

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 434, 438, and 447

[CMS–2400–F]

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: Final rule.

SUMMARY: This final rule will implement section 2702 of the Patient Protection and Affordable Care Act 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 specified in the regulation. It will also authorize States to identify other provider-preventable conditions for which Medicaid payment will be prohibited.

DATES: These regulations are effective on July 1, 2011.

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SUPPLEMENTARY INFORMATION:

Acronyms

To assist the reader, the following list of the acronyms are used in this final 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
 IH Inpatient Hospital
 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 title XIX, 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 services 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 in part 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 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.

Section 5001(c) of the DRA amended section 1886(d)(4) of the Act to adjust 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 select codes associated with at least two conditions to be identified as HACs. 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

Under the provisions of section 1886(d)(4)(D)(ii) of the Act, when a 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 was the only reason for this assignment.

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 Medicare HACs for FY 2011 (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 and does so through notice and comment rulemaking.

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 29 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 to correct adverse outcomes that may result from such errors. To address and reduce the occurrence of these surgeries, CMS issued three NCDs. Under these NCDs, CMS 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 payment under the Medicare IPPS 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 three 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 of the Act.

We believe, and confirmed through public comment, that incorporating Medicare’s HACs in Medicaid’s policy is inherently complex because of population differences across programs. We fully understand that the HACs developed for Medicare’s population will not directly apply to various subsets of Medicaid’s population. While we have established Medicare as a baseline, we understand that States will, through their payment policies, appropriately address these differences.

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. For a list of the items considered, see the February 17, 2011 proposed rule (76 FR 9283, 9286 through 9287).

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 were 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. We have received helpful 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 were 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 HACs, 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 proposed to implement Medicaid HCAC regulations that would provide some consistency across health care payers (Medicare and Medicaid). At the same time, we also

proposed 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. The July 31, 2008 SMDL (#08-004) instructed States to submit SPAs to enact nonpayment provisions. Thirteen States submitted SPAs to include PPC related nonpayment provisions in their Medicaid State plans. 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

The final rule includes the umbrella term, "Provider-Preventable Conditions (PPC)" which is defined as two distinct categories, Health Care-Acquired Conditions (HCAC) and Other Provider-Preventable Conditions (OPPC).

Health Care Acquired Conditions:

- Apply to Medicaid inpatient hospital settings; and
- Are defined as the full list of Medicare's HAC, with the exception of Deep Vein Thrombosis/Pulmonary Embolism following total knee replacement or hip replacement in pediatric and obstetric patients, as the minimum requirements for States' PPC non-payment programs.

Other Provider-Preventable Conditions include the following:

- Apply broadly to Medicaid inpatient and outpatient health care settings where these events may occur;
- Are defined to include at a minimum, the three Medicare National Coverage Determinations (surgery on the wrong patient, wrong surgery on a patient, and wrong site surgery);
- Would allow States to expand to settings other than IH with CMS approval by nature of identifying events that occur in other settings; and
- Would allow States to expand the conditions identified for non-payment with CMS approval, based on criteria set forth in the regulation.

The final rule requires that States revise Medicaid plans to comply with this provision and mandates that States implement provider self reporting through claims systems. The final rule protects beneficiary access to care by eliminating States' ability to unduly impact providers for the occurrence of conditions identified. The final rule requires that:

- No reduction in payment for a provider preventable condition will be imposed on a provider when the condition defined as a PPC for a particular patient existed prior to the initiation of treatment for that patient by that provider.

- Reductions in provider payment may be limited to the extent that the identified provider-preventable conditions would otherwise result in an increase in payment; and the State can reasonably isolate for nonpayment the portion of the payment directly related to treatment for, and related to, the provider-preventable conditions.

While the Statutory effective date is July 1, 2011, CMS intends to delay compliance action on these provisions until July 1, 2012.

We proposed 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 acquired 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 quality of care, efficiency, and economy.

With the introduction of this term, we proposed to include two categories of PPCs—HCACs and other provider-preventable conditions (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 excludes the three Medicare NCDs. Additionally, the Affordable Care Act definition of HCACs only applies to the inpatient hospital 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. Section

1886(d)(4)(D)(iv) of the Act applies specifically to conditions applicable to inpatient hospital patients and reimbursed under the IPPS. We did look to the Affordable Care Act in creating the terms PPCs and OPPCs.

We did look to the Affordable Care Act in creating the terms PPC and OPPC. 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 potential 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" for use in Medicaid 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 proposed 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 related to PPCs 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 hospitals to report to CMS or the National Health Safety Network, but decided against this because of concerns about the capacity within these systems to accommodate State specific reporting of varied measures and the fact that this might not be consistent with what most States are currently requiring providers to report.

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 to avoid negative health outcome indicators.

In consideration of our research, we proposed a requirement that existing claims systems be used as a platform for provider self-reporting. We also proposed 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. 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.

II. Summary of the Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

A. General Discussion

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

We encouraged 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 proposed that PPCs are defined under two categories: HCACs and OPPCs. We proposed 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. We also noted 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.

We proposed to require that States implement requirements for provider self-reporting of HCACs in the Medicaid claims payment process. We also proposed 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.

We further proposed 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.

We received the following comments in response to our general discussion.

1. General Comments

Comment: One commenter expressed the view that the original Medicare HAC policy adopted by CMS in FY 2008 for hospitals subject to the Medicare Inpatient Prospective Payment System (IPPS hospitals), in response to the requirements of the DRA, was flawed policy and that many physicians disagreed with the notion that some of

the identified Medicare HACs are reasonably preventable. The commenter was opposed to extending these provisions to Medicaid and suggested that CMS abandon the notion of a nonpayment policy for HACs in both Medicare and Medicaid and replace it with a policy encouraging compliance with evidence-based guidelines.

Response: We disagree. The Medicare HAC payment policy was established under the authority of section 5001(c) of the DRA and has been in place since FY 2008. Section 2702 of the Affordable Care Act requires that CMS adopt similar regulations for the Medicaid program taking into consideration existing State practices and the appropriate application to the Medicaid program. This regulation, like the Medicare HAC rule that preceded it, was developed in direct response to the enactment of that provision. While we recognize that some of the PPCs are not entirely preventable and should therefore be excluded from the program. However, most of these PPCs are never events, which means they should never happen, in the first place, and they are entirely preventable if providers follow best medical practices. This is true regardless of whether a patient is a senior citizen on Medicare or a child on Medicaid. PPCs that used to be regarded as not entirely preventable, like CLABSI (or CAUTI), have been shown to be preventable by providers. We believe that the provisions of this rule will provide a strong incentive for the provider to apply best medical practice and seek innovative methods to prevent adverse outcomes. The HACs were adopted by Medicare through an evidence-based process. In addition, the definition used for OPPC in new § 447.26 provides that States must consider evidence-based guidelines in adopting optional PPCs.

Comment: Some commenters supported the policy of payment adjustment when conditions were demonstrated to be reasonably preventable based on the evidence, but thought that the population differences between Medicare and Medicaid may present distinct issues and considerations in considering events for nonpayment. Some commenters questioned the appropriateness of the application of Medicare HACs to Medicaid populations, specifically children and pregnant women.

Response: We agree that Medicare's population is generally different than Medicaid's and that those differences may present distinct issues and considerations. We realize that some categories of Medicare's HACs, like Surgical Site Infection following CABG

or Bariatric surgery, are not typically applicable to pediatric or obstetric populations because the underlying conditions associated with each of Medicare's HACs will not typically occur in those populations, thus limiting the frequency and relevance of the HAC. We reviewed each of Medicare's HACs and the related evidence-based prevention protocols to determine whether the final rule should specifically exclude any of the conditions identified by Medicare, with respect to populations more characteristic of Medicaid, particularly children and pregnant women. We considered each in relation to the following:

(1) *Clinical applicability.* That is, does this condition occur in pediatric and obstetric populations enough to significantly impact the populations or provider reimbursement?

(2) *Availability of evidence based guidelines appropriate for prevention for the pediatric and obstetric populations.* Are there bundles specific to preventing these conditions and infections in the pediatric and obstetric populations? If bundles do not exist, are there other bundles that can be appropriately applied to these populations?

(3) *Reasonable preventability.* Can the conditions or infections be reasonably prevented through the use of evidence based guidelines to warrant financial penalties? Our research determined that certain Medicare HACs, such as Foreign Objects Retained After Surgery, Air Embolism, Blood Incompatibility, Stage 3 and 4 Pressure Ulcers, Falls and Trauma, and Manifestations of Poor Glycemic Control, Catheter Associated Urinary Tract Infections, and Vascular-Catheter Associated Blood Stream Infections, are clinically applicable to all Medicaid populations, including children and pregnant women. We determined that there are evidence-based guidelines to support the reasonable preventability of these conditions in pediatric and obstetric populations, and that there is no indication that these prevention guidelines would cause harm if appropriately applied. There was no evidence to indicate that a provider adhering to these evidence based guidelines could not reasonably prevent these infections in every case in Medicaid populations.

