DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 480

[CMS–3239–F]

RIN 0938–AQ55

Medicare Program; Hospital Inpatient Value-Based Purchasing Program

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

ACTION: Final rule.

SUMMARY: This final rule implements a Hospital Inpatient Value-Based Purchasing program (Hospital VBP program or the program) under section 1886(o) of the Social Security Act (the Act), under which value-based incentive payments will be made in a fiscal year to hospitals that meet performance standards with respect to a performance period for the fiscal year involved. The program will apply to payments for discharges occurring on or after October 1, 2012, in accordance with section 1886(o) (as added by section 3001(a) of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act)). Scoring in the Hospital VBP program will be based on whether a hospital meets or exceeds the performance standards established with respect to the measures. By adopting this program, we will reward hospitals based on actual quality performance on measures, rather than simply reporting data for those measures.

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

FOR FURTHER INFORMATION CONTACT: Allison Lee, (410) 786–8691.

Table of Contents

I. Background
A. Overview
B. Hospital Inpatient Quality Data Reporting Under Section 501(b) of Public Law 108–173
C. Hospital Inpatient Quality Reporting Under Section 5001(a) of Public Law 109–171
D. 2007 Report to Congress: Plan To Implement a Medicare Hospital Value-Based Purchasing Program
E. Provisions of the Affordable Care Act
II. Provisions of the Final Rule and Response to Comments
A. Overview of the Proposed Rule
B. Overview of the Hospital Value-Based Purchasing Program
C. Performance Period
D. Measures
E. Performance Standards
F. Methodology for Calculating the Total Performance Score
G. Applicability of the Value-Based Purchasing Program to Hospitals
H. The Exchange Function
I. Hospital Notification and Review Procedures
J. Reconsideration and Appeal Procedures
K. FY 2013 Validation Requirements for Hospital Value-Based Purchasing
L. Additional Information
M. QIO Quality Data Access
III. Collection of Information Requirements
IV. Economic Analyses
A. Regulatory Impact Analysis
B. Regulatory Flexibility Act Analysis
C. Unfunded Mandates Reform Act Analysis
V. Federalism Analysis

Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

ACM Appropriate Care Model
AHRQ Agency for Healthcare Research and Quality
AMI Acute Myocardial Infarction
CCN CMS Certification number
CLABSI Central line-associated bloodstream infections
CMMI Center for Medicare and Medicaid Innovation
CMS Centers for Medicare & Medicaid Services
CV Coefficient of variation
DRA Deficit Reduction Act of 2005
DRG Diagnosis-Related Group
EHR Electronic Health Record
EKG Electrocardiogram
FISMA Federal Information Security and Management Act
HAC Hospital acquired conditions
HAI Healthcare-associated infections
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HF Heart Failure
HIPAA Health Insurance Portability and Accountability Act
HOP QDRP Hospital Outpatient Quality Data Reporting Program
IPPS Inpatient prospective payment systems
IQI Inpatient Quality Indicator
IQR Inpatient Quality Reporting
MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003
NQF National Quality Forum
PMA Patient-mix adjustment
PN Pneumonia
POA Present on Admission
PQRI Physician Quality Reporting Initiative
PRRB Provider Reimbursement Review Board
PSI Patient Safety Indicator
QIO Quality Improvement Organization
QRS Quality Review Study
RFA Regulatory Flexibility Act
RHQDAPU Reporting Hospital Quality Data for the Annual Payment Update Program
RIA Regulatory Impact Analysis
SCIP Surgical Care Improvement
SDPS Standard Data Processing System
SES Socioeconomic status
SSI Surgical site infections
VBP Value-Based Purchasing

I. Background

A. Overview

The Centers for Medicare & Medicaid Services (CMS) promotes higher quality and more efficient health care for Medicare beneficiaries. In recent years, we have undertaken a number of initiatives to lay the foundation for rewarding health care providers and suppliers for the quality of care they provide by tying a portion of their Medicare payments to their performance on quality measures. These initiatives, which include demonstration projects and quality reporting programs, have been applied to various health care settings, including physicians' offices, ambulatory care facilities, hospitals, nursing homes, home health agencies, and dialysis facilities. The overarching goal of these initiatives is to transform Medicare from a passive payer of claims to an active purchaser of quality health care for its beneficiaries.

This effort is supported by our adoption of an increasing number of widely-agreed upon quality measures for purposes of our existing quality reporting programs. We have worked with stakeholders to define measures of quality in almost every setting. These measures assess structural aspects of care, clinical processes, patient experiences with care, and, increasingly, outcomes.

We have implemented quality measure reporting programs that apply to various settings of care. With regard to hospital inpatient services, we implemented the Hospital IQR program. In addition, we have implemented quality reporting programs for hospital outpatient services through the Hospital Outpatient Quality Reporting program (HOQR), formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), and for physicians and other eligible professionals through the Physician Quality Reporting System (formerly referred to as the Physician Quality Reporting Initiative or PQRI). We have also implemented quality reporting programs for home health agencies and skilled nursing facilities based on conditions of participation, and an end-stage renal disease quality incentive program that links payment to performance.

This new program will necessarily be a fluid model, subject to change as knowledge, measures and tools evolve. We view the Hospital VBP program under section 1886(o) as the next step

in promoting higher quality care for Medicare beneficiaries and transforming Medicare into an active purchaser of quality health care for its beneficiaries.

In developing this rule as well as other value-based quality initiatives, CMS applied the following principles for the development and use of measures and scoring methodologies.

Purpose

CMS views value-based purchasing as an important step toward revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume.

Use of Measures

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, CMS seeks to move as quickly as possible to using primarily outcome and patient experience measures.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare's and Medicaid's public reporting and payment systems. CMS also seeks to develop a focused core-set of measures appropriate to each specific provider category that reflects the level of care and the most important areas of service furnished by that provider.
- The collection of information should minimize the burden on providers to the extent possible. As part of that effort, CMS will continuously seek to align its measures with the adoption of meaningful use standards for health information technology (HIT).
- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should also be aligned with best practices among other payers and the needs of the end users of the measures.

Scoring Methodology

- Providers should be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal.
- Measures or measurement domains need not be given equal weight, but over time, scoring methodologies should be weighted more heavily towards outcome, patient experience, and functional status measures.
- Scoring methodologies should be reliable, as straightforward as possible, and stable over time and enable consumers, providers, and payers to make meaningful distinctions among providers' performance.

Comment: A number of commenters expressed their general support for these principles. One commenter provided additional remarks on the principles and made a number of comments on the interactions between the principles, including risk adjustment, measure reliability, patient experience of care measures, and measure endorsement. For example, this commenter expressed agreement with our stated principle that public reporting and value-based payment systems should rely on a mix of standards, processes, outcome and payment experience measures. In supporting this principle, the commenter related that health and health care are complex, which requires a multifaceted accountability framework. This commenter also supported our statement that scoring methodologies should be reliable, as straightforward as possible, and stable over time. The commenter further remarked that VBP relies on the support of consumers in the marketplace to drive improvement, and that consumers must understand the measures and how they are used in order to make informed decisions.

Response: We appreciate the comments and input on these principles, and will keep them in mind as we continue to enhance, develop and implement the Hospital VBP program, other quality reporting programs, and other value-based incentive programs.

Comment: A number of commenters stated that CMS must ensure that value-based purchasing programs foster the development of innovative, quality care and provide an adequate level of reimbursement for innovative medical technologies. One commenter reiterated that value-based purchasing programs should not place the provision of lower cost services and products in conflict with what is best for the patient.

Response: We agree that value-based purchasing programs should not hinder innovation and should result in improved patient care. We believe that the Hospital VBP program will drive improvements in the quality of care for Medicare beneficiaries, including the provision of innovative technologies, because of its financial incentives for providers to provide high-quality, patient-centered care coupled with high levels of patient satisfaction. We note that our measure development and selection activities take into account national priorities, including those established by the National Priorities Partnership and the Department of Health and Human Services, as well as other widely accepted criteria established in the medical literature. We will continue to seek to align all of our quality initiatives to promote high-quality care and continued innovation. We intend to monitor this program over time for unintended consequences.

Comment: One commenter requested that CMS extend the 60-day comment period.

Response: We decline to extend the comment period. Based on the volume and depth of comments we received in response to the Hospital Inpatient VBP proposed rule, we believe that commenters had ample opportunity to submit meaningful comments on our proposals and did so. Specifically, we received comments discussing a wide range of issues on nearly every aspect of that proposed rule, including its potential impact on the health care system, the provision of high-quality medical care and effects on patient satisfaction. We received comments from a wide range of stakeholders, including hospitals, health care providers, professional associations, trade groups, advocacy organizations, Medicare beneficiaries, private citizens, and others. We have had a sufficient opportunity to consider the issues raised by the commenters and have taken their comments into account in developing this final rule.

Comment: One commenter stated that "the specific process for how the agency proposes to achieve 'transparency' is not described or attained," and that the proposed rule did not offer sufficient information and disclosure of the "methods and data the agency proposes to use" in developing the Hospital VBP program.

Response: We disagree. We believe that we have been transparent in making public our goals for the Hospital VBP program and numerous documents that informed our rulemaking on this program, including the 2007 Report to Congress, Congressional testimony and public listening session transcripts. We also believe that the proposed rule contains detailed information regarding the data and analyses we considered in developing our proposals.

However, because we seek to ensure that the continued development of the Hospital VBP program take place in as transparent a manner as possible, we will make available additional information regarding our analyses, study results, and methods and will inform the public accordingly.

We have addressed specific issues relating to the use of measures, scoring

methodology, and other aspects of the Hospital VBP program below.

B. Hospital Inpatient Quality Data Reporting Under Section 501(b) of Public Law 108–173

Section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, added section 1886(b)(3)(B)(vii) to the Act. This section established the original authority for the Hospital IQR program and revised the mechanism used to update the standardized amount for inpatient hospital operating costs. Specifically, section 1886(b)(3)(B)(vii)(I) of the Act provided for a reduction of 0.4 percentage points to the applicable percentage increase (sometimes referred to at that time as the market basket update) for FY 2005 through FY 2007 for a subsection (d) hospital if the hospital did not submit data on a set of 10 quality indicators established by the Secretary as of November 1, 2003. It also provided that any reduction applied only to the fiscal year involved, and would not be taken into account in computing the applicable percentage increase for a subsequent fiscal year. The statute thereby established an incentive for many subsection (d) hospitals to submit data on the quality measures established by the Secretary.

We implemented section 1886(b)(3)(B)(vii) of the Act in the FY 2005 IPPS final rule (69 FR 49078) and codified the applicable percentage increase change in § 412.64(d) of our regulations. We adopted additional requirements for the Hospital IQR program in the FY 2006 IPPS final rule (70 FR 47420).

C. Hospital Inpatient Quality Reporting Under Section 5001(a) of Public Law 109–171

1. Change in the Reduction to the Applicable Percentage Increase

Section 5001(a) of the Deficit Reduction Act of 2005 (DRA), Public Law 109–171, further amended section 1886(b)(3)(B) of the Act to, among other things, revise the mechanism used to update the standardized amount for hospital inpatient operating costs by adding a new section 1886(b)(3)(B)(viii) to the Act. Specifically, sections 1886(b)(3)(B)(viii)(I) and (II) of the Act, as added by the DRA, provided in part that the applicable percentage increase for FY 2007 and each subsequent fiscal year shall be reduced by 2.0 percentage points for a subsection (d) hospital that does not submit quality data in a form and manner and at a time specified by the Secretary. Section 1886(b)(3)(B)(viii)(I) of the Act also provided that any reduction in a hospital's applicable percentage increase will apply only with respect to the fiscal year involved, and will not be taken into account for computing the applicable percentage increase for a subsequent fiscal year.

In the FY 2007 IPPS final rule (71 FR 48045), we amended our regulations at § 412.64(d)(2) to reflect the 2.0 percentage point reduction required under the DRA.

2. Selection of Quality Measures

Section 1886(b)(3)(B)(viii)(V) of the Act, before it was amended by section 3001(a)(2)(B) of the Affordable Care Act, required that, effective for payments beginning FY 2008, the Secretary add other measures that reflect consensus among affected parties, and to the extent feasible and practicable, have been set forth by one or more national consensus building entities. The National Quality Forum (NQF) is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process. We have generally adopted NQF-endorsed measures for purposes of the Hospital IQR program. However, we believe that consensus among affected parties also can be reflected by other means, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus achieved through public comment.

Section 1886(b)(3)(B)(viii)(VI) of the Act authorizes the Secretary to replace any quality measures or indicators in appropriate cases, such as when all hospitals are effectively in compliance with a measure, or the measures or indicators have been subsequently shown to not represent the best clinical practice. We interpreted this provision to give us broad discretion to replace measures that are no longer appropriate for the Hospital IQR program.

We adopted 45 measures under the Hospital IQR program for the FY 2011 payment determination. Of these measures, 27 are chart-abstracted process of care measures, which assess the quality of care furnished by hospitals in connection with four topics: Acute Myocardial Infarction (AMI); Heart Failure (HF); Pneumonia (PN); and Surgical Care Improvement (SCIP) (75 FR 50182). Fifteen of the measures are claims-based measures, which assess the quality of care furnished by hospitals on the following topics: 30-day mortality and 30-day readmission rates for Medicare patients diagnosed with AMI, HF, or PN; Patient Safety Indicators/Inpatient Quality Indicators/Composite Measures; and Patient Safety Indicators/Nursing Sensitive Care. Three of the measures are structural measures that assess hospital participation in cardiac surgery, stroke care, and nursing sensitive care systemic databases. Finally, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey is included as a measure for the FY 2011 payment determination.

The technical specifications for the Hospital IQR program measures, or links to Web sites hosting technical specifications, are contained in the CMS/The Joint Commission Specifications Manual for National Hospital Inpatient Quality Measures (Specifications Manual). This Specifications Manual is posted on the CMS QualityNet Web site at *https://www.QualityNet.org/*. We maintain the technical specifications by updating this Specifications Manual semiannually, or more frequently in unusual cases, and include detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required measures. These semiannual updates are accompanied by notifications to users, providing sufficient time before the effective date of the change in order to allow users to incorporate changes and updates to the specifications into data collection systems.

3. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2)(C) of the Affordable Care Act, requires that the Secretary establish procedures for making information regarding measures submitted under the Hospital IQR program available to the public after ensuring a hospital has the opportunity to review its data. To meet this requirement, we display most Hospital IQR program data on the *Hospital Compare* Web site, *http://www.hospitalcompare.hhs.gov,* after a 30-day preview period. An interactive Web tool, this Web site assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. It further serves to encourage beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thereby providing an additional incentive to hospitals to improve the quality of care that they

furnish. The *Hospital Compare* Web site currently makes public information on a wide range of measures, including clinical process of care measures, risk adjusted outcome measures, the HCAHPS patient experience of care survey, and structural measures. However, data that we believe is not suitable for inclusion on *Hospital Compare* because it is not salient or will not be fully understood by beneficiaries, as well as data for which there are unresolved display or design issues, may be made available on other CMS Web sites that are not intended to be used as an interactive Web tool, such as *http://www.cms.hhs.gov/HospitalQualityInits/.* In such circumstances, affected parties are notified via CMS listservs, CMS e-mail blasts, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare.*

D. 2007 Report to Congress: Plan To Implement a Medicare Hospital Value-Based Purchasing Program

Section 5001(b) of the DRA required the Secretary to develop a plan to implement a value-based purchasing program for subsection (d) hospitals. In developing the plan, we were required to consider the on-going development, selection, and modification process for measures of quality and efficiency in hospital inpatient settings; the reporting, collection, and validation of quality data; the structure, size, and sources of funding of value-based payment adjustments; and the disclosure of information on hospital performance.

On November 21, 2007, we submitted the Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program, which is available on the CMS Web site. The report discusses options for a plan to implement a Medicare hospital value-based purchasing program that builds on the Hospital IQR program. We recommended replacing the Hospital IQR program with a new program that would include both a public reporting requirement and financial incentives for better performance. We also recommended that a hospital value-based purchasing program be implemented in a manner that would not increase Medicare spending.

To calculate a hospital's total performance score under the plan, we analyzed a potential performance scoring model that incorporated measures from different quality "domains," including clinical process of care and patient experience of care. We examined ways to translate that score into an incentive payment by making a portion of the base DRG payment contingent on performance. We analyzed criteria for selecting performance measures and considered a potential phased approach to transition from Hospital IQR to value-based purchasing. In addition, we examined redesigning the current data transmission process and validation infrastructure, including making enhancements to the *Hospital Compare* Web site, as well as an approach to monitor the impact of value-based purchasing.

E. Provisions of the Affordable Care Act

Section 3001(a) of the Affordable Care Act added a new section 1886(o) to the Act, which requires the Secretary to establish a hospital value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary. Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to FY 2013 base operating DRG payments for each discharge of 1.0 percent, as required by section 1886(o)(7). Section 1886(o)(1)(C) provides that the Hospital VBP program applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B)), but excludes from the definition of the term "hospital," with respect to a fiscal year: (1) A hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) for such fiscal year; (2) a hospital for which, during the performance period for the fiscal year, the Secretary cited deficiencies that pose immediate jeopardy to the health and safety of patients; and (3) a hospital for which there is not a minimum number (as determined by the Secretary) of applicable measures for the performance period for the fiscal year involved, or for which there is not a minimum number (as determined by the Secretary) of cases for the applicable measures for the performance period for such fiscal year.

