reasonably been prevented through the application of evidence based guidelines.

(ii) Has a negative consequence for the beneficiary.

(iii) Is identified in the State plan.

(iv) Is auditable.

(v) Includes, at a minimum, wrong surgical or other invasive procedure performed on a patient; surgical or other invasive procedure performed on the wrong body part; surgical or other invasive procedure performed on the wrong patient.

Provider-preventable condition means a condition that meets the definition of a "health care-acquired condition" or an "other provider-preventable condition" as defined in this section.

(c) General rules.

(1) A State plan must provide that no medical assistance will be paid for "provider-preventable conditions" as defined in this section.

(2) Reductions in provider payment may be limited to the extent that the following apply:

(i) The identified provider-preventable conditions would otherwise result in an increase in payment.

(ii) The State can reasonably isolate for nonpayment the portion of the payment directly related to treatment for, and related to, the provider-preventable conditions.

(3) FFP will not be available for any State expenditure for provider-preventable conditions.

(4) A State plan must ensure that payment for services is sufficient to assure access to services for Medicaid beneficiaries in accordance with section 1902(a)(30)(A) of the Act.

(d) Reporting. State plans must require that providers identify provider-preventable conditions that are associated with claims for Medicaid payment or with courses of treatment furnished to Medicaid patients for which Medicaid payment would otherwise be available.

CMS-2400-P

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

Dated: November 17, 2010.

Donald M. Berwick,
Administrator,
Centers for Medicare & Medicaid
Services.

Approved: December 13, 2011.

Kathleen Sebelius,
Secretary,
Department of Health and Human
Services.

BILLING CODE 4120-01-P

[FR Doc. 2011-3548 Filed 02/16/2011 at 8:45 am; Publication
Date: 02/17/2011]