Our research determined that Surgical Site Infection following CABG, Bariatric Surgery, or Orthopedic procedures is not typically applicable to children and pregnant women because it is not likely that these populations would be subject to some of the primary surgical

procedures. However, we determined that there are evidence-based guidelines to support the reasonable preventability of Surgical Site Infection following the specified procedures when they do occur in these populations.

Furthermore, there is no indication that these prevention guidelines would cause harm when appropriately applied. There is no evidence to indicate that a provider adhering to these evidence based guidelines could not reasonably prevent, though not absolutely prevent, these infections in every case in Medicaid populations.

Our research also determined that the Medicare HAC Deep Vein Thrombosis/Pulmonary Embolism (DVT/PE) as related to a total knee replacement or hip replacement is not a common occurrence for children or pregnant women because it is not likely that these populations would be subject to the primary surgical procedures of total knee replacement or hip replacement. We determined that evidence-based guidelines available support the reasonable preventability of DVT/PE in most cases, however, the related prevention protocols have not been proven appropriate for application in children and pregnant women. Therefore, we are not identifying the Medicare HAC, DVT/PE as related to total knee replacement, or hip replacement for pediatric or obstetric populations under Medicaid's PPC policy. We have revised the final rule to reflect this determination.

We remind commenters that the Medicare HACs serve as a baseline, and that States electing to expand their policies to consider other conditions associated with children and pediatric quality measures may do so through the SPA process. We encourage States to collaborate both with CMS and other States, as well as their provider communities and stakeholders like CDC and AHRQ to implement informed policies appropriate to their Medicaid populations. We will support State efforts and cross-educate, through the State plan amendment process and by providing information that we gather from States and other programs.

Comment: One commenter believed that the expansion of PPCs for Medicaid under the proposed rule goes beyond any previous guidance shared by CMS with the State during Affordable Care Act-related conference calls.

Response: Discussions held with the States, stakeholder groups and various provider communities regarding this policy were necessary to determine existing State practices regarding non-payment for health care-acquired conditions. They were informational for

CMS and did not in any way commit the Secretary to a particular policy direction. They were also a first effort in allowing States without existing policies to gather some general information from and network with States with existing policies.

The final regulation incorporates conditions identified as Medicare's HACs, with the exception of DVT/PE as related to total knee replacement and total hip replacement for pediatric and obstetric populations, and 3 NCDs as the minimum requirement for State PPC nonpayment policies. The rule allows States the flexibility, if desired, but does not require, States to identify additional conditions as PPCs under their Medicaid programs. Additionally, States have already begun to develop PPC-related non-payment policies and this rule would allow that work to continue.

Comment: A few commenters believed that there was not sufficient time to implement these provisions for providers that had not already been subject to Medicare's policy, and were particularly concerned with the implementation timeframes for reporting.

Response: We anticipate that States and providers, especially those groups of providers that have not been subject to Medicare's HAC policy, will need to work collaboratively to develop policies and implement reporting systems that would complement existing payment structures. We believe given the timeframes involved and the need for States to provide guidance to providers, it would be appropriate to delay compliance action on the provisions of the rule until July 1, 2012.

Comment: One commenter requested that we strike § 447.26(c)(4) because they believed the access requirements proposed there were already reflected in 447.204 which requires that payment be sufficient to assure beneficiary access. The commenter thought that any dual interpretations could lead to unwarranted litigation risks.

Response: We thank the commenter for this comment. We have revised the language at 447.26(c)(4) to clarify that, "A State plan must ensure that non-payment for provider-preventable conditions does not prevent access to services for Medicaid beneficiaries."

2. Conditions Identified and Providers Affected

Comment: Some commenters pointed out that Medicare's HAC policy applies only to Medicare IPPS hospitals. These commenters believed that CMS should limit Medicaid PPC payment restrictions to Medicaid participating hospitals that are similar to Medicare

IPPS hospitals. Other commenters asked for clarification on this same point. Most of these commenters also believed that we should limit States ability to identify other PPCs, proposing that the set of Medicare's HACs and 3 NCDs be used as a ceiling instead of as a floor for Medicaid's PPC policy.

Response: The Affordable Care Act requires that HACs identified under the Medicare IPPS are applicable to all entities that operate as Medicaid inpatient hospitals. We do not have the authority to exempt any Medicaid inpatient hospital providers from these requirements. States currently have the authority to extend PPC-related non-payment policies to other conditions.

Comment: Some commenters objected to the entire category of OPPC (affecting providers other than hospitals) included in the proposed regulation. Commenters recommended that CMS consider and impose a number of parameters related to States' implementation and selection of the OPPC category.

Response: In preparing this regulation, the Statute required that CMS consider existing State practices and determine whether, as a matter of policy, it was appropriate to include those established practices in these final regulations. We determined that, in some instances, States had implemented provisions that applied to providers in settings other than inpatient hospital settings, including outpatient hospital settings. We did not believe that it was prudent to require of all States what had been done in a few, but we wanted to provide States the flexibility to do so. Accordingly, we designed the PPC provisions to allow the expansion of State policies to other care settings, and other conditions. In light of the differences between the types of participating providers and the enrollee populations in Medicare and Medicaid, we provided flexibility for States in the identification and application of OPPCs. We anticipate that States will consider arguments made by particular providers that these OPPCs should be defined so that they do not apply to them. We believe this is the appropriate forum for consideration of the unique circumstances of particular providers.

Comment: Some commenters recommended that we consider the benefits of and establish a nationally consistent set of conditions identifiable as PPCs for Medicaid.

Response: We determined that the conditions identified as Medicare's HACs, with the exception of DVT/PE as related to total knee replacement and total hip replacement for pediatric and obstetric populations, and 3 NCDs are appropriate to serve as the baseline for

Medicaid's PPC policy. We are strongly committed to permitting State flexibility to innovate in this area. State innovation has been a significant driver of Federal policy, and States have direct experience with utilization and claims review with respect to Medicaid services.

Comment: Some commenters suggested that the initial set of conditions be more limited and targeted, and that they be expanded incrementally over time.

Response: 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." The provision also allows the Secretary to exclude conditions not appropriate for application in Medicaid. As such, the final regulation incorporates conditions identified as Medicare's HACs, with the exception of DVT/PE as related to total knee replacement and total hip replacement for pediatric and obstetric populations, and 3 NCDs. Additionally, we believe that the flexibility provided States in developing additional PPCs, beyond those established as the floor in the final rule, allow for the type of incremental expansion of this policy that the commenters suggest.

Comment: Other commenters recommended that Medicaid PPCs focus on conditions specific to the Medicaid population. A few commenters offered that it would be ideal for CMS to evaluate other Medicaid specific conditions that would apply specifically to pregnant women or children.

Response: We believe that the flexibility provided States in the final rule will facilitate the development of additional Medicaid specific conditions to be identified for nonpayment. Some State Medicaid programs with existing policies have identified conditions specific to certain populations like Obstetrical Hemorrhage with Transfusion, which is a condition specific to pregnant women. We encourage States to follow CMS's example in identifying conditions by working with provider communities and industry partners.

Comment: A few commenters suggested that CMS coordinate Federal PPCs policies across agencies and with other organizations developing quality measures specific to Medicaid populations.

Response: We are actively working to coordinate with other health reform initiatives such as the pediatric core quality measures, accountable care

organizations, and health insurance exchanges to develop coordinated Federal policy in the area of Health System Quality. We continue to collaborate with States, providers, and other stakeholders to inform policy decisions related to this area.

Comment: Some commenters stated that any extension of PPC beyond the hospital setting was premature, and emphasized that application of PPC to other providers was not feasible because of the different patient populations, payment structures and conditions that applied in different environments. These commenters stated unique issues in various provider settings including long-term care settings, dialysis clinics, and skilled nursing facilities.

Response: We disagree with the point that the PPC provisions should be limited to the hospital environment. This rule requires that States adopt minimum requirements for each category of PPC. States have the flexibility to identify additional OPPCs if desired, but there is no requirement to do so. Many States have already identified conditions beyond the minimum requirements in this final rule. We understand clearly that the category of OPPCs would allow expansion beyond the hospital environment and must be done in close consultation with affected providers and limited to situations where a State has made a finding that the condition could reasonably have been prevented in ordinary cases. We have revised regulatory text to make clear that these are State determinations that must be made based on State findings that the condition is reasonably preventable using procedures supported by evidence-based guidelines. The identification of PPCs in settings other than the hospital setting makes sense because, from the perspective of the patient, it matters very little whether a wrong site surgery occurred in a hospital, an ambulatory surgery center, or in a minor surgery done in the physician's office. Moreover, States have already gone beyond the hospital setting in their individual PPC policies. All that this Federal regulation adds is the HCAC category which requires nonpayment for the full list of Medicare's HACs, with the exception of Deep Vein Thrombosis/Pulmonary Embolism following total knee replacement or hip replacement in pediatric and obstetric patients and the OPPC category which requires the minimum mandatory inclusion of what are now the three Medicare NCDs: Surgery on the wrong patient, wrong surgery on a patient, and wrong site surgery. We are simply replicating the

mandatory provisions in the Medicare program, and adding these to the existing State flexibility under Medicaid to establish payment and quality standards.