II. Provisions of the Final Rule and Response to Comments

A. Overview of the January 7, 2011 Hospital Inpatient VBP Program Proposed Rule

On January 7, 2011, we issued a proposed rule that proposes to implement a Hospital VBP program under section 1886(o) of the Act (76 FR 2454, January 13, 2011). Specifically, we proposed to initially adopt for the FY 2013 Hospital VBP program 18 measures that we have already adopted for the Hospital IQR program, categorized into two domains, as follows: 17 of the measures would be clinical process of care measures, which we would group into a clinical process of care domain, and 1 measure would be the HCAHPS survey, which would fall under a patient experience of care domain. With respect to the clinical process of care and HCAHPS measures, we proposed to use a three-quarter performance period from July 1, 2011 through March 31, 2012 for the FY 2013 Hospital VBP payment determination. We proposed to determine whether hospitals meet the performance standards for the selected measures by comparing their performance during the performance period to their performance during a three-quarter baseline period of July 1, 2009 through March 31, 2010. We also proposed to initially adopt for the FY 2014 Hospital VBP program three outcome measures. With respect to the outcome measures, we proposed to use an 18-month performance period from July 1, 2011 to December 31, 2012. Furthermore, for these outcome measures, we proposed to establish performance standards and to determine whether hospitals meet those standards by comparing their performance during the performance period to their performance during a baseline period of July 1, 2008 to December 31, 2009.

We also proposed to adopt 8 Hospital Acquired Condition measures and 9 AHRQ Patient Safety Indicator and Inpatient Quality Indicator outcome measures. We further proposed to begin the performance period for each of these proposed measures 1 year after we included the measure on the *Hospital Compare* Web site.

In general, we proposed to implement a methodology for assessing the total performance of each hospital based on performance standards, under which we would score each hospital based on achievement and improvement ranges for each applicable measure. Additionally, we proposed to calculate a total performance score for each hospital by combining the greater of the

hospital's achievement or improvement points for each measure to determine a score for each domain, multiplying each domain score by a proposed weight (clinical process of care: 70 percent, patient experience of care: 30 percent), and adding together the weighted domain scores. We proposed to convert each hospital's Total Performance Score into a value-based incentive payment utilizing a linear exchange function.

We provided a 60-day public comment period in which we received approximately 319 timely comments from hospitals, health care facilities, advocacy organizations, researchers, patients, and other individuals and organizations. Summaries of the public comments, as well as our responses to those comments, are set forth below.

Comment: A number of commenters requested clarification on the interaction between the Hospital IQR program and the Hospital VBP program. Commenters specifically requested that we explain more fully how the penalties under the two programs will interact, as well as clarify if we intend to continue the Hospital IQR program in the future.

Response: The Affordable Care Act did not repeal section 1886(b)(3)(B)(viii), the statutory authority for the Hospital IQR program, and that program will continue to exist side-by-side with the Hospital VBP program. However, we note that beginning in FY 2015, the reduction to the applicable percentage increase under the Hospital IQR program changes from a straight 2.0 percentage point reduction to a reduction equal to "one quarter of such applicable percentage increase" (determined without regard to several other applicable statutory reductions).

We also note that under section 1886(o)(1)(C)(I), hospitals that are subject to the Hospital IQR program payment reduction for a fiscal year are excluded from the definition of "hospital" for purposes of the Hospital VBP program for that fiscal year. We interpret this provision to mean that a hospital that does not meet the requirements of the Hospital IQR program with respect to a fiscal year and, as a result, will receive a reduction to the applicable percentage increase for that fiscal year, will not be subject to the reduction to its base operating DRG payment amount under the Hospital VBP program for that fiscal year or be eligible to receive a value-based incentive payment for that fiscal year.

Comment: Some commenters requested that CMS delay implementation of the Hospital VBP program. A number of commenters urged CMS to adopt the implementation calendar discussed in 2007 Report to Congress, in which the first performance period would begin April 1, 2013.

Response: We are statutorily required to begin making value-based incentive payments under the Hospital VBP program to hospitals for discharges occurring on or after October 1, 2012 under section 1886(o)(1)(B) of the Act. Thus, the first performance period must begin before April 1, 2013, which is the time suggested by the commenters. As we stated in the proposed rule, in determining what performance period to propose to adopt, we were cognizant that hospitals submit data on the chart abstracted measures adopted for the Hospital IQR Program on a quarterly basis, and for that reason, we believed that the performance period should commence at the beginning of a quarter. We also recognized that we needed to balance the length of the performance period for collecting measure data with the need to undertake the rulemaking process in order to establish the performance period and provide the public with an opportunity to meaningfully comment on that proposal. With these considerations in mind, we proposed July 1, 2011 as the start of the performance period.

Comment: Some commenters requested additional information on how we will educate consumers about the Hospital VBP program.

Response: We understand how crucial it is to communicate clearly and consistently with all stakeholders in order to provide accurate and timely information about the Hospital VBP program. We believe that communicating in a way that promotes transparency and understanding of the Hospital VBP program will help reduce confusion and misunderstanding while enhancing the program's success.

To this end, we will be undertaking an extensive outreach and education campaign to ensure that all stakeholders understand how the Hospital VBP program works. In addition to providing information on www.cms.gov and www.medicare.gov, as well as through other existing mechanisms that we use to communicate with the public such as newsletters, e-mail blasts, listserv communications, special forums, and webinars, an important element of this campaign will be a new Hospital VBP page on *http://www.cms.gov.* In addition, as required under sections 1886(o)(10)(A) and (B), hospital specific and aggregate information for the Hospital VBP program will be made available on the Hospital Compare Web site.

Comment: One commenter stated that the Hospital VBP program statutory authority overlaps with other provisions of the Affordable Care Act and asked CMS to address the various incentives created by the Affordable Care Act, how it intends to differentiate among separate policies, and how it will ensure that incentives will not overlap or be duplicative. The commenter specifically cited efforts to increase productivity and efficiency through Accountable Care Organizations, market basket reductions for productivity, penalties related to hospital-acquired conditions, and payment reductions for readmissions.

Response: While there may be specific areas of overlap addressed by the various statutory provisions and policies, the legislative requirements, programs, and policies cited by the commenter represent interrelated but distinct areas of efforts to improve quality in the Medicare program. We will continue to monitor the interactions between the policies cited by the commenter and will continue discussions with stakeholders on this topic.

Comment: One commenter stated that all purchaser/payer value-based strategies and programs should be supported and encouraged through the Center for Medicare and Medicaid Innovation (CMMI).

Response: Created by the Affordable Care Act and launched on November 16, 2010, the CMMI will examine new ways of delivering health care and paying health care providers that can save money for Medicare and Medicaid while improving the quality of care. CMMI will consult a diverse group of stakeholders including hospitals, doctors, consumers, payers, States, employers, advocates, relevant federal agencies and others to obtain direct input and build partnerships for its upcoming work. We agree that CMMI is an important contributor in developing innovative strategies for value-based purchasing programs, and look forward to continuing to leverage the Center's resources and expertise in future years of the Hospital VBP program.

Comment: One commenter suggested that we establish a "Pay to Share" pool under which funding would be provided to enable higher-rated hospitals to instruct lower-rated hospitals on best practices.

Response: While we appreciate the comment, we do not believe we have the statutory authority under the Act to implement such a program at this time.

C. Performance Period

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for a fiscal year that begins and ends prior to the beginning of such

fiscal year. In considering various performance periods that could apply for purposes of the fiscal year 2013 payment adjustments, we recognized that hospitals submit data on the chart-abstracted measures adopted for the Hospital IQR program on a quarterly basis, and for that reason, we proposed that the performance period commence at the beginning of a quarter. We also recognized that we must balance the length of the period for collecting measure data with the need to undertake the rulemaking process in order to propose a performance period and provide the public with an opportunity to meaningfully comment on that proposal. With these considerations in mind, we concluded that July 1, 2011 is the earliest date that the performance period could begin.

Therefore, we proposed to use the fourth quarter of FY 2011 (July 1, 2011 through September 30, 2011) and the first and second quarters of FY 2012 (October 1, 2011 through March 31, 2012) as the performance period for the clinical process of care and HCAHPS measures we proposed to initially adopt for the FY 2013 Hospital VBP program. Under the proposed approach, hospitals would be scored based on how well they perform on the clinical process of care and patient experience measures during this performance period. For the three mortality outcome measures currently specified for the Hospital IQR program for the FY 2011 payment determination (MORT–30–AMI, MORT–30–HF, MORT–30–PN) that we proposed to adopt for the FY 2014 Hospital VBP program payment determination, we proposed to establish a performance period of July 1, 2011 to December 31, 2012. We also proposed to begin the performance period for the 8 proposed HAC measures and 9 proposed AHRQ Patient Safety Indicator (PSI) and Inpatient Quality Indicator (IQI) outcome measures 1 year after those measures were included on the *Hospital Compare* Web site. The proposed HAC and AHRQ measures were included on *Hospital Compare* on March 3, 2011.

Comment: A number of commenters requested that we adopt a 12-month performance period for the proposed mortality measures rather than the proposed 18-month performance period. Some were concerned that seasonal fluctuations in mortality rates would impact the measure rates if an 18-month performance period were used instead of a 12-month period.

Response: We proposed to use an 18-month performance period (July 1, 2011 through December 31, 2012) for the three proposed mortality measures in order to be able to increase the reliability of the measure rates by including more cases. However, in response to the commenters' concern about how the use of a period that is not equal to a year (or multiple years) could introduce seasonal fluctuations into the measure rates, we conducted additional reliability analyses on the hospital-level risk standardized mortality rates for the proposed 30-day mortality measures using 12 months, 18 months, and 24 months, and have concluded that 12 months of data provides moderate to high reliability for the Heart Failure and Pneumonia 30-day mortality measures, and is sufficiently reliable for the AMI 30-day mortality measure. Therefore, we are finalizing a 12-month performance period of July 1, 2011 to June 30, 2012 for the three proposed 30-day mortality measures for the FY 2014 Hospital VBP payment determination.

Comment: Some commenters expressed concern about the proposed baseline period for the FY 2014 mortality outcome measures. Commenters noted that the proposed 18-month baseline period would lead to data overlap during each program year.

Response: For the reasons noted above, we are finalizing a 12-month performance period of July 1, 2011 to June 30, 2012 for the three proposed 30-day mortality measures for the FY 2014 Hospital VBP payment determination. In accordance with our proposal that hospital performance should be evaluated based on how well hospitals performed during the same quarters in a baseline period, we are finalizing a 12-month baseline period for the mortality outcomes measures' performance standards calculations from July 1, 2009 to June 30, 2010. We believe that this change will address commenters' concerns about seasonal fluctuations in the data or overlap between program years.

Comment: Some comments requested that we require 2–3 years' worth of data for outcome measures to ensure that the measures do not result in any unintended consequences.

Response: As noted above, our reliability analyses for the proposed 30-day mortality measures indicate that using 12-months of data yields sufficient reliability (moderate to high) for the HF, PN and AMI 30-day mortality measures. We believe this time frame will enable us to calculate the measures using reliable data. CMS will monitor this policy to ensure that negative consequences do not occur as a result of the shortened performance period and, if indicated, would consider proposing to lengthen the performance period for future program years.

Comment: Many commenters generally supported our performance period proposals given the statutory deadlines.

Response: We thank commenters for their support.

Comment: Some commenters suggested that we use 12-month performance periods for all measures as soon as possible.

Response: We anticipate proposing to use a full year as the performance period for all measures in the future.

After considering the public comments, we are finalizing a performance period of July 1, 2011 through March 31, 2012 that will apply to the clinical process of care and patient experience measures for the FY 2013 Hospital VBP program. With respect to the FY 2014 Hospital VBP program, we are finalizing a 12-month performance period of July 1, 2011 through June 30, 2012 that will apply to the three 30-day mortality measures (AMI, HF, PN) that we are finalizing below. We are also finalizing our proposal to adopt a performance period that begins 1 year after any HAC and/or AHRQ measures that are specified for the Hospital IQR program are included on Hospital Compare, and in accordance with that finalized policy, the performance period for the 8 finalized HAC measures and 2 finalized AHRQ measures (discussed below) will begin on March 3, 2012. We intend to propose the end performance period date for the 8 finalized HAC measures and 2 finalized AHRQ measures in the CY 2012 Outpatient Prospective Payment System proposed rule.

D. Measures

Section 1886(o)(2)(A) of the Act requires the Secretary to select for the Hospital VBP program measures, other than readmission measures, from the measures specified for the Hospital IQR program. Section 1886(o)(2)(B)(i) of the Act requires the Secretary to ensure that the selected measures for FY 2013 include measures on the following specified conditions or topics: AMI; HF; PN; surgeries, as measured by the Surgical Care Improvement Project (SCIP); HAIs; and the HCAHPS survey. Section 1886(o)(2)(C)(i) of the Act provides that the Secretary may not select a measure with respect to a performance period for a fiscal year unless the measure has been specified under section 1886(b)(3)(B)(viii) of the Act and included on the *Hospital Compare* Web site for at least 1 year prior to the beginning of the performance period. Section 1886(o)(2)(C)(ii) of the Act provides that a measure selected under section

1886(o)(2)(A) of the Act shall not apply to a hospital if the hospital does not furnish services appropriate to the measure.

In the FY 2011 IPPS/RY 2011 LTCHPPS Final Rule (75 FR 50188), we stated that in future expansions and updates to the Hospital IQR program measure set, we will be taking into consideration several important goals. These goals include: (1) Expanding the types of measures beyond process of care measures to include an increased number of outcome measures, efficiency measures, and patients' experience of care measures; (2) expanding the scope of hospital services to which the measures apply; (3) considering the burden on hospitals in collecting chart-abstracted data; (4) harmonizing the measures used in the Hospital IQR program with other CMS quality programs to align incentives and promote coordinated efforts to improve quality; (5) seeking to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all payer claims databases; and (6) weighing the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital IQR program.

In addition, we stated in the proposed rule our belief that we must act with all speed and deliberateness to expand the pool of measures used in the Hospital VBP program. This goal is supported by at least two Federal reports documenting that tens of thousands of patients do not receive safe care in the nation's hospitals. For this reason, we proposed to adopt measures for the Hospital VBP program relevant to improving care, particularly as these measures are directed toward improving patient safety, as quickly as possible. We believe that speed of implementation is a critical factor in the success and effectiveness of this program.

The Hospital VBP program that we proposed to implement has been developed with the focused intention to motivate all subsection (d) hospitals to which the program applies to take immediate action to improve the quality of care they furnish to their patients. Because we view as urgent the necessity to improve the quality of care furnished by these hospitals, and because we believe that hospitalized patients in the United States currently face patient safety risks on a daily basis, we proposed to adopt an initial measure set for the Hospital VBP program. However, we also proposed to add additional measures to the Hospital VBP program in the future in such a way that their performance period would begin immediately after they are displayed on Hospital Compare for a period of time of at least one year, but without the necessity of notice and comment rulemaking. We proposed this because of the urgency to improve the quality of hospital care, and in order to minimize any delay to take substantive action in favor of patient safety.

We stated that for the Hospital IQR Program, we give priority to quality measures that assess performance on: (a) Conditions that result in the greatest mortality and morbidity in the Medicare population; (b) conditions that are high volume and high cost for the Medicare program; and (c) conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. In addition, we stated that we seek to select measures that address the six quality aims of effective, safe, timely, efficient, patient centered, and equitable healthcare. Current and long term priority topics include: Prevention and population health; safety; chronic conditions; high cost and high volume conditions; elimination of health disparities; healthcare-associated infections and other adverse healthcare outcomes; improved care coordination; improved efficiency; improved patient and family experience of care; effective management of acute and chronic episodes of care; reduced unwarranted geographic variation in quality and efficiency; and adoption and use of interoperable health information technology.

We also stated that these criteria, priorities, and goals are consistent with section 1886(b)(3)(B)(viii)(X) of the Act, as added by section 3001(a)(2)(D) of the Affordable Care Act, which requires the Secretary, to the extent practicable and with input from consensus organizations and other stakeholders, to take steps to ensure that the Hospital IQR program measures are coordinated and aligned with quality measures applicable to physicians and other providers of services and suppliers under Medicare.

As discussed in the Hospital Inpatient VBP Program proposed rule (76 FR 2459), to determine which measures to propose to initially adopt for the FY 2013 Hospital VBP program, we examined whether any of the eligible Hospital IQR measures should be excluded from the Hospital VBP program measure set because hospital performance on them is "topped out," meaning that all but a few hospitals have achieved a similarly high level of performance on them. We stated our belief that measuring hospital performance on topped-out measures would have no meaningful effect on a hospital's total performance score.