We encourage States to collaborate both with CMS and other States, as well as their provider communities and stakeholders like CDC and AHRQ to implement informed policies appropriate to their Medicaid populations. We will support State efforts and cross-educate, through the SPA process and by providing information that we gather from States and other programs.

Comment: A number of commenters requested that CMS clarify that the HCAC category applies only to inpatient hospitals.

Response: This final rule has revised regulatory language to clarify that the HCAC category applies to all inpatient hospital settings under Medicaid. The OPPC category minimum requirements (Medicare's 3 NCDs) are applicable in any healthcare service setting where these events may occur.

Comment: One commenter expressed concern that expansion of PPC to nonhospital providers threatened the access of Medicaid beneficiaries to care. In particular, the commenter asked CMS to clarify that Medicaid payment disallowance for PPC would not apply when the PPC was present at the time the provider commenced treatment of the patient.

Response: The language in the proposed regulation was intended to cover only situations where payment reduction was being applied to treatment for a condition not present on admission or commencement of treatment by that provider. However, we understand that clarifying the language of the regulation to emphasize this point would be helpful and have done so in this final regulation. New § 447.26 (c)(2) explicitly states that “* * * no reduction in payment for a PPC will be imposed on a provider when the condition defined as a PPC for a particular patient existed prior to the initiation of treatment for that patient by that provider.” This was implied in the previous language, but has now been made explicit. CMS agrees with the comment and is providing this clarification.

CMS disagrees with the commenter's point that the expansion of State PPC policies beyond the hospital environment will limit access. We understand clearly that expansion beyond the hospital environment must be done in close consultation with affected providers and limited to situations where a provider could

reasonably have prevented the PPC. However, from the perspective of the patient, it matters very little whether a wrong site surgery occurred in a hospital, an ambulatory surgery center, or in a minor surgery done in the physician's office. Moreover, as the commenter notes, States have already gone beyond the hospital setting in their individual PPC policies.

Comment: One commenter requested that CMS provide States additional guidance on applying the Medicare HAC criteria to Medicaid providers and conditions. This commenter believed that we should partner with States to have continued dialogue on evidence-based guidelines.

Response: As stated throughout the rule, we intend to continue dialogue with States and other Agencies related to this issue.

3. PPC Terminology

Comment: A few commenters believed that the distinctions among the terms in the proposed rule were confusing and made it difficult to understand which term applied to which criteria.

Response: We have revised the regulatory text to clarify that PPCs are clearly defined into two separate categories, HCACs (conditions identified as Medicare's HACs (with the exception of DVT/PE following total knee replacement or hip replacement in pediatric and obstetric patients) for IPPS purposes, applied broadly to Medicaid inpatient hospitals) and OPPCs (conditions applicable in any healthcare service setting minimally defined as Medicare's 3 NCDs).

Comment: A few commenters objected to the use of the term PPC. One proposed the use of the alternative term “Preventable Healthcare Related Conditions.” The commenters noted that one proprietary organization is currently utilizing the acronym PPC for “Potentially Preventable Conditions.”

The commenters also questioned our use of the term other provider preventable condition and stated their biggest concern was with creating a new term that encompassed 3 NCDs so closely related with the NQF's “Serious Reportable Events in Healthcare.” The commenters recommended that CMS not create explicit category titles under the PPC umbrella term.

Response: As stated in the preamble, the designation of these terms is necessary to a policy that meets statutory requirements in setting Medicare's policy as the minimum and allowing States the flexibility to expand beyond that minimum. We do not believe that the term PPC has been

narrowly defined across the industry to include a specific set of policy provisions as would be required by this final rule. In addition, we do not believe that the use of the PPC acronym will infringe on any proprietary organizations' ability to continue to use that acronym. We have not made any revisions to this final rule to reflect this comment.

Comment: One commenter had questions regarding the definition of OPPC. The commenter questioned which evidence-based guidelines would be used and recommended that the regulation be expanded to include exact definitions of the guidelines.

Response: It would be difficult to determine a singular set of guidelines to be identified for the various conditions that States may identify under these provisions. The rule provides States flexibility in determining the conditions identified for nonpayment under their individual State plans. As States submit plans for approval, we will evaluate the conditions proposed by States and determine their appropriateness for the Medicaid program. Additionally, we would remind commenters that the Secretary has the authority to revisit these provisions and may do so as this policy area develops. We reject the commenters recommendation and have made no changes to the final provisions regarding this issue.

Comment: Many commenters recommended that more research be done by Medicare and Medicaid on applying PPC nonpayment policies to outpatient settings before conditions that occur in those settings are incorporated into PPC nonpayment policies or expanded. Some commenters objected to the designation of the 3 NCDs as a baseline for the Medicaid policy.

Response: Medicare is conducting additional research to inform its policy on applying its HAC provisions beyond its IPPS hospitals. In preparing this regulation, CMS was required to consider existing State practices and determine whether, as a matter of policy, it was appropriate to include those established practices in these final regulations. We determined that, in some instances, States had implemented provisions that applied to providers in settings other than inpatient hospital settings, including outpatient hospital settings. We did not believe that it was prudent to require of all States what had been done in a few, but we wanted to provide States the flexibility to do so. Accordingly, we designed the PPC provisions to allow the expansion of State policies to other care settings, and other conditions. We agree that States

should do additional research to evaluate the impact of applying nonpayment policies in outpatient settings before adopting such policies. It should also be noted that States with existing policies that do not meet the minimum provisions of this final rule and those without existing policies will need to submit for CMS approval SPAs implementing these policies.

The three events that we are requiring that States include in their OPPC are those events which already trigger payment reductions in the Medicare program as national coverage determinations (NCDs). In the Medicare program, NCDs are already applied to all providers, not just to specified hospitals. Medicare NCDs are detailed, evidence-based determinations that are supported by substantial data. Therefore, inclusion of these three events merely replicates evidence-based determinations that are already in effect in the Medicare program.

Comment: One commenter stated that the expansion of State PPC policies into non-inpatient settings will be extremely difficult to implement due to the very characteristics that are inherent to the outpatient setting, such as: The types of care and services provided; numerous providers and provider-types involved in care; periodic episodes of care provided by numerous providers over lengthy periods of time; and lack of systems and infrastructure to adequately coordinate care between visits and providers, among others. The wide variety of payment systems create enormous challenges for provider reporting, according to this commenter.

Response: We are encouraging States to work with provider communities and other stakeholders to carefully examine nonpayment policies in non-inpatient settings. Additionally, we are requiring that States submit for approval Medicaid State plan amendments that would implement PPC nonpayment policies. To support these Medicaid State plan amendments, we are clarifying that the State must have made findings that the proposed PPC is reasonably preventable through the application of evidence-based guidelines. The SPA review process will give CMS and providers the opportunity to consider State policy before it is implemented and to provide guidance and input based on our knowledge of the issues.

4. POA and Coding Systems

Comment: Several commenters objected to the burden of creating a POA system and the potential for variation in the different State PPC policies. Commenters are concerned that the

POA requirement and its impact on reimbursement may result in extraneous testing, delayed care, and further access issues for Medicaid patients. In emergency situations, it is often impossible to provide optimal patient care and simultaneously determine POA status, it was noted. One commenter also noted that many hospitals were not familiar with the intricacies of POA coding and would require CMS guidance and time to implement it.

Response: The POA system is not required by this final regulation, but obviously providers will need to carefully document the physical status of their patients on admission. That documentation is not simply done for legal purposes, but serves the legitimate medical purpose of allowing for careful evaluation the patient's condition prior to treatment and communicating that information to members of the treatment team. Ultimately, the provider will self-report PPCs to the State. The State may choose to verify this by a POA system or by other methods.

Comment: One commenter disagreed that relying on record review with the "Global Trigger Tool" to detect what is present on admission will be effective in detecting POA. The commenter requested clarification on the method and asserted that it is not CMS's responsibility to determine POA retrospectively. The commenter opined that since CMS is not the patient's care provider, this would be bureaucratic over-reach into the patient-provider relationship.

Response: We agree with the commenter that it is not CMS's responsibility to determine the POA status of a patient. The "Global Trigger Tool" is a tool by which providers would use a series of "triggers" to determine the possible occurrence of an adverse event and indicate further review of a particular case. Neither the proposed rule, nor this final rule include any requirement that a provider implement the use of the "Global Trigger Tool." We do suggest that our research indicates that this tool may be useful in identifying the occurrence of PPCs, as well as others like nursing reviews or concurrent utilization reviews.

Comment: One State commented that the POA indicator is a very useful resource to identify the specific hospital where an adverse event occurred.

Response: We thank the commenter for this information.

Comment: One commenter was concerned with the use of the POA indicator being applied to pediatric populations because it may be hard to determine whether a child entered an emergency department with an

asymptomatic yet incubating infection. This commenter recommended a study be done to determine whether the incubation period in a child is different from an adult because the information would influence the determination of POA in certain cases.

Response: The POA system is not required by this final regulation, but obviously providers will need to carefully document the physical status of their patients on admission. That documentation is not simply done for legal purposes, but serves the legitimate medical purpose of allowing for careful evaluation the patient's condition prior to treatment and communicating that information to members of the treatment team. Ultimately, the provider will self-report PPCs to the State. The State may choose to verify this by a POA system or by other methods.

In regard to the study of the incubation period of infections in children versus adults, the purpose of this rule is to deny Medicaid payment for PPCs. States will be required to submit SPAs to implement these policies, however, aside from the minimum requirements in the rule States have flexibility in determining how to implement the related provisions, including the conditions identified for nonpayment. That being said, we recognize the inherent differences between the Medicare and Medicaid populations and would note that a major consideration for allowing States such flexibility in the OPPC category is the idea that States will be able to work with their provider communities and industry partners to further consider the unique situation of Medicaid beneficiaries within each State. We realize that for children's hospitals and pediatric populations there are a number of conditions that could be otherwise identified. We believe that States, working with their provider communities, are in a better position to develop additional conditions specific to their Medicaid populations and programs. We continue to believe that innovations should be shared across programs and States. As information becomes available, we will share implementation examples with States. We also encourage States to collaborate in this policy area.

Comment: One commenter recommends that States consistently adopt the ICD-9-CM and ICD-10-CM codes as the only diagnostic standard for identifying conditions for purposes of Medicaid payment. According to this commenter, it would be administratively burdensome for providers, as well as result in lack of data comparability across Medicare and

Medicaid programs, to allow Medicaid programs to use alternative coding systems or their own method for identifying each PPC.

Response: We agree that the ICD-9-CM and ICD-10-CM codes present a reasonable alternative to developing and implementing unique diagnostic codes for the purposes of this provision. We encourage States to explore the use of the ICD-9-CM and ICD-10-CM codes for purposes of identifying PPCs under their existing programs.

Comment: One commenter expressed concern over identifying additional costs associated with an adverse event that occurs in a same day surgery center, a skilled nursing facility or a clinic. The commenter reported that it would be very difficult to identify the clinic or facility as the cause of the adverse event because they are not reimbursed through a DRG payment system. The commenter notes that its claims system would not isolate claim lines related to the adverse event to distinguish them from appropriate services.

Response: We appreciate the response. We understand the difficulty that States may face in applying this policy in settings other than inpatient hospital settings, but note that some States have managed to apply these policies quite broadly and successful quality outcomes have resulted. We encourage States to evaluate their populations and work with their provider communities to explore the possibilities of expanding PPC policies to non-inpatient hospital settings to support States efforts to improve the quality of care in their overall health systems.

Comment: One State with hospitals exempt from Medicare IPPS payment under 1814(b)(3) of the Act noted that its existing PPC policy, which started in 2008, has resulted in a 12 percent decrease in measured hospital complication rates with associated cost reductions of \$62 million which were subsequently redistributed within hospitals in that State. The State praised CMS for allowing State flexibility in developing PPC policy and outlined planned State initiatives in reducing preventable readmissions. This State also noted that since its policy is considerably expansive, it should be exempted from this final rule.

Response: We do not have legal authority to exempt any State from the statutorily required provisions. We disagree with the suggestion that a States existing policy should exempt a State from the requirements of this final rule. The provisions of the final rule are drafted to allow States flexibility in developing individual PPC policies,

while adhering to the minimum requirements set forth. While we appreciate the innovative nature of State programs, we believe that it is necessary for all States to appropriately amend their Medicaid State plans to comply with Federal law. This will also enable other States to learn and be better informed.

We also believe that this comment illustrates the value of the Federal-State partnership in Medicaid. Many of the ideas used in this regulation were originally developed by State Medicaid programs interested in improving the quality of care received by their Medicaid beneficiaries. States, like other stakeholders in the Medicaid system, share a common interest in the development of safe, efficient Medicaid systems which serve their beneficiaries. A common goal for CMS, States, providers and patients is the pursuit of better outcomes for individuals and populations, while reducing unsustainable costs through improved quality of care. The pursuit of this common goal strengthens not only Medicaid, but the entire American health care system.

Comment: Some commenters were strongly supportive of the approach taken by the proposed regulation. The commenters endorsed the use of the Medicare HAC as Medicaid HCAC and the provision of flexibility to States through the SPA process. In particular, one group favored the preservation of State ability to define PPC which occurred outside of hospitals and the three federally required OPPC. This commenter stressed the value of required State reporting systems and suggested public posting of such data after appropriate risk-adjustment and data validation. The comment also noted the importance of CMS monitoring to assure that the PPC policy had no adverse effects on beneficiary access to care.

Response: We appreciate the commenters' support. We will monitor the implementation of the final rule to assure that beneficiary access to care is not impaired.

5. General Comments

Comment: One commenter believes that the proposed rule is inconsistent because it states that hospitals will need additional infection control staff to prevent or reduce PPCs and that hospitals already have programs in place. The commenter also asks for clarification on whether the implementation cost estimates are academic or provided by hospitals.

Response: The commenter is taking these two points out of context. In the

preamble to the proposed rule in discussing options considered for reporting requirements we say, “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.” Later in the proposed rule where we discuss the regulatory impact analysis we state, “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.” There are hospitals that have existing programs. There are also hospitals that will need to use additional resources to meet State requirements. This will be determined by each individual hospital depending upon its existing resources. The estimates are based on our experience with the implementation of like provisions through the SPA process, as well as Medicare’s experience implementing its HAC policy.

Comment: Commenters were concerned that States would be too expansive in defining outpatient PPCs and noted that, in the outpatient area, there is limited provider control and patient compliance issues are essential.

Another commenter expressed concern that the provisions would allow States to identify conditions not based on accepted medical standards. It noted that, in its State, the automated Medicaid claims system used by Medicaid health plans had limited ability to report out or adjust for PPCs. The commenter was critical of the short timeline for compliance and expressed concern that, in the dual eligible category, there was a possibility of double payment reduction.

Response: We note that an OPPC must be supported by a finding by the State that it “could have reasonably been prevented through the application of evidence-based guidelines.” To address this comment, we have strengthened this language to require that the finding be based on a review of medical literature by qualified professionals. As a result, States PPCs will not be able to

identify a PPC without a strong basis to do so, and we do not anticipate great variation between States over time.

We are requiring that the providers self-report PPCs, at which time the health plan or State can, upon receipt of the self-report, make an appropriate payment correction. We believe that, once providers have put in place systems to track and report PPCs, they will be able to use this information to reasonably reduce the incidence of these defined events in their facilities. For dual eligibles, the intent of this rule is that no payment would be available under either Medicare’s IPPS or Medicaid for an identified HAC. We do not view this as a “double payment reduction” but as a consistent nonpayment policy. State Medicaid agencies have repeatedly expressed to CMS their concern that, with dual eligibles, the impact of a Medicare HAC denial was often that the provider would simply bill Medicaid as a secondary payer. This would result in no denial of payment even when a Medicare HAC occurred. Indeed, that complaint from State Medicaid agencies is one of the reasons that, in this regulation, we are attempting to coordinate Medicare and Medicaid policies.

Comment: Several commenters suggested that we develop a set of standard definitions that account for provider setting and other evidence-based factors that can be applied across health care settings and across State lines. Some also suggested that we remove the option providing States the ability to include any HCACs or OPPCs beyond those required by Medicare to encourage State-to-State uniformity.

Response: Medicaid is a State-administered program. By setting Medicare’s hospital IPPS HAC policy as the base policy, we are encouraging uniformity across the two programs while simultaneously allowing States to retain the flexibility that is statutorily-afforded to them under title XIX of the Act.

Comment: One commenter questioned what would prevent hospitals from spreading the cost of nonpayment for PPCs out among all health care consumers. The commenter suggested that CMS institute an incentive system by implementing a pre-paid provider incentive pool rather than a nonpayment system.

Response: The purpose of this regulation is to establish rules that would prevent Medicaid from paying for HCACs resulting from provider error and to encourage quality-based reimbursement. Hospitals will continue to be paid for the services provided. If

a patient enters the facility for a surgical procedure and in the process of that procedure a HCAC occurs, the hospital will receive payment for the initial surgical procedure but will not receive payment for services provided in addressing the HCAC. That being said, this final rule sets out broad parameters for allowing States to design PPC policies that complement their current systems. If a State is able to develop a system that complies with the requirements of this final rule through an incentive based program, we welcome the opportunity to review it as part of a SPA and share it with other States as appropriate.

Comment: Some commenters asked CMS to provide in the final rules specific guidance to States regarding the inclusion of additional preventable conditions; for example, issue specific, evidence-based parameters for defining “preventable” with consideration for issues like patient noncompliance. Other commenters provided specific conditions that they did not believe States should identify for nonpayment in their PPC policies. The commenters had various reasons for objecting to States’ inclusion of these conditions based on patient population, facility type, and administrative burden.

Response: The final rule does not require that States include other provider preventable conditions, but provides States with the option to do so. By allowing States to develop these programs through State plan amendments with the participation of the provider community, we believe that concerns such as this will be addressed at the State level.

Comment: One commenter highlights the fact the PPCs program’s impact on States includes the administrative and financial burden of building and maintaining data collection systems, not to mention the reality that State Medicaid programs are run by public administrators who may not have training or experience in clinical issues, comparative effectiveness research, and other factors that are critical when making payment restriction decisions.