We also stated that scoring a topped-out measure for purposes of the Hospital VBP program would present a number of challenges. First, as discussed below, we proposed that the benchmark performance standard for all measures would be performance at the mean of the top decile of hospital performance during the baseline period. We noted in the Hospital Inpatient VBP Program proposed rule that, when applied to a topped-out measure, this proposed benchmark would be statistically indistinguishable from the highest attainable score for the measure and, in our view, could lead to unintended consequences as hospitals strive to meet the benchmark. Examples of unintended consequences could include, but would not be limited to, inappropriate delivery of a service to some patients (such as delivery of antibiotics to patients without a confirmed diagnosis of pneumonia), unduly conservative decisions on whether to exclude some patients from the measure denominator, and a focus on meeting the benchmark at the expense of actual improvements in quality or patient outcomes. Second, we stated that we have found that for topped-out measures, it is significantly more difficult to differentiate among hospitals performing above the median. Third, because a measure cannot be applied to a hospital unless the hospital furnishes services appropriate to the measure, we stated our belief that data reporting under the Hospital VBP program would not be the same for all hospitals. To the extent that a hospital could report a higher proportion of topped-out measures, for which its scores would likely be high, we stated that we believed such a hospital would be unfairly advantaged in the determination of its Total Performance Score.

To determine whether an eligible Hospital IQR measure is topped out, we initially focused on the top distribution of hospital performance on each measure and noted if their 75th and 90th percentiles were statistically indistinguishable. Based on our analysis, we identified 7 topped-out measures: AMI–1 Aspirin at Arrival; AMI–5 Beta Blocker at Discharge; AMI–3 ACEI or ARB at Discharge; AMI–4 Smoking Cessation; HF–4 Smoking Cessation; PN–4 Smoking Cessation; and SCIP–Inf–6 Surgery Patients with Appropriate Hair Removal. We then observed that two of these measures identified as topped out (AMI–3 ACEI or

ARB at Discharge and HF–4 Smoking Cessation) had significantly lower mean scores than the others, which led us to question whether our analysis was too focused on the top ends of distributions and whether additional criteria that could account for the entire distribution might be more appropriate. To address this, we analyzed the truncated coefficient of variation (CV) for each of the measures. The CV is a common statistic that expresses the standard deviation as a percentage of the sample mean in a way that is independent of the units of observation. Applied to this analysis, a large CV would indicate a broad distribution of individual hospital scores, with large and presumably meaningful differences between hospitals in relative performance. A small CV would indicate that the distribution of individual hospital scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions between individual hospital performance scores. We used a modified version of the CV, namely a truncated CV, for each measure, in which the 5 percent of hospitals with the lowest scores, and the 5 percent of hospitals with highest scores were first truncated (set aside) before calculating the CV. This was done to avoid undue effects of the highest and lowest outlier hospitals, which if included, would tend to greatly widen the dispersion of the distribution and make the measure appear to be more reliable or discerning. For example, a measure for which most hospital scores are tightly clustered around the mean value (a small CV) might actually reflect a more robust dispersion if there were also a number of hospitals with extreme outlier values, which would greatly increase the perceived variance in the measure. Accordingly, the truncated CV was added as an additional criterion requiring that a topped-out measure also exhibit a truncated CV < 0.10. Using both the truncated CV and data showing whether hospital performance at the 75th and 90th percentiles was statistically indistinguishable, we reexamined the available measures and determined that the same seven measures continue to meet our proposed definition for being topped-out.

Our analysis of the impact of including the topped-out measures discussed above indicated that their use would mask true performance differences among hospitals and, as a result, would fail to advance our priorities for the Hospital VBP program. We therefore proposed to not include these 7 topped-out measures (AMI–1 Aspirin at Arrival; AMI–5 Beta Blocker at Discharge; AMI–3 ACEI or ARB at Discharge; AMI–4 Smoking Cessation; HF–4 Smoking Cessation; PN–4 Smoking Cessation; and SCIP–Inf–6 Surgery Patients with Appropriate Hair Removal) in the list of measures we proposed to initially adopt for the FY 2013 Hospital VBP program. We sought comment on that proposal.

We also examined and sought comment on whether the following outcome measures adopted for the Hospital IQR program were appropriate for inclusion in the FY 2013 Hospital VBP program. These measures are as follows: (1) AHRQ PSIs, IQIs and composite measures; (2) AHRQ PSI and nursing sensitive care measure; and (3) AMI, HF, and PN mortality measures (Medicare patients). We stated our belief that these outcome measures provide important information relating to treatment outcomes and patient safety. We also stated in the proposed rule that we believe that adding these outcome measures would significantly improve the correlation between patient outcomes and Hospital VBP performance. However, because under section 1886(o)(2)(C)(i) of the Act, we may only select measures if they have been included on Hospital Compare for a least 1 year prior to the beginning of the performance period, we stated that the AHRQ PSIs, IQIs and composite measures, and the AHRQ Nursing Sensitive Care measure were not yet eligible for inclusion in the FY 2013 Hospital VBP program. Although these measures are currently specified for the Hospital IQR program, we acknowledged that as of the time we issued the proposed rule, they did not meet the one year Hospital Compare inclusion requirement.

We also considered whether the current publicly-reported 30-day mortality claims-based measures (Mort–30–AMI, Mort–30–HF, Mort–30–PN) should be included in the FY 2013 Hospital VBP program. The mortality measures assess hospital-specific, risk-standardized, all-cause 30-day mortality rates for patients hospitalized with a principal diagnosis of heart attack, heart failure, and pneumonia. All-cause mortality is defined for purposes of these measures as death from any cause within 30 days after the index admission date, regardless of whether the patient died while still in the hospital or after discharge. The eligible clinical process of care measures we considered covered AMI, HF, PN, and surgeries as measured by the SCIP. Therefore, we believe that they meet the requirements of section 1886(o)(2)(B)(i)(I)(aa)–(dd) of the Act, which requires us to include measures covering these conditions or procedures. Section 1886(o)(2)(B)(i)(ee) of the Act also requires the Secretary to select for purposes of the FY 2013 Hospital VBP program measures that cover HAIs "as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections (or any successor plan) of the Department of Health and Human Services." The SCIP measures discussed above were developed to support practices that have demonstrated an ability to significantly reduce surgical complications such as HAIs. Compliance with the selected SCIP infection measures is also included as a targeted metric in the HHS *Action Plan to Prevent Healthcare-Associated Infections* issued in 2009, available on the HHS Web site. As a result, we believe that the SCIP–Inf–1; SCIP–Inf–2; SCIP–Inf–3; and SCIP–Inf–4 measures we have adopted for the Hospital IQR program meet the requirement in section 1886(o)(2)(B)(i)(I)(ee); we proposed to adopt them for the FY 2013 Hospital VBP program and to categorize them under the HAI condition topic instead of under the SCIP condition topic.

Under section 1886(o)(2)(B)(i)(II), the Secretary must select measures for the FY 2013 Hospital VBP program related to the HCAHPS survey. CMS partnered with AHRQ to develop HCAHPS. The HCAHPS survey is the first national, standardized, publicly reported survey of patients' experience of hospital care, and we proposed to adopt it for the FY 2013 Hospital VBP program. HCAHPS, also known as the CAHPS® Hospital Survey, is a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience.

The HCAHPS survey asks discharged patients 27 questions about their recent hospital stay that are used to measure the experience of patients across 10 dimensions in the Hospital IQR program. The survey contains 18 core questions about critical aspects of patients' hospital experiences (communication with nurses and doctors, the responsiveness of hospital staff, the cleanliness and quietness of the hospital environment, pain management, communication about medicines, discharge information, overall rating of the hospital, and whether they would recommend the hospital). The survey also includes four items to direct patients to relevant questions if a patient did not have a particular experience covered by the survey, such as taking new medications or needing medicine for pain. Three

items in the survey are used to adjust for the mix of patients across hospitals, and two items related to race and ethnicity support congressionally-mandated reports on disparities in health care.

The HCAHPS survey is administered to a random sample of adult patients across medical conditions between 48 hours and 6 weeks after discharge; the survey is not restricted to Medicare beneficiaries. Hospitals must survey patients throughout each month of the year. The survey is available in official English, Spanish, Chinese, Russian and Vietnamese versions. The survey and its protocols for sampling, data collection and coding, and file submission can be found in the HCAHPS *Quality Assurance Guidelines, Version 5.0,* which is available on the official HCAHPS Web site, *http://www.hcahpsonline.org.*

AHRQ carried out a rigorous, scientific process to develop and test the HCAHPS instrument. This process entailed multiple steps, including: A public call for measures; literature review; cognitive interviews; consumer focus groups; stakeholder input; a three-state pilot test; small-scale field tests; and soliciting public comments via several **Federal Register** notices. In May 2005, the HCAHPS survey was endorsed by the NQF, and in December 2005, the Federal Office of Management and Budget gave its final approval for the national implementation of HCAHPS for public reporting purposes. CMS adopted the entire HCAHPS survey as a measure in the Hospital IQR program in October 2006, and the first public reporting of HCAHPS results occurred in March 2008. The survey, its methodology, and the results it produces are in the public domain.

As previously discussed, in determining what clinical process of care measures to propose, we analyzed the impact of including topped-out measures and determined that their use would mask true performance differences among hospitals, thus failing to advance our quality priorities. As a result, we proposed to exclude 7 topped-out measures (AMI–1 Aspirin at Arrival; AMI–5 Beta Blocker at Discharge; AMI–3 ACEI or ARB at Discharge; AMI–4 Smoking Cessation; HF–4 Smoking Cessation; PN–4 Smoking Cessation; and SCIP–Inf–6 Surgery Patients with Appropriate Hair Removal) from the list of measures we proposed to initially adopt for the FY 2013 Hospital VBP program.

We did not propose to adopt the current Hospital IQR structural measures because we believe that these measures require further development if they are to be used for the Hospital VBP program. Therefore, we solicited public comment on the possible utility of adopting structural measures for the Hospital VBP program measure set and how these measures might contribute to the improvement of patient safety and quality of care.

Finally, we proposed to exclude the PN–5c measure from the Hospital VBP program. We do not believe that this measure is appropriate for inclusion because it could lead to inappropriate antibiotic use. We proposed retiring this measure, as well as several other measures that we will not adopt for the Hospital VBP program, from the Hospital IQR program in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011.

We proposed to initially select 17 clinical process of care measures and the HCAHPS measure for inclusion in the FY 2013 Hospital VBP program. The proposed list of initial measures is provided in Table 1.

TABLE 1—PROPOSED MEASURES FOR FY 2013 HOSPITAL VBP PROGRAM

Measure ID	Measure description
Clinical Process of Care Measures	
Acute myocardial infarction	
AMI–2	Aspirin Prescribed at Discharge.
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival.
Heart Failure	
HF–1	Discharge Instructions.
HF–2	Evaluation of LVS Function.
HF–3	ACEI or ARB for LVSD.
Pneumonia	
PN–2	Pneumococcal Vaccination.
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.
PN–7	Influenza Vaccination.
Healthcare-associated infections	
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients.
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.
Surgeries	
SCIP–Card–2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period.
SCIP–VTE–1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered.
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.

TABLE 1—PROPOSED MEASURES FOR FY 2013 HOSPITAL VBP PROGRAM—Continued

Measure ID	Measure description
Patient Experience of Care Measures	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey.[1]

In the Hospital Inpatient VBP Program proposed rule, we solicited public comments on our intention to add measures to the Hospital VBP Program as rapidly as possible for their availability in future performance periods. To that end, we proposed to implement a subregulatory process to expedite the timeline for adding measures to the Hospital VBP program beginning with the FY 2013 program. Under this proposed process, we could add any measure to the Hospital VBP program if that measure is adopted under the Hospital IQR program and has been included on Hospital Compare for at least 1 year. We proposed that the performance period for all of these measures would start exactly 1 year after the date these measures were publicly posted on Hospital Compare, consistent with section 1886(o)(2)(C)(i). Under this proposed subregulatory process for adopting new Hospital VBP program measures, we would solicit comments from the public on the appropriateness of adopting 1 or more Hospital IQR measures for the Hospital VBP program. We would also assess the reported Hospital IQR measure rates using the criteria we used to select the measures for the initial FY 2013 Hospital VBP measure set and would notify the public regarding our findings. We stated that we would propose to set performance period end dates for any measure we selected for future Hospital VBP program years in rulemaking.

We also proposed to implement a subregulatory process to retire Hospital VBP measures. Under the proposed process, we would post our intention to retire measures on the CMS Web site at least 60 days prior to the date that we would retire the measure. Also, as we do with respect to Hospital IQR measures that we believe pose immediate patient safety concerns if reporting on them is continued, we proposed that we would notify hospitals and the public of the retirement of the measure and the reasons for its retirement through the usual hospital and QIO communication channels used for the Hospital IQR program, which include e-mail blasts to hospitals and the dissemination of Standard Data Processing System (SDPS) memoranda to QIOs, as well as post the information on the QualityNet Web site. We would then confirm the retirement of the measure from the Hospital VBP program measure set in a rulemaking vehicle. We made this proposal because it would allow us to ensure that the Hospital VBP program measure set focuses on the most current quality improvement and patient safety priorities. We solicited public comment on our proposals and other methods that allow for the addition of measures to the Hospital VBP program as rapidly as possible in order to improve quality and safety for patients.

In addition, we sought public comment on efficiency measures required for inclusion in the Hospital VBP program for value-based incentive payments made with respect to discharges occurring during FY 2014 or a subsequent fiscal year. Specifically, we requested comment on what services should be included and what should be excluded in a "Medicare spending per beneficiary" calculation, and what, if any, type(s) of hospital segmentation or adjustment should be considered in such a measure. We also solicited comment on approaches for measuring internal hospital efficiency. We took these comments into account in the development of the Medicare spending per beneficiary measure that we proposed to adopt in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011, available at *http://www.ofr.gov/inspection.aspx?AspxAutoDetectCookieSupport=1*).

The public comments we received are set forth below.

Comment: Some commenters agreed with our proposed measure set and our proposal to exclude PN–5c and structural measures.

Response: We thank the commenters for their support. We believe that the structural measures we have adopted for the Hospital IQR program require further development before we can consider adopting them for the Hospital VBP program, including the development of an appropriate scoring methodology. We also believe that the inclusion of PN–5c measure could lead to inappropriate antibiotic use. We also note that we have proposed to retire the PN–5c measure from the Hospital IQR program in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011 for the same reason that we proposed to not include it in the Hospital VBP program measure set.

Comments: Some commenters noted that CMS is retiring PN–2 (Pneumococcal Vaccination) and PN–7 (Influenza Vaccination) from the Hospital IQR Program and asked why these measures were included in the proposed rule. These commenters wanted to know how the retirement of these measures from the Hospital IQR Program would affect how these measures were collected and scored under the Hospital VBP program. Other commenters were concerned about including pneumonia vaccination measures in the Hospital VBP program measure set because they stated that there may be clinical reasons why a physician does not want a patient to receive the vaccination. The commenters suggested adding an "allowable value" or allowable code to the measure specifications to avoid penalizing the hospital for that situation.

Response: Commenters are correct in that we finalized our retirement of PN–2 (Pneumococcal Vaccination) and PN–7 (Influenza Vaccination) beginning with the FY 2014 Hospital IQR program payment determination (75 FR 50211), and hospitals will no longer be required to submit data on these measures beginning with January 1, 2012 discharges (75 FR 50221). Because these measures will cease to continue being Hospital IQR program measures midway through the performance period we are finalizing for the FY 2013 Hospital VBP program, we do not believe that we can include them in the FY 2013 Hospital VBP measure set.

Comment: One commenter requested clarification on whether we proposed to include SCIP–Inf–6 in the FY 2013 Hospital VBP measure set.

Response: Table 2 of the Hospital Inpatient VBP proposed rule (76 FR 2462) listed our proposed measures for FY 2013, and Table 2 of this Final Rule lists the finalized measures. As we

[1] Proposed dimensions of the HCAHPS survey for use in the FY 2013 Hospital VBP program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital.

explained in the Hospital Inpatient VBP proposed rule (76 FR 2461), we proposed not to adopt SCIP–Inf–6 for the Hospital VBP program because we concluded that the measure had achieved a "topped out" status.

Comment: A commenter suggested that the proposed clinical process of care measures are flawed, suggesting that hospitals might choose not to submit records that could adversely impact their total performance score when submitting quality data.

Response: All Hospital VBP program measures must be selected from the measures specified under the Hospital IQR program, and the data that we will use to calculate a hospital's total performance score for the clinical process of care measures will be the same data that the hospital submitted on those measures under the Hospital IQR program.

We allow hospitals to submit Hospital IQR clinical process of care measure data either by abstracting the necessary data elements from all qualifying cases or by submitting data elements taken from a sample of those cases. If the hospital chooses to submit a sample, the sample must meet the population and sample requirements outlined in the Specifications Manual. This Specifications Manual is posted on the CMS QualityNet Web site at *https://www.QualityNet.org/.* The purpose of these requirements is to ensure that the sample is statistically valid. We also note that we have adopted a process for validating clinical process of care measure data submitted under the Hospital IQR program, and we stated in the Hospital Inpatient VBP program proposed rule our belief that this process will also assure us that the same data is accurate for purposes of assessing hospital performance under the Hospital VBP program.

Comment: Several commenters asked if CMS will monitor "topped-out" measures to ensure that they remain "topped-out".

Response: At this time, we do not have a mechanism in place to monitor whether measures we do not adopt for the Hospital VBP program on the basis that they are topped-out remain topped-out. We will consider such monitoring in the future.

Comment: Some commenters suggested that CMS include in the Hospital VBP program measures that meet the definition of "topped out" because some hospitals will still be able to demonstrate improvement on them.

Response: As detailed in the Hospital Inpatient VBP proposed rule (76 FR 2460), we proposed to define a "topped out" measure as a measure for which hospital performance at the 75th and 90th percentiles are statistically indistinguishable, and the truncated CV was set at <0.10. We believe that if a measure is "topped out," there is no room for improvement for the vast majority of hospitals, and that measuring hospital performance on that measure will not have a meaningful effect on a hospital's Total Performance Score. For that reason, we proposed to exclude 7 topped-out measures from the FY 2013 Hospital VBP measure set.

Comment: We received several comments asking us to re-run our analysis of "topped-out" measures using more recent data to determine if any other measures also met that status.

Response: At the time we issued the Hospital Inpatient VBP proposed rule, the most recent data that was available to assess whether the proposed measures met our proposed definition of "topped out" was data from July 1, 2008 through March 31, 2009 which was the most recent validated data available and publicly displayed under the Hospital IQR program. However, since that time, data from the period that we proposed to set as the baseline period for the FY 2013 proposed measures has been validated (that is, data from the period July 1, 2009 to March 31, 2010). Therefore, in response to these comments, we analyzed all of the proposed FY 2013 measures to see if any of them met our proposed definition of "topped out" using this more recent data. We determined that three additional measures: AMI–2: Aspirin Prescribed at Discharge; HF–2: Evaluation of LVS Function; and HF–3: ACEI or ARB for LVSD meet our proposed definition of "topped-out" based on this more recent data. Because one of our goals for the Hospital VBP program is to ensure that hospital performance can be meaningfully measured and distinguished, we believe that it is appropriate to exclude these three additional measures from the FY 2013 Hospital VBP measure set based on this more recent analysis.

Comment: Some commenters suggested that we consider SCIP–Inf–2 and PN–3b for "topped out" status. Other commenters stated, generally, that other measures should be considered for "topped-out" status, particularly those on which the difference between median performance and top performance is small. One commenter stated that it had calculated achievement thresholds and benchmark scores for the proposed measures using data available on *Hospital Compare* that most closely matched data from CMS' proposed baseline period. The commenter stated that its analysis showed that with respect to several measures, hospital scores were clustered at a high level of achievement, and suggested that such measures should also be considered as "topped out."

Response: As discussed above, we examined all of the proposed measures using data from the baseline period that we are finalizing in this final rule, and determined that three additional measures (AMI–2, HF–2, HF–3) are topped-out based on this data. As for other measures, including SCIP–Inf–2 and PN–3b, for which performance is high but which do not meet the proposed definition of "topped-out" based on the more recent data, the data show that hospital performance on these measures can still be meaningfully distinguished. For this reason, we believe that it is appropriate to include these measures in the FY 2013 Hospital VBP measure set.

Comment: One commenter suggested that we not include the HF–1 measure (Discharge Instructions) from the Hospital VBP program because the measure does not measure clinical care provided, but instead measures administrative processes. Another commenter suggested that we exclude AMI–2, HF–1, HF–2 and SCIP–VTE–2 from the Hospital VBP program because these measures do not represent a significant improvement in the clinical practices required to deliver high value health care.

Response: We disagree. The HF–1 measure, Discharge Instructions, assesses several critical elements important to a discharged patient: Activity level, diet, discharge medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen. These elements are critical to ensuring that patients continue to receive appropriate, high-quality health care services after their discharge from the hospital. We believe that SCIP–VTE–2 is important for the Hospital VBP program because the optimal start of pharmacologic prophylaxis in surgical patients can significantly decrease the mortality and morbidity associated with blood clot formation.

As described above, we are not finalizing our proposal to include AMI–2 and HF–2 in the FY 2013 Hospital VBP measure set because based on an analysis involving data from the proposed baseline period, these measures meet our proposed definition of "topped-out."

Comment: One commenter suggested that we review the technical specifications for AMI–7a and AMI–8a to ensure that intervention timing is based on diagnosis by EKG.

Response: The intervention timing for both AMI–7a and AMI–8a runs from the time of arrival, not the time of diagnosis by EKG. Specifically, the specifications for the AMI–7a measure state that AMI patients with ST-segment elevation or Left bundle branch block (LBBB) on the EKG closest to arrival time receiving fibrinolytic therapy during the hospital stay have a time from hospital arrival to fibrinolysis of 30 minutes or less. Similarly, the specifications for the AMI–8a measure state that AMI patients with ST-segment elevation or LBBB on the ECG closest to arrival time receiving primary PCI during the hospital stay have a time from hospital arrival to PCI of 90 minutes or less. These specifications can be found on the QualityNet Web site (*http://www.qualitynet.org*). We note that these specifications are based on clinical guidelines adopted by the American College of Cardiology (ACC) clinical guidelines for ST elevation MI.

Comment: Some commenters expressed support for our exclusion of structural measures. Others suggested that we consider using specific structural measures in the future such as participation in a systematic database or registry.

Response: We believe these measures require further analysis of how they could be scored, and how they would impact a hospital's total performance score before they can be adopted for the Hospital VBP program. We intend to consider these issues as the Hospital VBP program evolves.

Comment: One commenter suggested including the three smoking cessation measures adopted for the Hospital IQR program (AMI–4, HF–4, PN–4), despite their "topped out" status, because of the risk that hospitals will not focus on these measures and overall performance could begin to decline.

Response: These measures meet our proposed definition of topped-out status. As we have stated, we do not believe that measuring performance on a topped-out measure produces a meaningful differentiation of hospital performance. We also note that we have proposed to retire these measures from the Hospital IQR measure set in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011. Therefore, we are excluding these measures from the Hospital VBP measure set. We will consider the feasibility of proposing to adopt a global smoking cessation measure for the Hospital VBP program.

Comment: A number of commenters supported our proposal to include PN–6 and PN–3b in the Hospital VBP measure set, stating that these measures encourage use of new technologies after patient diagnosis.

Response: We appreciate the support, and we believe that the inclusion of these measures will help promote the provision of quality care by promoting appropriate laboratory testing (taking of blood cultures to facilitate selection of the most effective antibiotic for the patient) and actual selection of appropriate antibiotics based on patient data.

Comment: Some commenters supported our proposal to use SCIP measures to capture HAIs.

Response: We thank commenters for their support. As discussed in the Hospital Inpatient VBP Program proposed rule (76 FR 2461), the SCIP measures were developed to support practices that have demonstrated an ability to significantly reduce surgical complications such as HAIs. Compliance with the proposed SCIP infection measures is also included as a targeted metric in the HHS *Action Plan to Prevent Healthcare-Associated Infections* issued in 2009, a copy of which is available on the HHS Web site.

Comment: One commenter suggested that measures should assess services regularly provided by rural hospitals and hospitals that do not perform surgeries.

Response: The measures selected for the Hospital VBP program address services provided by subsection (d) hospitals, including rural hospitals and hospitals that do not perform surgeries. For example, the HCAHPS dimensions measure patients' experiences of care at hospitals; none of the dimensions are surgery-specific. Additionally, pneumonia and other conditions such as heart failure and acute myocardial infarction are treated by rural hospitals.

Comment: A number of commenters called on CMS to use the Joint Commission's accountability criteria for measure selection, which include strong scientific evidence of improved outcomes, proximity to impacted outcomes, accurate assessment of evidence-based processes and minimal adverse effects.

Response: In August 2010, The Joint Commission published an article in the New England Journal of Medicine discussing the criteria that should be used to define a measure that is used for accountability and public reporting purposes versus criteria that is used to define measures used strictly for performance improvement. The Joint Commission identified four criteria a measure must have in order to have the greatest positive impact on patient outcomes. These criteria include: Research, Proximity, Accuracy, and Adverse Effects. Further information on the Joint Commission's accountability criteria may be found at *http://www.jointcommission.org/about/JointCommissionFaqs.aspx?CategoryId=31.* We generally agree with the Joint Commission's list of criteria that would apply to measures used for accountability purposes and considered this criteria in determining whether certain measures may warrant retirement from the Hospital IQR program. However, we do not agree with their exclusion of HF–1 from the list of accountability measures as we believe HF–1 assesses a hospital's compliance with providing critical information to patients at the time of their discharge, including instructions regarding activity level, diet, discharge medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen. As stated above, we believe that this information is critical for hospitals to provide in order to facilitate appropriate self-care and provider follow up care after a patient is discharged from the hospital.

Comment: A number of commenters recommended that we analyze measures against pre-established, agreed-upon criteria to ensure that they are relevant to value-based purchasing and will improve health outcomes for patients. Some commenters suggested that our goal should be to find the most appropriate ways to tie measures to patient benefits. Some commenters argued that current measures which we have proposed to adopt for the Hospital VBP program do not sufficiently impact health outcomes. Other commenters wondered if any measures are "paper-only" and do not reflect the actual provision of quality medical care.

Response: To ensure that measures assess the quality of care provided to Medicare beneficiaries, we agree that measures should be scrutinized by experts and evaluated against objective criteria. We believe that these elements have been incorporated into our measure selection process in a variety of ways, including through endorsement by consensus-developing entities and through notice and public comment rulemaking. For example, most of the measures that we have selected for the Hospital IQR program, (which make them candidates for the Hospital VBP program) are endorsed by the NQF, the entity with a contract with the Secretary under Section 1890(a) of the Act. To the extent that we have determined that measurement is needed in a specified area for which there are no NQF endorsed measures, we give due consideration to measures endorsed or adopted by different consensus

organizations before specifying the measure. We also consider whether the measures meet the goals of the National Priorities Partnership, enable the Department to further its strategic goals and initiatives, and whether they are adopted by the HQA. This has resulted in our adoption of meaningful measures that assess the quality of care furnished by hospitals.

Comment: A few commenters were concerned that the HCAHPS scores publicly reported on Hospital Compare differ by bed size, type of hospital and geography and thought the HCAHPS scores should be adjusted for these factors. These commenters thought HCAHPS needs to be vetted more to understand these differences to ensure that HCAHPS is a reliable measure.

Response: Although we recognize that HCAHPS results differ by bed size and other hospital characteristics, we do not interpret these differing results to mean that the survey should be risk adjusted. HCAHPS results also differ among hospitals with the same characteristics, which we view as evidence that the results account for differences in the quality of care received by patients. In general, risk adjustment models control for exogenous factors that are beyond the control of a hospital, not for hospital characteristics that are endogenous, or within their control.

We also believe that the HCAHPS survey has been thoroughly vetted, including through reviews in peer-reviewed journals and through notice and comment rulemaking when we adopted it for the Hospital IQR program, and it is endorsed by the NQF.

Comment: One commenter questioned whether top-box responses in the HCAHPS survey are appropriate for urban, safety net hospitals that serve culturally diverse patients and may not be able to "always" communicate well with their patients.

Response: The "top-box" response to HCAHPS survey items is the most positive response that a patient can provide (often presented in the survey as "Always"). Medicare does not have an indicator for a "safety net hospital." However, we have examined the HCAHPS results submitted by urban hospitals, which we believe can serve as a rough proxy for a "safety net hospital." Urban hospitals, particularly large ones, have historically not performed as well on HCAHPS as rural hospitals. However, our internal studies of HCAHPS results show that hospitals in the following urban areas scored in the top 25 percent of hospitals overall: New York City, Boston, Baltimore, Atlanta, Chicago, Los Angeles, San Francisco, San Diego, Phoenix, Dallas, Houston, and San Antonio. We believe that these results suggest that urban hospitals are not being disadvantaged by the HCAHPS measurement.

Comment: Several commenters questioned the reliability of HCAHPS data. Some suggested that we consider possible negative consequences associated with its use.

Response: Since its national implementation in October 2006, when hospitals began to administer the HCAHPS survey, our analyses of HCAHPS results has shown that this standardized, publicly reported survey of patients' experience of hospital care is satisfactorily reliable at 100 completed surveys using statistical measures of reliability that calculate the proportion of the variance in reported hospital scores that is due to true variation between hospitals, rather than within hospital variation that reflects limited sample size.

We also note that since public reporting of HCAHPS scores began under the Hospital IQR program[?] in March 2008 there have been small but statistically significant improvements in 9 of 10 HCAHPS dimensions.[2] In addition, we are aware of abundant anecdotal evidence that hospitals are engaging in quality improvement efforts aimed at improving the quality of the inpatient experience. We believe that HCAHPS, in part, motivates these efforts and expect that hospitals will continue to improve their patients' experience of care as the incentives for doing so become more salient.

We believe that setting the minimum number of measures and cases as low as is reasonable is an essential component of implementing the Hospital VBP program and will help to minimize the number of hospitals unable to participate due to not having the minimum number of cases for a measure or the minimum number of measures. Therefore, we also proposed that, for inclusion in the Hospital VBP program for FY 2013, hospitals must report a minimum of 100 HCAHPS surveys during the performance period. Our statistical analyses show that HCAHPS is a reliable measure of patient experience and, therefore, we see no negative consequences with its use.

Comment: One commenter provided suggestions for additional items regarding palliative care that could be added to the HCAHPS instrument; another commenter suggested that CMS add questions about patient activation (patients' knowledge, skills, and confidence for self-management), care coordination, shared decision-making and support for patient self-management.

Response: As part of our ongoing maintenance activities for the HCAHPS survey, which include assessing whether it needs to be updated, we will consider the feasibility of adding the suggested survey items.

Comment: One commenter wanted to exclude the doctor communication dimension from the HCAHPS measure, reasoning that hospital payment under the IPPS should not be based in part upon physician behavior that it cannot control.

Response: We are including the doctor communication dimension as an HCAHPS dimension because it is a key aspect of care from the perspective of consumers. In addition, many hospitals employ their own doctors (hospitalists) who are directly under the hospitals' control.

Comment: Some commenters opposed combining the cleanliness and quiet items because they are conceptually different and the cleanliness item is important for patient safety.

Response: We thank commenters for their input. Although these two items were originally proposed to be one composite in the survey, we separated them into two individual measures for public reporting prior to the 2006 national implementation because it made more sense for consumers to see ''clean'' and ''quiet'' as distinct environmental aspects of hospitals. The ''clean'' and ''quiet'' HCAHPS measures will continue to be publicly reported separately on Hospital Compare for the Hospital Inpatient Quality Reporting program.

For purposes of the Hospital VBP program, these two items were combined so as not to put more weight on the environmental items compared to the rest of the HCAHPS items, which are composite measures (with the exception of Overall Rating). If the environmental items were separated, quietness of the hospital environment, for example, would receive as much weight as nurse communication, which includes 3 items from the HCAHPS survey. The combined ''cleanliness and quietness'' HCAHPS dimension will be publicly reported on Hospital Compare as part of the Hospital VBP program.

Comment: Some commenters were concerned that the risk adjustment models for the HCAHPS survey are not adequate and do not control for the severity of a patient's condition, socio-economic status, and geographic differences

[2] See "Hospital Survey Shows Improvements in Patient Experience." M.N. Elliott, W.G. Lehrman, E.H. Goldstein, L.A. Giordano, M.K. Beckett, C.W. Cohea and P.D. Cleary. *Health Affairs,* 29 (11): 2061–2067. 2010.

Response: HCAHPS dimensions are currently patient-mix adjusted. We adjust HCAHPS data for patient characteristics that are not under the control of the hospital that may affect patient reports of hospital experiences. The goal of adjusting for patient-mix is to estimate how different hospitals would be rated if they all provided care to comparable groups of patients. As part of the endorsement process for HCAHPS, the NQF endorsed the HCAHPS patient-mix adjustment currently in use.

The HCAHPS patient-mix adjustment (PMA) model incorporates important and statistically significant predictors of patients' HCAHPS ratings that also vary meaningfully across hospitals (O'Malley et al., 2005). The PMA model includes seven variables, as follows: Self-reported health status, education, service line (medical, surgical, or maternity care), age, response percentile order (also known as "relative lag time," which is based on the time between discharge and survey completion), service line by linear age interactions, and primary language other than English. Initially the model also included admission through an emergency room, but because admission through an emergency room is no longer available on the UB–92 Form, this adjuster is no longer available for the patient-mix model. We are exploring other options to obtain that information in the future. We have found that evaluations of care increase with self-rated health and age (at least through age 74), and decrease with educational attainment. Maternity service has generally more positive evaluations than medical and surgical services. Percentile response order (relative lag time) findings show that late responders tend to provide less positive evaluations than earlier responders. From research conducted during the development of HCAHPS, we found little evidence that DRG matters beyond the service line, which is included in the patient mix model.

To further address specific concerns about the adjustment model, it is important to note that self-reported health status is a widely accepted measure of a person's overall health status. In general, ''how would you rate your health'' is the most widely used single self-reported health item and is used in a plethora of national health surveys. Education also captures important aspects of socio-economic status. Income is generally not available to adjust survey data.

Patient-mix adjustment is based on variation by patient-level factors within hospitals so that true differences between hospitals are not included in the adjustment.[3] Controlling for geographic region (a hospital-level factor) as part of a patient-mix adjustment model could mask important differences in quality across the country.

Comment: Several commenters suggested changing the HCAHPS requirements to reduce the number of required mailings and telephone attempts, allow survey administration while patients are still in the hospital, and allow electronic administration of the survey to reduce the cost of survey administration.