Response: We agree that States may need to employ additional resources to implement a PPC policy, just as with any other payment policy implemented by States. The minimum requirements under this final rule are designed to minimize the administrative burden on all stakeholders. The PPC policy is designed to use existing data systems to identify conditions as they occur. We encourage States and providers to work together to craft comprehensive PPC nonpayment and reporting policies that are reasonable and effective.

Comment: One commenter noted that payment reductions for those hospitals that have a high burden of Medicaid and Medicare patients will challenge their ability to stay open at current capacity if they suffer significant payment reductions due to the new rule. Critical access hospitals may be the most vulnerable due to the lack of infrastructure to analyze their own data and develop corrective actions prior to the actual payment reductions, according to the commenter.

Response: Hospitals will continue to be paid for the provision of high quality care under the final rule. The Affordable Care Act requires that HACs identified under Medicare IPPS rules are applicable to all entities that operate as Medicaid inpatient hospitals. We do not have the authority to exempt any Medicaid inpatient hospital providers from these requirements.

Comment: One commenter noted that under Medicare, the cost savings seems relatively low as it pertains to all of the HACs, which is the baseline for this policy under Medicaid. According to this commenter, there is very little data to suggest that the savings under Medicaid would be greater even if the OPPCs are included. The commenter recommend that CMS take a slower approach to broadening the HCAC policy by expanding from the Medicare HACs over a longer period of time to evaluate the savings from nonpayment for HCACs under the Medicaid program.

Response: The purpose of this regulation is to drive quality care, it is not a cost savings exercise. We recognize there may be some cost savings and that it may take some time to realize the full extent of the cost savings, but this measure is important for the long-term benefit of the Medicaid program, Medicaid beneficiaries, and the health care industry as a whole. We intend for these provisions to be a catalyst for change where the infrastructure for quality measurement, as well as the methods for improvement that should be built into our system, are not currently in place.

Comment: One commenter wrote to share its success in quality improvement within a particular State. The commenter reported various collaborations that it has undertaken with its State and other stakeholder organizations resulting in delivery system innovations have proven valuable and efficient.

Response: We appreciate this comment and commend the commenter for taking the necessary steps to improve care to its beneficiaries. We encourage other States and

organizations to innovate in the same way.

Comment: One commenter recommended that national clinical consensus should be a component of the criterion as to whether a condition is "reasonably preventable."

Response: We agree that a finding as to whether a condition is "reasonably preventable." must be based on a solid basis in national medical literature, as determined by qualified professionals. Therefore, we are retaining and strengthening the portion of the OPPC definition from the proposed rule that requires that conditions identified by States must be supported by a finding that the conditions, "could have reasonably been prevented through evidence-based guidelines." We are adding that this State finding must be based upon a review of medical literature by qualified professionals. We believe that this stronger language will ensure a level of integrity and consistency in these determinations.

Comment: One commenter believed that Medicare has determined and will continue to determine, with the help of evidence-based guidelines, what is "reasonably preventable and what are "never events," and that this should be the standard across all regions of the country because there would not be any benefit to the population of beneficiaries for one state to have different quality health standards including for payment consideration.

Response: The work that Medicare has done in the process of developing its IPPS HAC policy is valuable and consistent. Adopting this work on a national level will benefit States and beneficiaries. This is part of the reason the final regulation incorporates conditions identified as Medicare's HACs, with the exception of DVT/PE as related to total knee replacement and total hip replacement for pediatric and obstetric populations, and 3 NCDs as the foundation of the Medicaid policy to be applied in States.

Comment: One commenter believed, in regard to flexibility as to the grouper that each State selects to use to process HCAC, that to achieve consistency there needs to be limits placed on the choice. Also, States need to be using the current HIPAA administrative code set versions that Medicare uses. This commenter also supported the standardization of public domain groupers to help reduce the cost to healthcare providers and States.

Response: States have great flexibility in designing their own payment systems and working with their provider communities in determining how best to implement these provisions. We do not

intend to restrict that flexibility with this final rule. We note that not all States reimburse providers using grouper methodologies. In regard to the adoption of the standardization of public domain groupers, we appreciate this comment, but it is outside the scope of this rule.

Comment: Many commenters recommended that we revise Medicare's HAC list to include or eliminate various conditions.

Response: We thank the commenters for their input. However, revisions to Medicare's IPPS HAC list are outside the scope of this rule.

Comment: Some commenters wrote requesting clarification of or on the application of Medicare's HAC list.

Response: The commenters' requests are outside the scope of this rule. We refer the commenter to the Medicare HAC page located at http://www.cms.gov/HospitalAcqCond/02_Statute_Regulations_Program_Instructions.asp#TopOfPage.

6. State Plan Amendments

Comment: One State noted that the preamble (see 76 FR 9289) proposes that States would be required to amend their Medicaid State plans to match any changes to Medicare's final IPPS rule that Medicare publishes 60 days prior to the beginning of the next Federal fiscal year. The State commented that 60 days does not allow enough time to identify ways to capture the data and program and test changes to the payment system. The State suggested that CMS clarify that a State could comply by the submission of a State plan amendment by the end of the Federal quarter in which the change takes effect, that is, by the end of the first quarter of the next Federal fiscal year.

Response: The Medicaid SPA process requires that States submit amendments to their Medicaid plans no later than the last day of the quarter in which the amendment would take effect. We have developed a State plan preprint that outlines the minimum provisions of this final rule and allows States the flexibility to identify OPPCs for nonpayment in their Medicaid State plans. States will define the related payment methodologies within the appropriate sections of their Medicaid State plans.

7. Reporting Requirements

Comment: One commenter recommended that reporting requirements be included in States' provider policies and included in provider contracts.

Response: As discussed in the proposed rule, a reporting component is

essential to building an effective PPCs policy for a number of reasons, including State and CMS ability to capture data related to these occurrences. We believe that States will need to work with their provider communities to implement an appropriate reporting system.

Comment: One commenter supports the requirement that existing claims systems be used as a platform for provider self-reporting because it is essential that their nonpayment policies are based on data provided through their claims systems.

Response: We thank the commenter for support on this issue.

Comment: One commenter remarked that provider self-reporting procedures should require providers to report conditions identified for nonpayment when they occur, regardless of the provider's intention to bill. Hospitals and providers have a clear incentive not to report quality errors beyond nonpayment provisions, according to the commenter. CMS must take a strong stance against underreporting and apply strict penalties. Another commenter requested that CMS clarify that States would be required to submit provider self-reporting data to CMS.

Response: In Medicaid, States are given a large degree of flexibility under title XIX of the Act. As such, providers submit Medicaid claims to States and not CMS. While we are requiring that States implement self-reporting requirements, States have the ability under the statute to determine how they will implement these requirements with input from the provider communities. Once data is collected at the State level, States will submit that data to CMS as part of their standard procedure for collecting and sharing Medicaid provider claims data.

Comment: Several commenters supported provisions in the proposed rule that would require States to implement provider self-reporting requirements through the claims submission processes.

Response: We agree and have retained these provisions in the final rule.

Comment: A few commenters believe that providers will be overburdened with the reporting requirements under this new regulation. Additionally, they disagreed with how long it would take States to develop and implement reporting requirements.

Response: The provisions of this final rule require reporting through State claims systems because they are existing resources that are routinely and regularly modified to accept State payment adjustments for other provisions. Most providers subject to

the minimum requirements of the final provisions will be familiar with when and how to report these conditions. In States with existing policies, there are already these types of reporting requirements for payment purposes. And, States electing to go beyond the minimum requirements of these provisions will need to work with their provider communities to ensure that all aspects of the provisions can be sufficiently implemented. Provider reporting is necessary to ensure that the payment preclusion is effective in eliminating PPCs, or determine whether additional measures may be required, or whether the measures applied are necessary.

Comment: One commenter requested clarification on the purpose of provider reporting and how CMS expects States to use reported information. Another commenter noted that there is no clear provision on how States are to report this data to CMS. One State asks whether the SPA will have to specify how the reporting will be done, or if States will need to assure that they will comply with the requirement.

Response: We are requiring that States impose provider self-reporting through claims systems because that information will be used to determine when a PPC occurred and trigger State payment action. The data will also be fed by States to CMS. CMS and States will use this data to inform policy making.

Comment: One commenter noted that the proposed rule requires States to establish a provider reporting requirement for PPCs. The commenter asked what the parameters will be for those guidelines and how much latitude CMS will give to the States.

Response: As a requirement of the final rule, States will implement the provider self-reporting through payment claims systems regardless of the provider's intention to bill. We are working to ensure that States consistently report at least the minimum requirements of the rule through the Medicaid Management Information Systems (MMIS). We anticipate that States and providers, especially those groups of providers that have not been subject to Medicare's HAC policy, will need to work cooperatively to develop and implement reporting systems that would complement existing payment structures. As discussed in the proposed rule, a reporting component is essential to building an effective PPCs policy for a number of reasons, including State and CMS ability to capture data related to these occurrences.

8. Medicare and Medicaid Dual Eligibles

Comment: One commenter supports nonpayment for all PPCs as they pertain to the dual eligible population. This commenter urges CMS to codify provisions that prohibit Medicaid claim payment for claims that have been denied by Medicare based on the presence of a HAC.

Response: We agree. This is a significant area of concern, and we have revised the final regulation to reflect that no FFP is available for a Medicare denied claim based on the presence of a HAC, "A State plan must provide that no medical assistance will be paid for 'provider-preventable conditions' as defined in this section; and as applicable for individuals dually eligible for both the Medicare and Medicaid programs."

Comment: Some commenters requested clarification on how these provisions would apply to Medicare cross over claims. Commenters wanted clarification on how to determine that Medicare has rejected a HAC claim for an individual dually eligible for Medicare and Medicaid.

Response: We agree that the proposed provisions lacked clarity in the application to individuals dually eligible for Medicare and Medicaid. We have revised the final rule to provide clarification. States may determine that Medicare has reduced payment based on the provisions of its HAC policy by working with their Medicare Fiscal Intermediary to identify the appropriate codes related to treatment for dually eligible individuals. Reference materials regarding POA coding for Medicare HACs may be found at https://www.cms.gov/HospitalAcqCond/05_Coding.asp#TopOfPage

To support State efforts, we will work with the Federal Coordinated Health Care Office to provide guidance on this issue.

9. Managed Care

Comment: One commenter wrote in support of the provision requiring States to modify their managed care contracts to reflect the PPCs payment adjustment.

Response: We agree and are retaining requirements that States include PPC payment restrictions in managed care contracts. All providers should be held to these quality standards and the final rule retains these requirements.

Comment: One commenter requested clarification of the expectation for MCOs to refund money derived from the nonpayment of PPCs back to States.

Response: We anticipate that savings gained from the application of State PPC policies to their managed care providers

will, ultimately, be factored into the individual contract rates established with those providers.

Comment: One commenter requested clarification that the amendments to § 434.6 do not apply to MCOs, and further, that the MCO contracts with providers will not have to require providers to report PPCs associated with claims to the MCOs.

Response: On its own, the provisions of § 434.6 do not apply to MCOs; however, by cross-reference, we are applying the specific provision in § 434.6(a)(12) regarding PPCs to MCO contracts. We do intend that MCO contracts with providers, identical to Medicaid State agency's contracts with providers, require those providers to report PPCs associated with claims to the MCO. Further, so that the Medicaid State agency will be able to quantify and report, if necessary, information on all PPCs in the Medicaid program, we expect that MCOs will track PPC data and make it available to the State upon request. Accordingly, we are modifying the proposed § 438.6 to clarify both intentions.

Comment: A few commenters requested that CMS provide guidance for States on how to apply the nonpayment requirement for HCACs to capitation payments, specifically those under § 438.6. Additionally, the commenters requested information on how these policies would apply to the development of actuarially sound rates.

Response: We believe that the implementation of State PPCs policies will be consistent with what we anticipate in the fee-for-service setting and have only minimal impact on provider payment and therefore the development of actuarially sound rates. However, as the MCOs spend less money on services, that decrease will be reported to the State which will in future rate-setting reflect the reduced expenditures in the rate setting. States will need to work with their MCOs to develop appropriate policies within their contracts.

Comment: One commenter recommended that CMS reinforce the importance of State compliance with the requirement that Medicaid managed care rate setting must be actuarially sound.

Response: The requirements of this final rule do not in any way preempt regulatory provisions otherwise in effect. We urge States to work with all of their provider communities to determine the best ways in which to implement related nonpayment policies.

10. Comment Period

Comment: A few commenters objected to the 30-day comment period. One commenter proposed that CMS issue a final rule with comment period to accept additional public comment and to provide additional time for States to articulate how they might comply with the regulations.

Response: This rule does not present a high level of complexity and we believe that the 30-day comment period provided commenters sufficient time to fully evaluate the proposed rule and submit comments to CMS. The 30-day comment period is consistent with the requirements of the Administrative Procedure Act codified at 5 U.S.C. 553, and a longer period is not warranted in light of the significant beneficiary protection that this rule would implement. For the same reasons, we do not agree that issuing a final rule with comment period is necessary.

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 proposed that any reduction in payment would be limited to the amounts directly identifiable as related to the PPC and the resulting treatment.

We received the following comments in response to our proposals concerning access to care.

Comment: One commenter stated that hospitals should not be penalized multiple times for the same occurrence.

Response: We agree and urge provider communities to engage States to ensure that methodologies implemented do not unduly impact providers.

Comment: Several commenters requested that we include a provider appeals process in these provisions. The commenters noted that the nature of identified conditions and the variation in State payment policies warranted the inclusion.

Response: Existing State appeal processes may be available for a provider to contest whether a State has improperly identified the occurrence of a condition identified as a PPC. We encourage States to develop appeals processes that will allow providers to object to any payment reduction when the provider can show that an identified PPC occurred despite all appropriate precaution.

Comment: Some commenters opined that allowing States any flexibility in defining PPC through the OPPC category would be an undue burden on providers who operate on a multistate basis.

Response: The underlying authority for this rule is found in provisions of title XIX of the Act that predated section 2702 of the Affordable Care Act. The proposed rule was supported by our existing authority under sections 1102, 1902(a)(19), and 1902(a)(30) of the Act. Providers that operate on a multistate basis must comply with the laws and rules of each State in which they operate. We see no compelling reason to limit State flexibility to identify PPC nonpayment rules to ensure high quality services for beneficiaries.

Comment: One commenter opposed the idea of States being allowed to define potential PPC and opined that this task was better left to national quality organizations such as NQF or IOM. While expressing support for the general concept of evidence-based quality standards, the commenter believed that it was important that these standards be national in scope and that the use of State Medicaid payment systems was not the appropriate vehicle for improvement of health care quality.

Response: The Medicaid program, by its very nature, is a partnership between the Federal and State governments, and is administered by States. While we are requiring that States rely on a review of medical literature by qualified professionals to identify evidence-based PPCs, we believe it is essential to allow States flexibility to develop payment strategies that provide strong incentives for high quality services.

Comment: Several commenters recommended that we limit State ability to create PPCs to only those which strictly met the Medicare criteria in section 1886 (d)(4)(D)(iv) of the Act.

Response: Section 2702 of the Affordable Care Act requires that the Secretary by rulemaking, establish a nonpayment policy for HCACs, the underlying authority for this rule is found in provisions of title XIX of the Act. The proposed rule was supported by our existing authority under sections 1102, 1902(a)(19), and 1902(a)(30) of the Act and States, using this authority, have already undertaken payment policies to drive quality outcomes. We see no compelling reason to limit State flexibility to identify PPC nonpayment rules to ensure high quality services for beneficiaries.

Comment: One commenter was supportive of the proposed regulation and of the addition of non-hospital providers through the OPPC category. The commenter suggested careful CMS scrutiny of proposed State PPC SPAs to assure no adverse impact on beneficiary access to care, the addition of a risk-adjustment mechanism to the regulation, careful monitoring to assure

that no access problems develop, and some mechanism to publicly report provider outcomes. The Maryland Medicaid model for PPC payment and reporting was offered as an exemplary model for national use.

Response: We reviewed the Maryland system in developing this regulation and, found it to be a useful State model that combined both financial incentives with overall quality improvement efforts. CMS will review State preprints, reimbursement State plan amendments, and supplementary information to determine final action on State PPC policies.

Comment: Some commenters expressed concern that the proposed regulation allowed too much discretion to individual States to use the SPA process to affect payment in areas where no national consensus about appropriate care existed.

Response: We are strongly committed to permitting State flexibility to innovate in this area. State innovation has been a significant driver of Federal policy, and States have direct experience with utilization and claims review for Medicaid services. While we anticipate that States will review data to identify evidence-based PPCs, we believe it is essential to allow States flexibility to develop payment strategies that provide strong incentives for high quality services.

The SPA review process will give CMS and providers the opportunity to consider State policy before it is implemented and to provide guidance and input based on our knowledge of the issues.

Comment: Several commenters expressed concern that the language of the proposed regulation allowed States excessive authority to use the PPC process to further reduce Medicaid compensation during a period when States are already under financial pressure to reduce Medicaid costs. One commenter suggested numerous additional limitations of State use of the PPC process be added to the final regulation.

Response: This final rule provides for nonpayment to the extent that an identified PPC would otherwise result in an increase in payment for additional services, and permits States to identify PPCs in addition to the core PPCs that are based on Medicare. This is consistent with the considerable flexibility that States have in setting payment rates and methodologies. States will need to file SPAs with CMS outlining the State's proposed nonpayment methodology, and their approach to inclusion of Federal minimum standards, as well as any

additional variations proposed by the State. The SPA process will allow the State's providers to file public comments on any proposed State changes.

Comment: Several commenters expressed concern over how the nonpayment policy would be implemented in States that do not use MS-DRG reimbursement systems. A few commenters requested that States that have elected to use per-diem, global payment, bundled payment or other non-MS-DRG systems to reimburse hospitals be allowed to continue to do so, and not be forced to move to MS-DRG.