Response: We know from our HCAHPS research that, on average, late responders report less positive experiences. For this reason, we believe that allowing hospitals to reduce their effort to obtain completed surveys by reducing the required number of mailings and telephone attempts would bias the HCAHPS results. Under the current HCAHPS requirements, which can be found in the HCAHPS Quality Assurance Guidelines available at *www.hcahpsonline.org,* the administration of the HCAHPS survey begins 48 hours following discharge to ensure that the patient has had an opportunity to return home or go to an alternative location. We also believe that allowing a hospital to administer the survey while the patient is still in the hospital has the potential to create biased results because the patient might not feel that he or she can freely answer the questions with hospital staff nearby.

We note that we have tested an Internet version of HCAHPS. However, at this point, we do not believe that hospitals routinely collect e-mail addresses or that the Medicare population has enough experience with the Internet to support allowing hospitals to administer the survey via the Internet. This is a technology that we will continue to explore because we agree with the commenters that electronic administration of the survey would be less expensive for hospitals.

Comment: One commenter was concerned that patients would be more likely to recommend larger hospitals due to the spectrum of services offered by them and, thus, smaller and rural hospitals would be disadvantaged by HCAHPS.

Response: Because HCAHPS focuses on the actual experiences of care by asking patients about what happened during the hospital stay, the HCAHPS data are not biased by the perceptions of patients in terms of the range of services offered by different hospitals. In fact, smaller hospitals generally tend to do better on HCAHPS relative to larger ones.

While most HCAHPS survey items assess the patient's actual experience in the hospital, two survey items ask for the patient's overall impressions of the hospital stay. Because these items are highly correlated and potentially draw on wider influences, we have proposed to include only one global dimension, Overall Rating, in the Hospital VBP program scoring for the HCAHPS measure.

Comment: Some commenters called on us to make HCAHPS patient mix adjustment formulas public.

Response: The HCAHPS patient-mix adjustment formulas are publicly available on *http://www.hcahpsonline.org.* The data on *http://www.hcahpsonline.org* regarding the adjustments are updated quarterly.

Comment: Some commenters opposed the use of 30-day mortality rates in the Hospital VBP program because they are "all-cause" measures and do not exclude deaths that are not attributable to a hospital's quality of care. One commenter questioned the use of the mortality measures, citing the possibility of unintended consequences and remarking that, "unless hospitals are provided with specific interventions which have been demonstrated to reduce morality, penalizing a hospital for an increase in mortality (or rewarding one for a decrease in mortality) is not rationally related to the operations of the hospital." Other commenters argued that the Hospital VBP program should focus on outcome measures that are risk adjusted to account for extremely ill patients.

Response: We appreciate commenters' input on measures for use in the Hospital VBP program. The proposed all-cause risk adjusted 30-day mortality measures are endorsed by the National Quality Forum (NQF). There are several reasons why we believe it is appropriate for us to adopt the NQF-endorsed all-cause mortality measures for the Hospital VBP program.

First, from the patient perspective, death is the key outcome regardless of its cause. Second, cause of death may be unreliably recorded. Third, the cause of death may represent a complication related to the underlying condition. For example, a patient with HF who develops a hospital-acquired infection may ultimately die of sepsis and multi-organ failure. It would be inappropriate to consider the death as unrelated to the care the patient received for HF.

[3] See "*Adjusting Performance Measures To Ensure Equitable Plan Comparisons.*" *Zaslavsky, A.M., L.B. Zaborski, D.J.A. Shaul, M.J. Cioffi, and P.D. Cleary. Health Care Financing Review'' 22(3): 109–26. 2001.*

Another patient might have a complication leading to renal failure, resulting in death, and yet quality of care could have reduced the risk of the complication. A patient with PN who did not receive deep vein thrombosis prophylaxis may ultimately die of a pulmonary embolism. It would be inappropriate to consider the death as unrelated to the care the patient received for PN. Although this approach will include some patients whose death may be unrelated to their care (for example, a casualty in a motor vehicle accident), events completely unrelated to the admission are expected to be uncommon and should not be clustered unevenly among hospitals.

Furthermore the NQF-endorsed measure methodology for all three of these all-cause mortality measures includes a risk adjustment for protein-calorie malnutrition, dementia, and metastatic cancer that are common among extremely ill patients.

Comment: Some commenters suggested that we should ensure that measures, particularly those added in FY 2014, appropriately capture services provided by hospitals, as not all hospitals treat all conditions.

Response: We agree and note that we proposed that hospitals must have at least 10 cases per measure in order to be scored on that measure and report on at least 4 measures to be included in the Hospital VBP program. We also believe that the finalized Hospital VBP measures capture a broad range of hospital services, which will enable a large number of hospitals to participate in the program.

Comment: One commenter suggested that we proceed cautiously in seeking to adopt outcome measures for the Hospital VBP program, and that we first demonstrate their statistical reliability for low-volume hospitals.

Response: We agree that acceptable statistical reliability is important to our analysis in determining what measures to adopt for the Hospital VBP program. As stated above, we conducted analyses on the 30-day outcome measures we are adopting for this program and have found them to be reliable for all hospitals for purposes of Hospital VBP scoring.

Comment: One commenter suggested that CMS use an error bar or other visual display of the confidence intervals surrounding mortality rate performance similar to the displays currently used on *Hospital Compare* for mortality measures.

Response: The confidence intervals currently shown on *Hospital Compare* are used to classify hospitals into broad categories for purposes of that display. For the Hospital VBP program, we will score all of the Hospital VBP measures using the scoring methodology that we finalize for the program. The use of this scoring methodology will result in each hospital being assigned a point estimate that reflects its score on each of the mortality measures, and it is those scores, rather than broad confidence intervals, that will be used for purposes of the public reporting.

Comment: Some commenters expressed general support for the 3 proposed 30-day mortality measures.

Response: We thank commenters for their support.

Comment: Some commenters suggested that we exclude some types of cases, including hospice or palliative care, from the mortality measure calculations. They also suggested that this "new" mortality rate measurement without hospice and palliative care patients should be displayed on *Hospital Compare* for one year prior to implementation.

Response: The risk-adjusted mortality measure methodology excludes admissions for Medicare fee-for-service patients who elect hospice care any time in the 12 months prior to the index hospitalization, including the first day of the index admission. Information on the methodology used to calculate the measures can be found at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1163010398556.*

Comment: Many commenters opposed our proposal to adopt HAC measures for the FY 2014 Hospital VBP program, arguing that we will be penalizing hospitals on those measures both under the Hospital VBP program, the HAC policy required by Section 3008 of the Affordable Care Act and the Medicaid penalties required by Section 2702 of the Affordable Care Act.

Response: We view the program authorized by section 3008 of the Affordable Care Act and the Hospital VBP Program as being related but separate efforts to reduce HACs. Although the Hospital VBP program is an incentive program that provides incentive-based payments to hospitals based on quality performance, the program established by section 3008 of ACA creates a payment adjustment resulting in payment reductions for the lowest performing hospitals. We also view programs that could potentially affect a hospital's Medicaid payment as separate from programs that could potentially affect a hospital's Medicare payment, although we intend to monitor the various interactions of programs authorized by the Affordable Care Act and their overall impact on providers and suppliers.

Comment: Several commenters requested that we ensure the harmonization of new programs and any overlay or duplication in the Affordable Care Act, generally.

Response: We are coordinating the development and implementation of all of these programs and will continue to monitor their impacts on providers and suppliers.

Comment: Some commenters argued that CMS should analyze HAC measures more closely to test the validity of "present on admission" (POA) diagnosis coding. The commenters suggested that CMS compare POA coding to chart-review to test the appropriateness of using claims-based measures for payment purposes. Commenters more generally argued that the current measure format does not allow for valid comparisons due to coding issues and physician behavior.

Response: The purpose of POA coding is to allow better discernment of whether a diagnosis is a complication of care received in the hospital or an adverse event occurring in the hospital. Beginning in FY 2007, we have proposed, solicited, and responded to public comments and have implemented the Hospital Acquired Condition Program under section 1886(d)(4)(D) of the Act and its accompanying POA coding requirement through the IPPS annual rulemaking process. For specific policies addressed in each rulemaking cycle, we direct readers to the following publications: the FY 2007 IPPS proposed rule (71 FR 24100) and final rule (71 FR 48051 through 48053); the FY 2008 IPPS proposed rule (72 FR 24716 through 24726) and final rule with comment period (72 FR 47200 through 47218); the FY 2009 IPPS proposed rule (73 FR 23547), and final rule (73 FR 48471); and the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43782). A complete list of the 10 current categories of HACs is included in section II.F.2.of FY 2011 IPPS/RY 2011 LTCH PPS (75 FR 50080 through 50101).

POA coding is also used in the specifications for the component indicators for the AHRQ Patient Safety composite measure we proposed to adopt for the Hospital VBP program for FY 2014. This composite measure consists of 8 component indicators, including PSI–3 (Pressure ulcer), PSI–6 (Iatrogenic Pneumothorax), PSI–7 (Central venous catheter-related bloodstream infections), PSI–8 (Postoperative hip fracture), PSI–12 (Postoperative pulmonary embolism or

deep vein thrombosis), PSI–13 (Postoperative sepsis), PSI–14 (Postoperative wound dehiscence), and PSI–15 (Accidental Puncture or Laceration). For each of these component indicators, present-on-admission coding is one of the exclusion criteria used to indicate whether a condition or an injury occurred before or after the patient was admitted to the hospital. Please refer to *www.qualityindicators.ahrq.gov* for further details about the technical specifications for these measures. We are using the POA information on the final adjudicated claim submitted by the hospital. These data are subject to the same scrutiny as other information on Medicare claims.

We also note that we are currently evaluating the Hospital Acquired Condition-Present on Admission (HAC–POA) Program. We appreciate the commenters' interest and will take it into consideration as we proceed with this evaluation.

Comment: Some commenters noted that the proposed HAC measures are limited to the Medicare fee-for-service population and suggested that these measures should not be used in Hospital VBP.

Response: The proposed HAC measures are calculated using only Medicare fee-for-service data because we do not currently have access to claims data that is submitted by hospitals to other payers. We also note that POA codes, which are required to calculate all of the proposed HAC measures and which must be included on Medicare Part A claims submitted to CMS by hospitals, may not be required to be included on inpatient claims submitted by hospitals to other payers. Despite this data limitation, we believe that the proposed HAC measures provide important information regarding patient safety events occurring during hospitalization, which reflect the quality of patient care provided, and we believe these measures should be included in the Hospital VBP program.

Comment: Some commenters questioned whether value-based incentive payments will be available only to Medicare FFS and Medicare cost payers and not Medicare Advantage Organization (MAO) payers.

Response: Value-based incentive payments made under the Hospital VBP program can be made only in the form of an adjustment to a subsection (d) hospital's base operating DRG payment amount under the IPPS.

Comment: Some commenters noted that the proposed HAC measures do not capture more than 9 diagnoses.

Response: CMS' current system limitations allow for the processing of only the first 9 diagnoses and 6 procedures. While CMS accepts all 25 diagnoses and 25 procedures submitted on the claims, we do not process all of the codes because of these system limitations.

In the FY 2011 IPPS/LTCH–PPS final rule, we discussed our plans to accept and process up to 25 diagnoses and procedures on the hospital inpatient claims submitted on the 5010 format beginning January 1, 2011 (75 FR 50127 through 50128). In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we responded to hospitals' requests that we process up to 25 diagnosis codes and 25 procedure codes (74 FR 43798). In that FY 2010 IPPS/RY 2010 LTCH PPS final rule, we referred readers to the ICD–10 final rule (74 FR 3328 through 3362) where we discuss the updating of Medicare systems prior to the implementation of ICD–10 on October 1, 2013. We mentioned that part of the system updates in preparation for ICD–10 is the "expansion of our ability to process more diagnosis and procedure codes." In the FY 2009 IPPS final rule (73 FR 48433 through 48444), we also responded to multiple requests to increase the number of codes processed from 9 diagnosis and 6 procedure codes to 25 diagnosis and 25 procedure codes.

We are currently making extensive system updates as part of the move to 5010, which includes the ability to accept ICD–10 codes. This complicated transition involves converting many internal systems prior to October 1, 2013, when ICD–10 will be implemented. One important step in this planned conversion process is the expansion of our ability to process additional diagnosis and procedure codes. We are currently planning to complete the expansion of this internal system capability so that we are able to process up to 25 diagnoses and 25 procedures on hospital inpatient claims as part of the HIPAA ASC X12 Technical Reports Type 3, Version 005010 (Version 5010) standards system update.

Comment: Many commenters recommended that CMS develop risk adjustment methods, measure exclusion criteria, or stratified scoring methods to account for variations in measure rates related to patient factors or hospital function. Commenters argued that many of the proposed outcome, patient experience, and other measures including HCAHPS, HACs, and mortality measures are not valid because they lack appropriate risk adjustment and exclusion criteria and called for their exclusion from the Hospital VBP program. One commenter suggested risk adjustments should specifically be employed for trauma patients. A number of commenters suggested that CMS consider other risk adjustment models used by the industry, such as those promulgated by the Society of Thoracic Surgeons. One commenter suggested that we include "median income of ZIP code of residence" in a risk adjustment methodology for mortality measures in order to account for socioeconomic variables that may lead to a greater rate of mortality. Additionally, some commenters suggested that CMS convene experts to develop a "population adjustment" and adopt only HACs that do not rely on claims data for the Hospital VBP program.

Response: For the measures that currently employ risk adjustment, we are using the risk adjustment models that are part of the NQF-endorsed measure specifications. In developing its risk adjustment model for the 30-day measures, the NQF performed an extensive literature review of risk factors employed by other models to inform the development of its model. We note that the current risk adjustment methodology for the three proposed mortality measures for FY 2014 was recently reevaluated and approved by an NQF steering committee. There is no risk adjustment for race and socioeconomic status, which we believe is appropriate because we do not want to hold hospitals with different racial or SES mixes to different performance standards. Adjusting for race or SES would also obscure differences that are important to identify if we want to reduce disparities where they do exist. We note that the NQF has issued guidance recommending against adjusting for patient characteristics such as socioeconomic status in outcomes measures, located at: *http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx.* We welcome collaboration on this issue with providers that serve unique patient populations and functions.

Furthermore, while we understand that claims-based measures such as HAC measures have certain limitations, as discussed below, HAC measures were defined in prior rulemaking, during which we conducted several listening sessions and had the benefit of receiving public comment. We note that some of the HACs are "never" events and therefore should not be risk adjusted. We will consider refinements to the HAC measures in future years. We will monitor the impact of the Hospital VBP program on the care provided to

vulnerable subpopulations of patients, including trauma patients.

Comment: Some commenters argued that the proposed HAC measures should be risk-adjusted before they are used in Hospital VBP.

Response: Six of the 8 HACs adopted for the Hospital VBP program are considered "never events," for which risk adjustment would not be appropriate because, in our view, such events should never happen under any circumstances. In the event that we do decide that some type of risk adjustment would be appropriate, we will seek input from the NQF as to whether or not this constitutes a substantive change to the measures, in which a formal consensus development process will be initiated. We will consider further refinements to the HAC measures in future years. We note that when we adopted the HAC vascular catheter-associated infection measure and the catheter-associated urinary tract infection measure in the FY 2008 IPPS final rule with comment period (72 FR 47202 through 47218), there were no related risk-adjustments under the DRG payment policy reforms (72 FR 47141).

Comment: Some commenters suggested that measures should be approved by the Hospital Quality Alliance (HQA) before use in the Hospital VBP program.

Response: In developing the Hospital VBP program, we took into account the input of a multitude of stakeholders, including the HQA. The HQA is a national, public-private collaboration committed to making meaningful, relevant, and easily understood information about hospital performance accessible to the public and to informing and encouraging efforts to improve quality. We will also continue to consider HQA input as part of our ongoing measure selection process for the Hospital VBP program.

Comment: Some commenters argued that the low incidence rates of HACs, particularly in academic medical centers, would lead to unstable statistics on which to base comparisons between hospitals.

Response: Low incidence of events does not equate to unstable rates for those events. We acknowledge that the rates of some of the HACs, particularly the ones measuring 'never events', may be rare. However, because these are considered events that should never happen, reporting their prevalence, though rare, is still meaningful. We have not found that HAC incidence is particularly low in academic medical centers. We believe that all of the proposed HAC measures are important to measure and report, despite their low incidence rates, and that the public reporting of the HACs on the *Hospital Compare* Web site will encourage improvement. We believe that the Hospital VBP program must emphasize patient safety and improved quality of health care, and we believe that holding hospitals accountable for HACs will further those goals.

Comment: Some commenters asked us to discuss the inclusion of HAIs in HACs. Specifically, the commenters asked us to include additional detail on how CMS plans to implement HHS's HAI Action Plan.

Response: Two of the eight proposed HAC measures (Vascular Catheter-Associated Infection and Catheter-Associated Urinary Tract Infection) capture HAIs. We are considering the feasibility of proposing to adopt all of the metrics listed in the HAI Action Plan for the Hospital IQR program in future years. In the FY 2011 IPPS/LTCH PPS final rule, we adopted two of the HAI measures from the HHS HAI Action Plan: the central line-associated bloodstream infection measure, for which reporting began with respect to January 2011 events; and the surgical site infection measure, which hospitals will begin reporting with respect to January 2012 events. In addition, we have proposed in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011, to adopt additional HAI measures: Catheter-associated urinary tract infection measure, central line insertion practices adherence percentage; Methicillin-resistant Staphylococcus aureus (MRSA), Clostridium difficile (C–Diff), and Health Care Personnel Influenza Vaccination measures. All of these measures, if finalized for the Hospital IQR program, will be eligible for inclusion in the Hospital VBP program, and would allow CMS to better address the important topic area of Healthcare Associated Infections.