Commenters were concerned that these States will need to identify methods appropriate to their reimbursement mechanisms to make payment reductions for PPCs and that resource-intensive post payment audits and payment adjustments are likely to be necessary. These commenters noted that they are encouraged by our attempt to provide flexibility to States, but requested that we issue guidance that includes best practice recommendations for developing efficient payment adjustments where reimbursement is not based on an MS-DRG system. Another commenter requested that we provide options for how States may identify or estimate the cost of services on a systematic basis without a case by case review. One commenter requested that we develop a crosswalk of HCAC conditions to non-DRG payment methodologies to assure consistency in reporting from States back to CMS. The commenter remarks that encouraging States and MCOs to create their own crosswalks will be counter-productive.

Response: CMS recognizes that many States do not use MS-DRG to reimburse hospital providers. As stated in the NPRM, we have no intention of requiring States to alter their current compensation systems to comply with this final regulation beyond the necessary adjustments needed to implement the PPCs non-payment provisions. This intention continues through the final rule.

States have flexibility to design their own payment systems within the guidelines of Federal regulations. The final rule allows States the flexibility to implement nonpayment policies through various mechanisms, but requires that States submit Medicaid SPAs setting forth their mechanism to comply with the required nonpayment for PPCs, with public notice for CMS approval. States will need to work with their provider communities, industry partners, and CMS to determine the most effective manner in which to

implement these nonpayment provisions. As we noted in the preamble to the proposed rule, we intend to continue to gather and share information related to States' implementation of PPCs nonpayment policies. However, we do not intend to endorse any particular best practices.

We do not wish to limit State flexibility by dictating methods in which PPCs should be translated or "cross walked" to individual State payment systems. However, we do agree that there is a need for as much consistency as possible in reporting from States to CMS. As a requirement of the final rule, States will implement the provider self-reporting through payment claims systems regardless of the provider's intention to bill. We are working to ensure that States consistently report at least the minimum requirements of the rule through the Medicaid Management Information Systems (MMIS). We anticipate that States and providers, especially those groups of providers that have not been subject to Medicare's HAC policy, will need additional time to develop and implement reporting systems that would complement existing payment structures. As discussed in the proposed rule, a reporting component is essential to building an effective PPC policy for a number of reasons, including State and CMS ability to capture data related to these occurrences.

Comment: A few commenters believed that it is unjust to penalize providers for complications that occur despite best evidence-based efforts to eliminate or avoid them. Commenters noted that some conditions have more to do with patient risk factors or patient compliance than with quality of care. Another commenter stated that not covering these conditions would encourage denial of care to high risk patient or a mass exodus of providers. Several commenters suggested that appeals processes be included in State Medicaid PPCs provisions that would allow providers to challenge payment denials.

Response: We agree that not all of the identified events will be avoidable in 100 percent of the cases even with appropriate precautions. But current Medicaid payment systems are designed to provide incentives to providers to efficiently provide high quality care and result in an aggregate payment that may be more or less than actual costs in a particular case. For example, payment is often based on a fee schedule or diagnosis related group methodology that considers average or target costs of the particular service or services and may differ from actual costs in a

particular case. Even “reasonable cost” rates do not necessarily include all costs a provider may incur. It is important to remember that the identified conditions have been determined through evidence-based medicine to be provider preventable. For the issue of appeal rights, existing State appeal processes may be available for a provider to contest whether a State has improperly identified the occurrence of a condition identified as a PPC. We encourage States to develop appeals processes that will allow providers to object to any payment reduction when the provider can show that an identified PPC occurred despite all appropriate precaution.

Comment: One commenter suggested, as an example, that we consider permitting Medicaid coordinated care plans to adopt inpatient concurrent review as a practice for addressing PPCs. The commenter noted that, “most Medicaid coordinated care plans utilize inpatient concurrent review as a unique reimbursement practice for addressing PPCs. Most Medicaid coordinated care plans utilize inpatient concurrent review to identify hospital days that are not medically necessary or represent delays in care. These days are generally not eligible for reimbursement in a non-DRG/per-diem environment. Expanding the concurrent review process to include identification of hospital days required solely for the treatment of PPCs would be one way to address this issue.”

Response: This is one example of how States may be able to identify amounts related to the treatment of PPCs. The final rule indicates that States may reduce payments to providers when the PPC would otherwise result in an increase in payment. The rule also requires that the State be able to reasonably isolate for nonpayment the portion of payment directly related to treatment for, and related to, the PPC. The rule does not limit State flexibility in accomplishing these requirements.

Comment: One commenter asked that we clarify that it recognizes that different reimbursement methodologies may result in no reduction or different reductions than the reductions under MS-DRGs. Another commenter asked that we confirm that, “if on the same inpatient hospital day, both services associated with a PPC and services not associated with a PPC are rendered and if payment is made on a per diem basis such that the presence of the PPC services would not result in an increased per diem payment even without this proposed regulation, then no adjustment to the payment for that day is necessary.”

Response: We agree that given the variations in Medicaid payment methodologies and systems across States, there may be differences in amounts identified for nonpayment based on the payment system employed by the individual State. And there is no requirement that State Medicaid payment adjustments to providers correlate specifically to Medicare’s payment adjustments for those same conditions. Payment methodologies are extremely complex, and we do not believe it is productive to address broad hypothetical scenarios regarding implementation of nonpayment policies. We intend to work with each State to develop implementation strategies that make sense with its particular payment methodologies.

Comment: Some commenters recommended that risk-adjustment be incorporated into PPCs policies.

Response: These comments appear to refer to payment methodologies that provide for case-mix adjustments to give higher payments to providers that treat sicker populations, to reflect the higher cost of treating such populations. Such methodologies are not related to the policies relating to PPCs that are reflected in this rule, and to combine the two would significantly weaken the incentives for providers to institute preventive measures to eliminate PPCs. We note that we strongly support the incorporation of risk-adjustment in State Medicaid programs, which States can elect under current law. We are urging provider communities to continue to work with States to develop successful risk-adjustment approaches on the State level.

Comment: One commenter suggested that hospitals which serve Medicare and Medicaid beneficiaries will decrease in quality as a result of the proposed policy because the fixed costs associated with providing medical services will become variable, and instead of absorbing the loss, investors will simply reduce capital investments. The commenter offers that one solution to this possible undesired consequence is to have the Medicaid and Medicare programs absorb such costs, albeit not through direct payments. Instead, the commenter suggested CMS could pay a flat rate at the beginning of the year covering all PPCs and require them to be fully serviced without charge. This way, they will still have the incentive to reduce HCACs but will not have to bear the costs.

Response: The policy set forth in this rule is designed to improve quality of services by providing a strong incentive for providers to take steps eliminate the incidence of preventable conditions. A

provider that does so will suffer no economic loss. In contrast, the flat rate payment approach proposed by the commenter would lock in a tolerance level for such conditions, instead of eliminating them, and would send a mixed message to providers about whether providers must take steps to eliminate preventable conditions.

C. Effective Date of the Final Provisions

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

We received the following comments in response to our proposals concerning the effective date.

Comment: Several commenters expressed concern that the July 1, 2011 effective date of the rule does not leave sufficient time for discussion of policy, implementation of required hospital changes, and development of the appropriate systems for reporting. Additionally, commenters suggested that States be permitted up to 60 days to incorporate Medicare HACs as Medicare updates its list.

Response: We are statutorily-required to implement these regulations effective July 1, 2011. We do believe, however, that States may need additional time to work with providers to implement sound policies and reporting mechanisms. We intend to delay compliance action on these provisions until July 1, 2012.

We disagree that this final rule should provide States up to 60 days to incorporate additional Medicare HACs as Medicare’s list changes. The publication of Medicare’s final IPPS rule is consistent and published in ample time to allow States to incorporate HAC changes. The Medicaid SPA process allows States sufficient time to propose and incorporate any changes that Medicare may make to its HAC list considering the timeframe in which Medicare publishes its final rule.

Comment: One commenter recommended that CMS not penalize States that are not prepared to implement the proposed Medicaid nonpayment policy or any future updates in a timely manner due to a vendor not modifying necessary software in a timely manner.

Response: States have great flexibility in administering their programs. We urge States to work with their provider communities and vendors to ensure that they meet the provisions of these rules in a timely fashion.

D. Specific Revisions to Regulations Text

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

Currently, the general rules regarding Medicaid State plan payments for Medicaid are provided at part 447 subpart A. We proposed 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. We proposed to 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 will require that necessary SPAs be submitted for implementation purposes.

In § 447.26(c), we proposed 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 specified that any reductions may be limited to the added cost resulting from the PPC.

In § 447.26(d), we have included a provision that will 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 proposed including 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 proposed including a requirement in § 438.6(f)(2) that contracts must comply with both § 434.6(a)(12) and § 447.26.

We proposed these particular provisions because the information gathered in preparation for issuing the proposed rule indicated the need for a consistent authority under which States could 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.

We received the following comments in response to our proposals to revise the regulations text.

Comment: One commenter believed that the language of the proposed regulation could be construed to limit payments even when the PPC condition was present on admission or initiation of provider treatment.