Comment: Some commenters noted that HACs are not entirely preventable and argued that they should not be a component of quality measurement.

Response: We believe that all 8 proposed HAC measures assess the presence of hospital acquired conditions that are reasonably preventable if high quality care is furnished to the patient. We also believe that the incidence of HACs in general raise major patient safety issues for Medicare beneficiaries. According to the 2010 Department of Health and Human Services Office of the Inspector General Report, entitled "Adverse Events in Hospitals: National Incidence among Medicare Beneficiaries," an estimated 13.5 percent of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays (OIG, November 2010, OEI–06–09–00090). We proposed to adopt 8 HAC measures for the Hospital VBP program because they are outcome measures (which are widely regarded by the provider community as strongly indicative of quality of medical care) that assess whether certain adverse events occurred during hospitalization. We believe that the adoption of these measures will facilitate our on-going efforts to hold hospitals accountable for these events, as well as reduce the incidence of these adverse events that result in harm to Medicare beneficiaries and higher costs of care.

Comment: Some commenters asked us to explain why HACs are appropriate for quality measurement and scoring given that they are derived from billing and payment methods.

Response: We believe that public reporting of the HACs on the *Hospital Compare* Web site will encourage improvement. We acknowledge that the incidence of HACs may be rare. However, many of the HACs are considered events that should never happen; reporting their prevalence, though rare, is still meaningful.

Medicare fee for service claims data is the source for many measures that are NQF endorsed. This data source was reviewed as part of the NQF endorsement process for such measures, and has been found to be an appropriate data source. We also refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47202 through 47218); section II.F. of the FY 2009 IPPS final rule with comment period (73 FR 48474 through 48486); and section II.F. of the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43782 through 43785) for detailed discussions regarding the selection of the current 10 HAC categories.

Comment: Some commenters suggested that CMS consider integrating HACs, complications and other causes of waste into an efficiency domain rather than in clinical process or outcomes.

Response: We believe that the proposed HAC measures best capture health care quality outcomes rather than efficiency and are therefore best included in the outcome domain.

Comment: One commenter suggested that we revise the definition of Falls and[?] Trauma. Specifically, the commenter suggested that the definition should be revised to require not only these injury codes, but also an e-code related to falls that are not POA.

Response: We appreciate the suggestion to refine the definition of this

HAC, and will consider refinements for future implementation.

Comment: Some commenters requested that we provide detailed measure specifications for the proposed HAC measures immediately if we intend to use them in the Hospital VBP program.

Response: The specifications for these proposed measures were made available on *QualityNet* at *http://www.qualitynet.org* earlier in the year.

Comment: Some commenters were opposed to the use of Nursing Sensitive measures in the Hospital VBP measure set while others, noting that nurses provide numerous services to patients, argued that nursing sensitive measures are essential quality indicators.

Response: We agree that nurses provide numerous services to their patients, and we are interested in nursing sensitive measures because those measures capture many processes and outcomes that are influenced by nursing practice. Currently, we only have one nursing sensitive measure in the Hospital IQR Program: Death among surgical inpatients with serious treatable complications (AHRQ PSI–04). We are also collecting the structural measure "Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care". We will consider adopting one or more measures in the nursing sensitive category for the Hospital IQR and Hospital VBP programs in the future.

Comment: Some commenters opposed the use of any AHRQ PSI and IQI measures or their composites in Hospital VBP. Others suggested that those measures should be evaluated for validity and reliability as they were not developed to be performance measures and are based on claims data. Others noted that hospitals have encountered technical and programming issues with respect to the proposed AHRQ measures.

Response: We thank commenters for their input. The AHRQ PSI and IQI measures that we proposed to adopt for the Hospital VBP measure set are NQF endorsed. In order to achieve NQF endorsement, measures must meet all of the criteria of the NQF consensus development process. Information on this process can be found at: *http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx.* We believe this consensus development process includes the necessary steps to assure that measures that are NQF endorsed have been tested for validity and reliability of the data. This endorsement includes the data source needed to calculate the measures (Medicare fee for service claims). We believe these measures are appropriate for use in the Hospital VBP program as they meet the statutory requirements for inclusion and address the topic of patient safety, which is a high priority that we believe should be addressed in the Hospital VBP program. We also note that because these measures are claims-based, no separate data reporting is needed.

Comment: One commenter objected to the use of PSI 4, arguing that about 25 percent of surgical patients are admitted with sepsis or acute illness and multiple organ failure for surgical exploration, then coded as surgical patients even if the surgery doesn't find anything and doesn't contribute to death.

Response: We have not proposed to adopt PSI 4, Death among surgical inpatients with serious, treatable complications, for inclusion in the Hospital VBP program. However, we note that the specifications for that measure specifically exclude patients with a diagnosis of sepsis or infection in the primary diagnosis field and patients who are immunosuppressed.

Comment: Some commenters argued that the proposed AHRQ measures amount to double-counting for purposes of scoring, as two of the proposed AHRQ measures are composites of the other AHRQ measures.

Response: We appreciate commenters' concerns. We agree that the use of all of the proposed AHRQ measures, including the two composite measures, would result in "double-counting" each of the individual measures. While each of the individual AHRQ measures capture important components of quality care, we believe that scoring hospital performance on the two composite measures simply and clearly captures the provision of high quality care that we wish to incentivize in the Hospital VBP program. Therefore, we are only finalizing the 2 proposed AHRQ composite measures, which will avoid any double-counting.

Comment: Some commenters argued that all outcome, process, and patient experience measures should be posted on *Hospital Compare* for one year prior to use in the Hospital VBP program, and that, during this year, CMS should provide quarterly hospital preview reports on *qualitynet.org* with a percentile ranking for each measure in order to prepare for public reporting.

Response: In accordance with statutory requirements, all measures will be included on *Hospital Compare* for at least one year prior to the beginning of the performance period for which we propose to adopt them under the Hospital VBP program. The process of care measures and HCAHPS are updated quarterly, and facilities that submit data are provided a 30-day preview of their data before public reporting occurs. The outcomes of care measures are updated annually, usually in July. The new outcomes data is included in the preview reports for this display period. As stated below, we will provide details on the information to be reported on *Hospital Compare* in future rulemaking. We will consider commenters' suggestion for quarterly preview reports on *qualitynet.org* before public reporting. However, we believe that providing robust quality information to the public as soon as possible is a desired outcome of quality reporting and performance scoring.

Comment: One commenter noted that the requirement that measures be included on *Hospital Compare* appears to be a significant barrier to timely adoption of the HAI Action Plan metrics in the Hospital VBP program. Other commenters encouraged us to accelerate the adoption of those metrics for the Hospital IQR program, *Hospital Compare,* and NQF endorsement.

Response: We agree that the requirement that measures be included on the Hospital Compare Web site for at least one year before the performance period for them can begin under the Hospital VBP program has the potential to limit the speed at which we can adopt measures for the program, however we intend to propose to adopt measures that drive quality improvements and improve patient safety, such as the prevention metrics included in the HHS Action Plan to Prevent HAIs, as quickly as possible within that constraint.

Comment: Some commenters argued that CMS's data collection system does not adequately differentiate among conditions acquired in the hospital and those that are "present on admission" (POA) for purposes of scoring outcome measures. Commenters recommended that CMS allow hospitals to use POA claims indicators or consider other methods for outcome measure scoring, particularly since certain types of hospitals such as trauma centers or tertiary referral centers could be penalized on those measures because they receive a disproportionate share of transfers from other hospitals. Some commenters suggested that transferee and transferor hospitals should share in mortality rates for transferred patients.

Response: We are currently using the POA indicator to calculate the proposed HAC and AHRQ patient safety composite measures, and we believe that the use of this indicator will better enable us to identify patient safety events, conditions and complications arising during hospital stays. We also

note that, under the specifications for the 30-day mortality measures, if the primary discharge diagnosis at the receiving hospital matches the primary discharge diagnosis at the transferring hospital, the patients are included in the transferring hospital's mortality measure calculations. We believe this approach encourages coordination between hospitals and their referral networks. Further, we believe that this approach promotes the best interests of the patient because it does not create an incentive for hospitals to transfer patients who are critically ill or at high risk of dying.

Comment: Some commenters were concerned about the accuracy of claims-based quality measures. In particular, they questioned how claims-based quality measurements will be accurate given hospitals' technical and programming issues with the AHRQ measures, which are claims based rather than chart abstracted.

Response: Both the AHRQ measures and their data source have been endorsed by NQF. We note that other quality initiatives, such as the Medicare End-Stage Renal Disease Quality Incentive Program, require reporting on claims-based measures. While they have certain limitations, claims-based measures provide important information on hospital quality of care. We also note that hospitals are not required to submit data for the AHRQ measures; rather, the calculations are derived from Medicare fee-for-service claims data. Thus, neither technical nor programming issues should arise. For the reasons discussed above, we are only finalizing the two composite AHRQ measures.

Comment: Some commenters opposed our proposal to implement a subregulatory process for adding or retiring measures, calling on CMS to use full notice and comment rulemaking instead. A few commenters supported the proposed subregulatory process.

Response: We appreciate the comments, and understand that stakeholder input is critical to ensuring that the Hospital VBP program and measure set improves the quality of care and patient safety. As stated in the Hospital Inpatient VBP proposed rule (76 FR 2458 through 2459), we believe that we must act with all speed and deliberateness to expand the pool of measures used in the Hospital VBP program. This goal is supported by at least two Federal reports documenting that tens of thousands of patients do not receive safe care in the nation's hospitals.[4]

For this reason, we believe that we should adopt measures for the Hospital VBP program relevant to improving care, particularly as these measures are directed toward improving patient safety, as quickly as possible. Additionally, we believe that we should retire measures from the Hospital VBP program as quickly as possible to ensure that they do not detract from other measures that we believe will be more impactful in improving patient health. We believe that speed of implementation is a critical factor in the success and effectiveness of this program.

However, we are aware of stakeholders' concerns about the proposed subregulatory process. We understand commenters' point that notice-and-comment rulemaking is important to ensure that hospitals are aware of the applicable measures. In response to those comments, we will not finalize the proposed subregulatory process for adding or retiring measures. Instead, we have proposed in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011 that we might choose to propose to simultaneously adopt one or more measures for both the Hospital IQR Program and the Hospital VBP program. We refer readers to that proposal for further information.

Comment: Some commenters suggested that we consider adopting quality measures covering more conditions to ensure that hospitals improve the quality of care that they furnish to all patients, not just those diagnosed with conditions covered by current quality measures.

Response: We thank commenters for the suggestion. The Affordable Care Act specifically names AMI, HF, PN, SCIP, HAIs and HCAHPS as initial topics to be included in the Hospital VBP program in FY 2013. We will consider other measures and conditions for inclusion in the Hospital VBP program for future years.

Comment: Some commenters strongly opposed use of the IQI stroke mortality measure, arguing that it is not adjusted for stroke severity.

Response: We thank commenters for their suggestion. The current methodology for this measure, including the risk adjustment methodology is NQF endorsed.

Comment: A number of commenters asked how hospitals will be scored and payments will be adjusted when measure specifications change.

Response: We understand that from time to time measure specifications require updating. We maintain the technical specifications by updating the Specifications Manual semiannually, or more frequently in unusual cases, and include detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required measures. While many of these updates or changes do not impact the calculation of the measures, we are aware that substantive changes to the specifications for a measure may impact the score a hospital receives.

Comment: Some commenters asked if measure adoption will expand at a rate that keeps pace with hospital resources. Other commenters expressed concern that measure reporting might burden hospitals, while others suggested that we consider how difficult measures are for hospitals to improve upon.

Response: We are cognizant of the reporting burden on hospitals associated with the adoption of new measures under both the Hospital IQR program and the Hospital VBP program. In proposing to adopt new measures for the Hospital IQR program, which make them candidates for the Hospital VBP program, we have emphasized on many occasions that we take into consideration the burden that additional reporting will have on hospitals, and we seek, for that reason, to limit our proposals to adopt chart-abstracted measures. We also carefully consider whether the benefit that we believe will be realized from adopting additional measures (such as encouraging hospitals to improve their performance on those measures) will outweigh the burden associated with their collection.

Comment: Some commenters asked if 30-day readmission rates will be included in the Hospital VBP program.

Response: Measures of readmissions are statutorily excluded under section 1886(o)(2)(A) of the Act and therefore cannot be included in the Hospital VBP program.

Comment: A commenter asked if measure scores will be based on all-payer data or Medicare data only. Some commenters argued that the Hospital VBP program's measures should capture data for all patients, not Medicare patients only so that hospitals are ranked and incentivized according to their care for all patients, rather than for Medicare patients only.

Response: Measures in the clinical process and patient experience domains are scored using all-patient data while measures in the outcome domain will be scored using Medicare claims data only. Although we generally agree that all-patient data would be a preferable

[4] See OEI–06–09–00090 "Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries." Department of Health and Human Services, Office of Inspector General, November 2010. See also, 2009 National Healthcare Quality Report, pp. 107–122. "Patient Safety," Agency for Healthcare Research and Quality.

source of data for purposes of calculating all Hospital VBP measures, we currently do not have access to claims data submitted by hospitals to other payers.

Comment: Some commenters suggested that we more forcefully endorse the NQF process, expressing concern that marginalizing the NQF endorsement process might discourage hundreds of hard working volunteers.

Response: We work closely with the NQF on issues related to measure endorsement because that entity holds the contract under section 1890(a) of the Act. However, we note that in the case of a specified area or medical topic determined appropriate by the Secretary for which there is no NQF-endorsed measure, section 1886(b)(3)(B)(viii)(IX)(bb) of the Act allows us to specify a measure that is not NQF-endorsed so long as due consideration has been given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Comment: Several commenters suggested that we consider adopting a central line-associated blood stream infections measure, a surgical site infections measure, and/or the National Database of Nursing Quality Indicators for the Hospital VBP program.

Response: We thank commenters for their input. We note that we have adopted a central line-associated blood stream infection measure (CLABSI) and surgical site infection measure (SSI) for the Hospital IQR program, and we anticipate proposing to adopt these measures for the Hospital VBP program in the future. The National Database of Nursing Quality Indicators (NDNQI) were previously considered for Hospital IQR program adoption (See 72 FR 47351), and we remain interested in these measures.

Comment: Some commenters asked us to explain why the current requirement by CMS for NHSN reporting begins with January 2011 events for CLABSI and with January 2012 events for SSI.

Response: In response to public comments on the FY 2011 IPPS/LTCH PPS proposed rule, we adopted one NHSN collected measure (the CLABSI measure) for the FY 2013 Hospital IQR payment determination (with reporting beginning with respect to January 2011 events) to allow hospitals to gain experience with the NHSN collection mechanism for one year before requiring hospitals to begin reporting a second measure (SSI) using that mechanism (75 FR 50202).

Comment: Some commenters argued that the FY 2013 measures do not reflect nurses' contributions to patient care.

Response: We disagree. Many of the process of care measures reflect the contributions of a broad range of healthcare professionals, including nurses. Furthermore, a number of measures rely heavily on nursing input and documentation. Additionally, one of the eight HCAHPS dimensions focuses exclusively on nurses' role in communicating with patients regarding their care.

Comment: One commenter suggested that we post measure information on *Hospital Compare* for 2 years prior to adopting them in the Hospital VBP program.

Response: We thank the commenter for the input. Although we acknowledge that section 1886(o)(2)(C)(i) provides, in part, that measures must be included on the Hospital Compare Web site for at least one year prior to the performance period, we believe that a one year period is sufficient to ensure that hospitals, Medicare beneficiaries and other stakeholders are fully aware of and familiar with the measures before they are added to the Hospital VBP program. We also believe that any further delay would unnecessarily postpone the adoption of important measures for the Hospital VBP program.

Comment: One commenter noted that care coordination measures are not included in the Hospital VBP measure set.

Response: We will consider this comment as we seek to expand the Hospital VBP measure set in the future.

Comment: One commenter called on us not to use the Krumholtz methodology for mortality measures. The commenter noted that this methodology has only been applied in very narrow ranges of diagnoses; may not be useful for comparing mortality rates; has weak explanatory power; omits variables that should be considered; and would be difficult if not impossible to generalize.

Response: We disagree. The risk-standardized mortality rates for the three proposed mortality measures are derived from administrative data for Medicare patients with a principal discharge diagnosis of AMI, HF, and PN from all acute care and critical access hospitals in the nation. The model used for calculation includes several variables and has a relatively high discrimination rate. As a result we believe this methodology is appropriate to use. Additionally, this methodology falls within the scope of the NQF-endorsement for the three proposed mortality measures.

Comment: One commenter asked us to clarify whether hospital data reported on *Hospital Compare* that are also collected by the Joint Commission will continue to be included on *Hospital Compare.*

Response: Yes. Many of the AMI, Heart Failure, Pneumonia and SCIP measures reported to CMS for Hospital IQR and publicly reported on *Hospital Compare* are also collected and utilized by the Joint Commission. In addition, hospitals can voluntarily choose to allow CMS to publicly report the Joint Commission's children's asthma care measures, which are not part of Hospital IQR, on *Hospital Compare.* We will continue to publicly report all Hospital IQR measures and other quality information on *Hospital Compare.*

Comment: One commenter questioned whether the proposed clinical process of care measures have been tested in older patients and women to assure applicability to Medicare's patient subpopulations.