Response: The language in the proposed regulation was intended to cover only situations where payment reduction was being applied to treatment for a condition not present on admission or commencement of treatment by that provider. However, we understand that clarifying the language of the regulation to emphasize this point would be helpful to and we have done so in this final rule. New § 447.26(c)(3) language explicitly states that “* * * no reduction in payment for a PPC will be imposed on a provider when the condition defined as a PPC for a particular patient existed prior to the initiation of treatment for that patient by that provider.” This was implied in the previous language, but has now been made explicit. We agree with the comment and are providing this clarification.

Comment: A number of commenters requested that CMS clarify that the HCAC category applies only to inpatient hospitals.

Response: The final rule has revised regulatory language to clarify that HCAC category applies to all Medicaid inpatient hospital settings.

Comment: One commenter expressed concern that expansion of PPC to nonhospital providers threatened the access of Medicaid beneficiaries to care.

In particular, commenters asked CMS to clarify that Medicaid payment disallowance for PPC would not apply when the PPC was present at the time the provider commenced treatment of the patient.

Response: The language in the proposed regulation was intended to cover only situations where payment reduction was being applied to treatment for a condition not present on admission or commencement of treatment by that provider. However, we understand that clarifying the language of the regulation to emphasize this point would be helpful and we have done so in this final rule. New § 447.26(c)(2) language explicitly states that “* * * no reduction in payment for a PPC will be imposed on a provider when the condition defined as a PPC for a particular patient existed prior to the initiation of treatment for that patient by that provider.” This was implied in the previous language, but has now been made explicit. CMS agrees with the comment and is providing this clarification.

Comment: A few commenters believed that the distinctions among the terms in the proposed rule were confusing and made it hard to understand which term applied to which criteria.

Response: We have revised the regulatory text to make it clear that provider preventable conditions are clearly defined into two separate categories, healthcare acquired conditions (Medicare's HACs applicable only to inpatient hospital providers paid under the IPPS) and other provider-preventable conditions (conditions minimally defined as Medicare's 3 NCDs, applicable in any healthcare service setting).

Comment: One commenter requested clarification on the purpose of provider reporting and how CMS expects States to use reported information. Another commenter noted that there is no clear provision on how States are to report this data to CMS. One State questioned whether the SPA will have to specify how the reporting will be done, or if States will need to assure that they will comply with the requirement.

Response: We are requiring that States impose provider self-reporting through claims systems because that information will be fed by States to CMS. CMS and States will use this data to inform policy making. Language assuring compliance with this provision is incorporated in the State plan pre-print associated with this provision.

Comment: One commenter supports nonpayment for all PPCs as they pertain to the dual eligible population. This

commenter urges CMS to codify provisions that prohibit Medicaid claim payment for claims that have been denied by Medicare based on the presence of a HAC.

Response: This is a significant area of concern, and we have revised the final regulation to clarify the prohibition on Medicaid payment for claims that have been denied (in full or in part) by Medicare, to reflect this recommendation.

Comment: One commenter noted that the proposed rule requires States to establish a provider reporting requirement for PPCs and requested that amend the final rule to allow States time to implement the PPC policies in general.

Response: As a requirement of the final rule, States will implement the provider self-reporting through payment claims systems regardless of the provider's intention to bill. We anticipate that States and providers, especially those groups of providers that have not been subject to Medicare's HAC policy, will need to work collaboratively to develop and implement reporting systems that would complement existing payment structures.

III. Provisions of the Final Rule

This final rule incorporates the provisions of the proposed rule with the following exceptions.

In § 447.26(b), we are revising the definition of health care-acquired condition to mean a condition occurring in any inpatient hospital setting, identified as a HAC by the Secretary under section 1886(d)(4)(D)(iv) of the Act for purposes of the Medicare program identified in the State plan as described in section 1886(d)(4)(D)(ii) and (iv) of the Act; other than Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) related to total knee replacement or hip replacement surgery in pediatric and/or obstetric patients.

In § 447.26(c)(1), we are revising the language to read "A State plan must provide that no medical assistance will be paid for "provider-preventable conditions" as defined in this section; and as applicable for individuals dually

eligible for both the Medicare and Medicaid programs."

IV. 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.

In accordance with the Act, we solicited public comments on the proposed collection of information, with a 30-day comment period, in the proposed rule that published on February 17, 2011 (76 FR 9283). We did not receive any substantive comments related to the proposed information collection requirements or burdens and, therefore, we are retaining the following requirements and estimates that were set out in the proposed rule.

A. ICRs Regarding Contract Requirements (§ 438.6)

Section 438.6(f)(2) will 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 estimated that 48 States will be required to comply with this requirement. We also estimated that it will 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.

B. ICRs Regarding the Prohibition on Payment for Provider-Preventable Conditions (§ 447.26)

Effective July 1, 2011, § Section 447.26(c)(1) will require States to submit SPAs for CMS approval that would reduce payments to providers by amounts related to PPCs. The burden associated with this requirement will be the time and effort necessary for a State to submit its SPA and the associated pre-print. We estimated that 50 States, the District of Columbia, and Territories will be required to comply with this requirement. We further estimated 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 385 hours at a cost of \$20.67 per hour per State.

We estimated 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.

Section 447.26(c)(2) will 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 estimated that 50 States, the District of Columbia, and Territories will be required to comply with this requirement. We estimated 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 will be 1320 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.

TABLE 1—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
438.6(f)(2)	0938-NEW	48	48	8	384	20.67	7,937.28	0	7,937.28
447.26(c)(1)	0938-NEW	55	55	7	385	20.67	7957.95	0	7,957.5
447.26(c)(2)	0938-NEW	55	55	24	1,320	20.67	27,284.4	0	27,284.4
Total	158	158	39	2089	0	43,179.18

The estimated annual burden associated with the requirements under 438.6(f)(2), 447.26(c)(1), and 447.26(c)(2) is 2,089 hours (total) at a cost of \$43,179.18 (total) or \$806.13 (per State).

TABLE 2—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
438.6(f)(2)	0938-NEW	48	48	8	384	20.67	7,937.28	0	7,937.28
447.26(c)(1)	0938-NEW	50	50	7	350	20.67	7,234.5	0	7,234.5
447.26(c)(2)	0938-NEW	50	50	24	1,200	20.67	2,4804	0	2,4804
Total	98	148	39	1,934	0	39,975.78

The estimated annual burden associated with the requirements under 438.6(f)(2), 447.26(c)(1), and 447.26(c)(2) is 1,934 hours (total) at a cost of \$39,975.78 (total) or \$806.13 (per State).

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on July 7, 2011.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806. Fax Number: (202) 395-6974.

V. Regulatory Impact Statement

A. Statement of Need

This final rule implements section 2702 of the Affordable Care Act 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 will 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 PPCs.

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 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.

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 Affordable Care 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 of the Affordable Care Act 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. These estimates could be higher if States elect to expand beyond the minimum requirements of this rule.

TABLE 3—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 final rule 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 IV of this final rule, Collection of Information Requirements, amount to an additional \$39,976 dollars aggregate across all States.

Hospitals may incur additional costs to reduce PPCs. 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 HCACs. 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 final 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 PPCs.

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 final 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area 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 final 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 final 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 final rule derives from section 2702 of the Affordable Care Act and other CMS statutory authority. 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 final 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 final rule does not completely preempt State law, but merely sets a Federal minimum standard.

We are meeting the requirements of Executive Order 13132 by issuing this final rule 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 final 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 final 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. To provide States full flexibility to protect beneficiaries and the program, we elected the more comprehensive approach that we discussed in the proposed rule. 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 proposed that the term be defined as, "a condition that could have reasonably been prevented through the application of evidence based guidelines."

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 final 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

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 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 replacing them with 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 the following:

(i) Compliance with the requirements mandating provider identification of provider-preventable conditions as a condition of payment, as well as the prohibition against payment for provider-preventable conditions as set forth in § 434.6(a)(12) and § 447.26 of this subchapter.

(ii) Reporting all identified provider-preventable conditions in a form or frequency as may be specified by the State.

(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 Affordable Care Act 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 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 occurring in any inpatient hospital setting, identified as a HAC by the Secretary under section 1886(d)(4)(D)(iv) of the Act for purposes of the Medicare program identified in the State plan as described in section 1886(d)(4)(D)(ii) and (iv) of the Act; other than Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) as related to total knee replacement or hip replacement surgery in pediatric and obstetric patients.

Other provider-preventable condition means a condition occurring in any

health care setting that meets the following criteria:

(i) Is identified in the State plan.

(ii) Has been found by the State, based upon a review of medical literature by qualified professionals, to be reasonably preventable through the application of procedures supported by evidence-based guidelines.

(iii) Has a negative consequence for the beneficiary.

(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; and as applicable for individuals dually eligible for both the Medicare and Medicaid programs.

(2) No reduction in payment for a provider preventable condition will be imposed on a provider when the condition defined as a PPC for a particular patient existed prior to the initiation of treatment for that patient by that provider.

(3) 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.

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

(5) A State plan must ensure that non-payment for provider-preventable conditions does not prevent access to services for Medicaid beneficiaries.

(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.

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

Dated: May 25, 2011.

Donald M. Berwick,

*Administrator, Centers for Medicare &
Medicaid Services.*

Approved: May 27, 2011.

Kathleen Sebelius,

*Secretary, Department of Health and Human
Services.*

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