Response: The clinical process of care measures proposed for the Hospital VBP program have been tested and used in all patients 18 years and older which includes older patients and women if they meet criteria for inclusion in the measure.

Comment: Some commenters recommended that CMS and outside experts study the measures' actual impact on patients and caregivers. Commenters also expressed concern about possible unintended consequences for patient care due to measure design, such as some hospitals refusing to admit high-risk patients in an effort to improve their Total Performance Score.

Response: We thank commenters for their input. We intend to monitor the initial impacts of the Hospital VBP program, including its impacts on costs, quality, outcomes, and patient experiences with care. We believe the Hospital VBP program represents a significant next step in aligning payment with the quality of care delivered to beneficiaries. We firmly believe that these efforts will increase the quality of care provided, resulting in improved health outcomes. However, we will monitor and evaluate the impact of the Hospital VBP program on access to and quality of care, including monitoring any unintended consequences.

Comment: One commenter stated that the proposal to use electronic submission for measures in future years was misaligned with one of the potential future measures. The measure, "median time from admit decision time to time of departure from the emergency department (ED) for ED patients admitted to inpatient status" differs from the specifications put forth by

HITSP (Health Information Technology Standards) which specifies the measure as, Admit Decision Time to ED Departure Time. The difference is that the former does not allow for the use of Admit Orders Date (or Admit Orders Time) in the measures specification while the HITSP specifications do allow the use of this data.

Response: We agree that the measure specifications for "median time from admit decision time to time of departure from the emergency department (ED) for ED patients admitted to inpatient status" require manual chart abstraction, and is specified slightly different than electronic health record version of the measure. This is because of the availability of the data. When abstracting data manually, a human abstractor uses specific guidelines for abstraction. Admit order date/time are not included in the chart abstracted version as the intent of the measure is to calculate throughput time (that is, how long the patient is in the ED) which is calculated from admit decision to departure from the Emergency Department. The admit decision time is generally found in a note written in the chart, and therefore, a human abstractor can interpret that data element per the guidelines for abstractions. In contrast, admit date/time are used in the electronic specifications as the two fields are readily available in the electronic health record (EHR), and there is no human interpretation. At this time, data from a progress note is not considered a discreet data element and therefore cannot be used for EHR abstraction.

After consideration of public comments, we are finalizing our proposed definition of "topped out" for purposes of measure selection under the Hospital VBP program. We will use this definition to inform our measure proposals for future Hospital VBP program years and will use the most recently available data at the time to conduct our analysis. Additionally, we are finalizing our proposal to adopt 12 of the 17 proposed clinical process of care measures for the FY 2013 Hospital VBP program, but for the reasons discussed above, are not finalizing our proposal to adopt the following measures: PN–2, PN–7, AMI–2, HF–2 and HF–3.

Table 2 lists the 13 measures we are finalizing for the FY 2013 Hospital VBP measure set.

TABLE 2—FINAL MEASURES FOR FY 2013 HOSPITAL VBP PROGRAM

Measure ID	Measure description
Clinical Process of Care Measures	
Acute myocardial infarction	
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival.
Heart Failure	
HF–1	Discharge Instructions.
Pneumonia	
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.
Healthcare-associated infections	
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients.
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.
Surgeries	
SCIP–Card–2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period.
SCIP–VTE–1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered.
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.
Patient Experience of Care Measures	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey.[5]

With respect to the FY 2014 Hospital VBP measure set, we are finalizing our proposal to adopt the three 30-day mortality claims-based measures, MORT–30–AMI, MORT–30–HF, and MORT–30–PN, as well as the 8 proposed HAC measures. In light of the public comments we received regarding the proposed AHRQ measures and as discussed above, we are only finalizing the 2 composite measures: Complication/patient safety for selected indicators (composite) and Mortality for selected medical conditions (composite). The measures that we are finalizing in this final rule for the FY 2014 Hospital VBP Program are listed in Table 3 below.

[5] Proposed dimensions of the HCAHPS survey for use in the FY 2013 Hospital VBP program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital.

TABLE 3—FINALIZED OUTCOME MEASURES FOR THE FY 2014 HOSPITAL VBP PROGRAM

Mortality Measures (Medicare Patients):
• Acute Myocardial Infarction (AMI) 30-day mortality rate.
• Heart Failure (HF) 30-day mortality rate.
• Pneumonia (PN) 30-day mortality rate.
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) Composite Measures:
• Complication/patient safety for selected indicators (composite).
• Mortality for selected medical conditions (composite).
Hospital Acquired Condition Measures:
• Foreign Object Retained After Surgery.
• Air Embolism.
• Blood Incompatibility.
• Pressure Ulcer Stages III & IV.
• Falls and Trauma: (Includes: Fracture Dislocation Intracranial Injury Crushing Injury Burn Electric Shock).
• Vascular Catheter-Associated Infection.
• Catheter-Associated Urinary Tract Infection (UTI).
• Manifestations of Poor Glycemic Control.

As noted above, we have proposed in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011 to adopt an additional measure, Medicare spending per beneficiary, for the FY 2014 Hospital VBP program. We also intend to propose to adopt additional measures for the FY 2014 Hospital VBP program in the CY 2012 OPPS proposed rule.

E. Performance Standards

To determine what the performance standard for each proposed clinical process of care measure and the proposed HCAHPS measure should be for purposes of the FY 2013 Hospital VBP program, we analyzed the most reliable and current hospital data that we had on each of these measures by virtue of the Hospital IQR program. Because we proposed to adopt a performance period that was less than a full year for FY 2013, we were sensitive to the fact that hospital performance on the proposed measures could be affected by seasonal variations in patient mix, case severity, and other factors. To address this potential variation and ensure that the hospital scores reflect their actual performance on the measures, we believe that the performance standard for each clinical process of care measure and HCAHPS should be based on how well hospitals performed on the measure during the same time period in the applicable baseline period. In determining what three-quarter baseline period would be the most appropriate to propose to use for the FY 2013 Hospital VBP program, we wanted to ensure that the baseline would be as close in time to the proposed performance period as possible. We stated our belief that selecting a three-quarter baseline period from July 1, 2009 to March 31, 2010 will enable us to achieve this goal. We also believe that an essential goal of the Hospital VBP program is to provide incentives to all hospitals to improve the quality of care that they furnish to their patients. In determining what level of hospital performance would be appropriate to select as the performance standards for each measure, we focused on selecting levels that would challenge hospitals to continuously improve or maintain high levels of performance.

As required by Section 1886(o)(3)(D), we specifically considered hospitals' practical experience with the measures, particularly through the Hospital IQR program, examining how different achievement and improvement thresholds would have historically impacted hospitals, how hospital performance may have changed over time, and how hospitals could continue to improve.

We proposed to set the achievement performance standard (achievement threshold) for each proposed FY 2013 Hospital VBP measure at the median of hospital performance (50th percentile) during the baseline period of July 1, 2009 through March 31, 2010. As proposed in the Hospital Inpatient VBP proposed rule (76 FR 2463 through 2464), hospitals would receive achievement points only if they exceed the achievement performance standard and could increase their achievement score based on higher levels of performance. We believe these achievement performance standards represent achievable standards of excellence and will reward hospitals for meritorious performance on quality measures. We also proposed to set the improvement performance standard (improvement threshold) for each measure at each specific hospital's performance on the measure during the baseline period of July 1, 2009 through March 31, 2010. We believe that these proposed improvement performance standards ensure that hospitals will be adequately incentivized to improve.

We proposed to set the achievement performance standard (achievement threshold) for each of the proposed FY 2014 Hospital VBP mortality measures at the median of hospital performance (50th percentile) during the baseline period. We proposed to set the improvement performance standard (improvement threshold) for each mortality measure at each specific hospital's performance on each measure during the baseline period of July 1, 2008 to December 31, 2009. The comments we received on these proposals and our responses are set forth below.

Comment: A number of commenters suggested that we publish baseline achievement thresholds and benchmarks for clinical process measures and HCAHPS dimensions on *Hospital Compare.*

Response: The finalized achievement thresholds and benchmarks that apply to the FY 2013 Hospital VBP program are provided in Table 4 of this final rule. We will consider the commenters suggestion to publish baseline achievement thresholds and benchmarks on Hospital Compare in the future.

Comment: One commenter requested that CMS clarify whether hospitals lacking the minimum number of patients or measures would be included in baseline period calculations of thresholds and benchmarks.

Response: The achievement thresholds and benchmarks will be calculated using data from a baseline period comparable in length to the performance period. For this reason, we believe that we should also use the same minimums for purposes of those calculations.

Comment: One commenter suggested that we compare performance among similar hospitals rather than against

national data. Other commenters asked if CMS was going to adjust the baseline period data based on any factors such as geographic region.

Response: We believe that achievement thresholds and benchmarks based on national data provide balanced, appropriate standards of high quality care for hospitals to work towards under the Hospital VBP program. Some groups of hospitals may perform better or worse than other hospitals on certain measures, but we do not believe it would appropriate to raise or lower the performance standards based on such observations. For example, we do not wish to lower the performance standards for a hospital simply because average performance in its local region is subpar compared to national performance. Similarly, we do not wish to raise or lower the performance standards for large hospitals, teaching hospitals, or others based on any observations that classes of hospitals differed in their average performance on individual measures. We note that consumers will be able to compare geographically and demographically similar hospitals' performance on measures as they currently do on the *Hospital Compare* Web site.

Comment: One commenter asked us to clarify the baseline periods for Hospital VBP program years after FY 2013.

Response: We intend to propose all future baseline periods in future rulemaking and specifically, intend to propose the FY 2014 Hospital VBP payment determination baseline period in the CY 2012 OPPS rule.

Comment: One commenter asked how CMS will address hospital mergers that occur during the performance period.

Response: The issue of how to address the calculation of the total performance score in the context of hospital mergers will be the subject of future rulemaking.

After considering the public comments, we are finalizing the proposed definitions of the achievement performance standard (achievement threshold) and the improvement performance standard (improvement threshold) for the FY 2013 Hospital VBP program as displayed below in Table 4. Because our process for validating the proposed baseline period of data was not yet complete at the time we issued the proposed rule, we were unable to provide the precise achievement threshold values; instead we provided example achievement performance standards. We also stated that these values would be specified in the final rule (76 FR 2464), and they are shown below.

TABLE 4—ACHIEVEMENT THRESHOLDS THAT APPLY TO THE FY 2013 HOSPITAL VBP PROGRAM MEASURES

Measure ID	Measure description	Performance standard (achievement threshold)
Clinical Process of Care Measures		
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0.6548
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0.9186
HF–1	Discharge Instructions	0.9077
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.	0.9643
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	0.9277
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0.9735
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients	0.9766
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	0.9507
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	0.9428
SCIP–VTE–1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered	0.9500
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.	0.9307
SCIP–Card–2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period.	0.9399
Patient Experience of Care Measures		
HCAHPS	Communication with Nurses	75.18%
	Communication with Doctors	79.42%
	Responsiveness of Hospital Staff	61.82%
	Pain Management	68.75%
	Communication About Medicines	59.28%
	Cleanliness and Quietness of Hospital Environment	62.80%
	Discharge Information	81.93%
	Overall Rating of Hospital	66.02%

We are also finalizing the achievement thresholds for the three mortality measures, (displayed as survival rates) in Table 5 below based on a 12-month baseline period from July 1, 2009 to June 30, 2010:

TABLE 5—ACHIEVEMENT THRESHOLDS FOR THE FY 2014 HOSPITAL VBP PROGRAM MORTALITY OUTCOME MEASURES (DISPLAYED AS SURVIVAL RATES)

Measure ID	Measure description	Performance standard (achievement threshold)
	Mortality Outcome Measures	
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate	84.8082%
MORT–30–HF	Heart Failure (HF) 30-Day Mortality Rate	88.6109%
MORT–30 PN	Pneumonia (PN) 30-Day Mortality Rate	88.1795%

F. Methodology for Calculating the Total Performance Score

1. Statutory Provisions

Section 1886(o)(5)(A) of the Act requires the Secretary to develop a methodology for assessing each hospital's total performance based on performance standards with respect to the measures selected for a performance period. Using such methodology, the Secretary must provide for an assessment for each hospital for each performance period.

Section 1886(o)(5)(B) of the Act sets forth 5 requirements related to the scoring methodology developed by the Secretary under section 1886(o)(5)(A). Specifically, section 1886(o)(5)(B)(i) requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of value-based incentive payments among hospitals receiving different levels of hospital performance scores, with hospitals achieving the highest hospital Total Performance Scores receiving the largest value-based incentive payments.

Section 1886(o)(5)(B)(ii) provides that, under the methodology, the hospital Total Performance Score must be determined using the higher of the applicable hospital's achievement or improvement score for each measure. Section 1886(o)(5)(B)(iii) requires that the hospital scoring methodology provide for the assignment of weights for categories of measures as the Secretary deems appropriate. Section 1886(o)(5)(B)(iv) prohibits the Secretary from setting a minimum performance standard in determining the hospital performance score for any hospital. Finally, section 1886(o)(5)(B)(v) requires that the hospital performance score for a hospital reflect the measures that apply to the hospital.

2. Additional Factors for Consideration

As discussed in the Hospital Inpatient VBP Program proposed rule, in addition to statutory requirements, we also considered several additional factors when developing the proposed performance scoring methodology for the Hospital VBP program. First, we stated our belief that it is important that the performance scoring methodology is straightforward and transparent to hospitals, patients, and other stakeholders.

Hospitals must be able to clearly understand performance scoring methods and performance expectations to maximize quality improvement efforts.

The public must understand performance score methods to utilize publicly reported information when choosing hospitals.

Second, we stated our belief that the scoring methodologies for all Medicare Value-Based Purchasing programs, including (but not limited to) the End Stage Renal Disease Quality Incentive Program should be aligned as appropriate given their specific statutory requirements. This alignment will facilitate the public's understanding of quality information disseminated in these programs and foster more informed consumer decision making about health care. Third, we stated our belief that differences in performance scores must reflect true differences in performance. In order to ensure this in the proposed Hospital VBP Program, we assessed the quantitative characteristics of the measures we are proposing to use to calculate the Total Performance Score, including the current state of measure development, distribution of current hospital performance in the proposed measure set, number of measures, and the number and grouping of measure domains. Fourth, we stated that we must appropriately measure both quality achievement and improvement in the Hospital VBP program. Section 1886(o)(5)(B)(ii) of the Act specifies that performance scores under the Hospital VBP program be calculated utilizing the higher of achievement and improvement scores for each measure; that explicit direction has implications for the design of the performance scoring methodology. We must also consider the impact of performance scores utilizing achievement and improvement on hospital behavior due to payment implications. Fifth, we stated that we wished to eliminate unintended consequences for rewarding inappropriate hospital behavior and outcomes to patients in our performance scoring methodology. Sixth, we stated that we wished to utilize the most currently available data to assess hospital improvement in a performance score methodology. We believe that more current data would result in a more accurate performance score, but recognize that hospitals require time to abstract and collect quality information. We also require time to process this information accurately.

The methodology proposed in the Hospital Inpatient VBP Program proposed rule for calculating the improvement score relies on a comparison of the hospital's performance during the performance period against its performance during a baseline period rather than a comparison of the hospital's performance during a particular year against its performance during a previous year (as was outlined in the 2007 Report to Congress).

We stated that we planned to propose future annual updates to the baseline period through future rulemaking. We recognize that comparing a payment year's performance period with the previous year's performance period may be a better estimate of incremental improvement.

In the Hospital Inpatient VBP Program proposed rule, we solicited comment on the merits and impact of all of the factors related to our performance score methodology alternatives, including the choice of how to define the baseline year.

We welcomed suggestions on improving the simplicity of the Hospital VBP program performance score methodology and its alignment with other CMS quality initiatives.

3. Background

In November 2007, CMS published the 2007 Report to Congress.[6] In addition to laying the groundwork for hospital value-based purchasing, the 2007 Report to Congress analyzed and presented a potential performance scoring methodology (called the Performance Assessment Model) for the Hospital VBP program. The Performance Assessment Model combines scores on individual measures across different quality categories or "domains" (for example, clinical process of care, patient experience of care) to calculate a hospital's Total Performance Score.

The Performance Assessment Model provides a methodology for evaluating a hospital's performance on each measure based on the higher of an attainment score in the measurement period or an improvement score, which is determined by comparing the hospital's current measure score with a baseline period of performance.

The use of an improvement score is intended to provide an incentive for a broad range of hospitals that participate in the Hospital VBP program by awarding points for showing improvement on measures, not solely for outperforming other hospitals.

Under the Performance Assessment Model, measures are grouped into domains, for example, clinical process of care (which could include AMI, HF, PN, and SCIP) and patient experience of care (for example, HCAHPS).

A score is calculated for each domain by combining the measure scores within that domain, weighting each measure equally. The domain score reflects the percentage of points earned out of the total possible points for which a hospital is eligible. A hospital's Total Performance Score is determined by aggregating the scores across all domains. In aggregating the scores across domains, the domains could be weighted equally or unequally, depending on the policy goals. The Total Performance Score is then translated into the percentage of the Hospital VBP incentive payment earned using an exchange function, which aligns payments with desired policy goals.

4. FY 2013 Hospital VBP Program Scoring Methodology

As stated in the Hospital Inpatient VBP Program proposed rule, we believe that the Performance Assessment Model presented and analyzed in the 2007 Report to Congress provides a useful foundation for developing the FY 2013 Hospital VBP program performance scoring methodology that comports with the requirements in section 1886(o) of the Act. The Performance Assessment Model outlines an approach that we believe is well-understood by patient advocates, hospitals and other stakeholders, was developed during a year-long process that involved extensive stakeholder input, and was presented by us to Congress. Since issuing the report, we have conducted further, extensive research on a number of important methodology issues for the Hospital VBP program, including the impact of topped-out measures on scoring, appropriate case minimum thresholds for measures, appropriate measure minimum thresholds per domain, and other issues required to ensure a high level of confidence in the scoring methodology (all of which we discussed in this Final Rule).

After carefully reviewing and evaluating a number of potential performance scoring methodologies for the Hospital VBP program, we proposed to use a Three-Domain Performance Scoring Model, although we proposed that only two domains would receive weight in FY 2013. This methodology is very similar to the Performance Assessment Model; however, it incorporates an outcome measure domain in addition to the clinical process of care and patient experience of care domains.

While we did not propose to adopt any outcome measures for the FY 2013 Hospital VBP program, we proposed to adopt these measures as part of an outcome measures domain for FY 2014. The proposed Three-Domain Performance Scoring Model includes setting benchmarks and thresholds, scoring hospitals on achievement and improvement for three domains (clinical process of care, patient experience of care, and outcomes), weighting the domains, and calculating the hospital Total Performance Score.

a. Setting Performance Benchmarks and Thresholds

As stated above, section 1886(o)(5)(B)(ii) of the Act requires that under the Hospital VBP program performance scoring methodology, hospital performance scores be determined using the higher of achievement or improvement scores for each measure. With respect to scoring hospital performance on the proposed clinical process of care and outcome measures, we propose to use a methodology based on the scoring methodology set forth in the 2007 Report to Congress Performance Assessment Model.

In the Hospital Inpatient VBP Program proposed rule, we proposed that hospitals will receive points along an achievement range, which is a scale between the achievement threshold (the minimum level of hospital performance required to receive achievement points) and the benchmark (the mean of the top decile of hospital performance during the baseline period). In determining the improvement score, we proposed that hospitals will receive points along an improvement range, which is a scale between the hospital's prior score on the measure during the baseline period and the benchmark.

Under this methodology, we proposed to establish the benchmarks and achievement thresholds for the FY 2013 Hospital VBP program using national data from a three-quarter baseline period of July 1, 2009 through March 31, 2010.

To define a high level of hospital performance on a given measure, we proposed to set the benchmark at the mean of the top decile of hospital scores on the clinical process of care, and outcome measures during the baseline period. For the patient experience of care measures, we proposed to set the benchmark at the 95th percentile of hospital performance during the baseline period. We stated that this would ensure that the benchmark represents demonstrably high but achievable standards of excellence; in other words, the benchmark will reflect observed scores for the highest-performing hospitals on a given measure.

We proposed to set the achievement threshold at the 50th percentile of hospital performance on the measure during the baseline period. Hospitals will have to score at or above this achievement threshold to earn achievement points.

Comment: We received many comments stating that the proposed benchmarks were too high. Some commenters stated that this was evidenced by the fact that for many of the proposed measures, performance at the benchmark would require hospitals to achieve 100 percent success on the measure. In addition to stating that this level of performance could be too difficult for some hospitals to achieve, some commented that this would serve as an inappropriate benchmark in light of the fact that the measures do not incorporate all clinically relevant exclusion criteria based on every patient's particular situation. One commenter supported setting the benchmark at the 80th percentile in the

[6] The report may be found at *http://www.cms.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf.*

baseline period for the patient experience of care domain to ensure that every hospital has a chance of exceeding the benchmark.

Response: As we stated in the Hospital Inpatient VBP program proposed rule, the benchmark is intended to represent an empirically-demonstrated level of excellent performance during the baseline period (76 FR 2471), and we believe that this standard represents achievable excellence for all hospitals during the performance period. We recognize that some of the proposed clinical process of care measures do not meet our criteria for topped-out status but still have a benchmark of 100 percent success.

We consider a benchmark to be an empirically-observed level of excellent performance to which we believe hospitals generally should aspire. Using the proposed definition of a benchmark (mean value for the top 10 percent of hospitals during the baseline period), typically only about 5 percent of all hospitals will be observed to have achieved the benchmark level for an individual measure during the baseline period. However, any number of hospitals could score at or above the benchmark during the performance period, and under the proposed performance scoring methodology, such hospitals would receive the full 10 points on the measure. A benchmark level of 100 percent is a special case in which at least 10 percent of hospitals achieved a 100 percent success rate on the measure during the baseline period. When a benchmark for a measure is 100 percent, at least half of all reporting hospitals will receive at least some achievement points on the measure (assuming no general degradation of performance among hospitals), which is the same as every other measure. Arbitrarily setting benchmark levels (for example, at 80th percentile) would undermine its empirically-based definition, as would, for example, arbitrarily setting the benchmark at 100 percent for every measure.

As stated above, when a benchmark is 100 percent, at least 10 percent of hospitals would have to have achieved 100 percent on the measure during the baseline period; this suggests that achieving 100 percent success on a measure is not prohibitively difficult as a portion of hospitals will have actually achieved that standard. In rare instances, a hospital might not provide a process covered by a clinical process of care measure because none of those measures currently allow for blanket discretionary exclusions that would enable a hospital to exclude a case based on any conceivable set of circumstances. As a result, a measure calculation might capture a rare case that arguably could have been excluded, such as a case where the patient was allergic to all indicated drugs, or the patient refused services and/or asked to be discharged against medical advice. As new information becomes available concerning possible unintended consequences of measures, their specifications can be reviewed and revised as necessary, including the addition of supplemental exclusion criteria. This process is ongoing and, we believe, is a better way to deal with rare cases instead of setting a benchmark at an indiscriminate, low value such as the 80th percentile.

All measures have limitations and it is therefore possible that a hospital, in the unfortunate but rare instance in which it provides what it believes is the best quality of care, will fail to achieve the benchmark. It is partly for this reason that we proposed to set the achievement performance standard for each measure at the achievement threshold rather than the benchmark. We also emphasize that a hospital's value-based incentive payment is based on its Total Performance Score, not on performance at the benchmark for every measure. Our analysis indicates that small differences in points on a single measure caused by missing the benchmark have little impact on the distribution of incentive payments and rank correlation of hospitals.

Comment: One commenter argued that high-performing hospitals "who already beat national benchmarks" have incentives to perform poorly "in the short term" so that they can then win improvement points and receive higher payments.

Response: We assume that the commenter is suggesting a scenario in which a high-performing hospital might attempt to intentionally score lower on one or more measures during the baseline period in order to score improvement points during the performance period. First, we expect all Medicare hospitals to provide high-quality care to their patients regardless of whether they are included in the Hospital VBP program or not. Furthermore, we disagree that high-achieving hospitals would have an incentive to lower their performance in order to win improvement points in the Hospital VBP program. We note that under the proposed Three-Domain Scoring Methodology, the maximum number of achievement points possible on a given measure is higher (10 points) for achieving the benchmark, than the maximum number of improvement points possible (9 points). It is difficult to envision a scenario in which a high-performing hospital would earn more overall points on a measure (that is, the higher of achievement and improvement points) by intentionally lowering its performance during the baseline period and increasing performance during the performance period versus simply maintaining high performance during the baseline period and seeking to maintain or improve on that performance during the performance period. However, we plan to closely monitor and evaluate the impact of the Hospital VBP program on the quality of care provided to Medicare beneficiaries.

After consideration of the public comments, we are finalizing as proposed the definition of the benchmark as the mean of the top decile of hospital performance during the baseline period for the clinical process of care and outcome measures. In response to numerous public comments (further discussed below) requesting greater uniformity between the scoring of clinical process of care measures, outcome measures, and HCAHPS dimensions, we are also finalizing the definition of the benchmark as the mean of the top decile of performance during the baseline period for the patient experience of care domain.

The finalized benchmarks for the clinical process of care and patient experience of care domains for the FY 2013 Hospital VBP Program are provided below in Table 6. The finalized benchmarks for the three 30-day mortality outcome measures for the FY 2014 Hospital VBP Program are provided below in Table 7.

TABLE 6—BENCHMARKS THAT APPLY TO THE FY 2013 HOSPITAL VBP PROGRAM MEASURES

Measure ID	Measure description	Benchmark
Clinical Process of Care Measures		
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0.9191
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	1.0

TABLE 6—BENCHMARKS THAT APPLY TO THE FY 2013 HOSPITAL VBP PROGRAM MEASURES—Continued

Measure ID	Measure description	Benchmark
HF–1	Discharge Instructions	1.0
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.	1.0
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	0.9958
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0.9998
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients	1.0
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	0.9968
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	0.9963
SCIP–VTE–1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered	1.0
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.	0.9985
SCIP–Card–2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period.	1.0
HCAHPS	Communication With Nurses	84.70%
	Communication With Doctors	88.95%
	Responsiveness of Hospital Staff	77.69%
	Pain Management	77.90%
	Communication About Medicines	70.42%
	Cleanliness and Quietness of Hospital Environment	77.64%
	Discharge Information	89.09%
	Overall Rating of Hospital	82.52%

TABLE 7—FINAL BENCHMARKS FOR THE FY 2014 HOSPITAL VBP PROGRAM MORTALITY OUTCOME MEASURES (DISPLAYED AS SURVIVAL RATES)

Measure ID	Measure description	Benchmark
	Mortality Outcome Measures	
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate	86.9098%
MORT–30–HF	Heart Failure (HF) 30-Day Mortality Rate	90.4861%
MORT–30 PN	Pneumonia (PN) 30-Day Mortality Rate	90.2563%

b. Calculating Achievement, Improvement Points, and Consistency Points

We proposed a scoring methodology that would assign an achievement and improvement score to each hospital for each of the clinical process of care and outcome measures that apply to the hospital, and for each HCAHPS dimension. We proposed that a hospital will earn 0–10 points for achievement based on where its performance for the measure fell relative to the achievement threshold and the benchmark.

We proposed that a hospital would earn 0–9 points based on how much its performance on the measure during the performance period improved from its performance on the measure during the baseline period. A unique improvement range for each measure would be established for each hospital that defines the distance between the hospital's baseline period score and the national benchmark for the measure.

The scoring methodology we proposed to implement for HCAHPS includes achievement, improvement, and consistency points. We proposed that for the FY 2013 Hospital VBP program hospitals may earn from 0–20 consistency points based on the lowest of its 8 HCAHPS dimension scores.

We refer readers to the Hospital Inpatient VBP Program proposed rule (76 FR 2470–2487) for the details of the proposed scoring methodologies and examples of how hospital total performance scores are calculated under the Three-Domain Performance Scoring Model.

Our responses to public comments are provided below.

Comment: One commenter asked us to outline the scoring model for outcome measures before proposing their use.

Response: As detailed in the Hospital Inpatient VBP Program proposed rule (76 FR 2466), we proposed that the outcome domain would be scored using the same methodology that we proposed to use to score the clinical process of care domain. That methodology is finalized in this final rule.

Comment: We received numerous comments asking CMS to more closely align the scoring methodologies and formulas used to calculate points in the clinical process of care and patient experience of care domains. Commenters specifically suggested that we use percentages rather than percentiles in the HCAHPS scoring methodology and questioned why we chose different methodologies to calculate the benchmarks in the clinical process of care and patient experience of care domains. These commenters suggested that the patient experience of care scoring model laid out in the proposed rule was too complex and differed too greatly from the clinical process of care scoring model. Commenters also suggested that CMS create greater uniformity in Hospital VBP scoring formulas across the domains, including the formulation of the benchmarks.

Response: In the initial analyses of HCAHPS data for the 2007 Report to Congress, which was based on about 500 hospitals and three quarters of HCAHPS results, we found that a few small hospitals achieved much higher HCAHPS scores than most. Thus, a non-percentile approach for HCAHPS would have led to a skewed distribution of achievement points (most clustered at the low end and few high scores). At the time of the 2007 Report to Congress, the percentile approach did a better job of spreading out the achievement points.

When we re-examined this issue in response to comments to the Hospital Inpatient VBP Program proposed rule, we found that our current data, which is based upon over 3,000 hospitals with several years of experience using HCAHPS, show that the distribution of scores has changed over time and that there is no longer a skewed distribution of achievement points using a non-percentile approach.

Therefore, we will abandon the use of percentiles for calculating the benchmark in HCAHPS in Hospital VBP and instead will finalize the use of percentages of top-box scores in our HCAHPS calculations. As stated below, we believe that this change will both simplify the calculation of HCAHPS scores and will make HCAHPS scoring more comparable to that of the clinical process of care and outcome measures in the Hospital VBP program.

In response to numerous comments received, we are finalizing the definition of the benchmark for each measure in the patient experience of care domain as the mean of the top decile of hospital performance on the measure (for purposes of the HCAHPS measure, this would be each HCAHPS dimension) during the baseline period. We believe this policy results in more uniform scoring methodologies across domains and appropriately reflects our decision to abandon the use of percentiles in the patient experience of care domain. We have made technical changes to the formulas used to calculate achievement and improvement points reflecting these finalized policies below.

As shown in Table 8, for each of the 8 HCAHPS dimensions we are finalizing for the FY 2013 Hospital VBP program, scores will be based on the publicly-reported proportions of best category ("top-box") responses. (As noted above, top-box responses, as publicly reported on the *Hospital Compare* Web site, are the most positive responses to HCAHPS survey questions and are adjusted for patient-mix and survey mode). Please note that the "Cleanliness and Quietness" dimension is the average of the publicly reported stand-alone "Cleanliness" and "Quietness" ratings.

TABLE 8—EIGHT HCAHPS DIMENSIONS FOR THE FY 2013 HOSPITAL VBP PROGRAM

Dimension (composite or stand-alone item)	Constituent HCAHPS survey items
1. Communication with Nurses (% "Always")	Nurse—Courtesy/Respect. Nurse—Listen. Nurse—Explain.
2. Communication with Doctors (% "Always")	Doctor—Courtesy/Respect. Doctor—Listen. Doctor—Explain.
3. Responsiveness of hospital staff (% "Always")	Bathroom Help. Call Button.
4. Pain management (% "Always")	Pain Control. Help with Pain.
5. Communication about Medicines (% "Always")	New Medicine—Reason. New Medicine—Side Effects.
6. Hospital Cleanliness & Quietness (% "Always")	Cleanliness and Quietness.
I. Discharge Information (% "Yes").	Discharge—Help.
7. Overall rating (% "9 or 10")	Discharge—Systems.
8. Overall Rating of Hospital (% "9 or 10")	Overall Rating.

Comment: Some commenters recommended that HCAHPS be excluded from the Hospital VBP program until an examination and public vetting of the scoring methodology takes place.

Response: The scoring methodology proposed for HCAHPS was part of the original Report to Congress in 2007 and was subject to stakeholder input through multiple listening sessions. The final methodology described in this final rule is more similar to the clinical process of care scoring methodology since it now uses percentages not percentiles. The notice and comment rulemaking process for this rule has allowed the public to vet CMS' proposals. In response to public comments, CMS is making an additional change to the HCAHPS scoring methodology (this change is discussed below).

Comment: Many commenters opposed our proposal to use consistency points in the patient experience of care domain. Others suggested that we consider using consistency points in the clinical process of care domain.

Response: For reasons detailed in the 2007 Report to Congress and the Hospital Inpatient VBP Program proposed rule (76 FR 2472), we believe that consistency points recognize and reward consistent achievement across HCAHPS dimensions. By offering hospitals additional incentives to achieve across all HCAHPS dimensions, consistency points promote wider systems changes within hospitals to improve quality. We will consider developing consistency points for the clinical process of care domain in the future. However, we note that applying consistency points in that domain would be methodologically challenging. All hospitals must report all dimensions of the HCAHPS survey, and for that reason, all hospitals will earn scores on all dimensions on which we can use to fairly reward consistency. Applying consistency points to the clinical process of care domain when different numbers of measures might apply to different hospitals may result in unfair distributions of consistency points. We welcome input on an appropriate methodology for clinical process of care consistency points.

Comment: A number of commenters suggested technical changes to the formulas proposed to be used to calculate achievement and improvement points. In suggesting these technical changes, commenters pointed out that under the proposed formulas for clinical process of care and outcome measure scoring, a hospital with a score equal to the achievement threshold would receive a score of .5, which rounds to 1, while a hospital with a score equal to the benchmark would receive a score of 9.5, which rounds to 10. Commenters pointed out that this formula effectively creates a scale of 0.5 to 9.5 instead of a scale from 1 to 10. These commenters urged CMS to modify the formula so that the scale "starts" at 1 instead of 0.5, and urged CMS to make similar modifications for the formula used to calculate improvement points for the

clinical process of care and outcome measures.

Response: The formula for achievement points reflects the description of how points are assigned to hospitals with scores between the threshold and benchmark values. For such hospitals, the range between the achievement threshold and benchmark values is partitioned into 9 equally spaced intervals and a hospital is awarded from 1 to 9 points, depending on which of the nine equally spaced intervals its score falls. The offered alternatives satisfy much of this description, but fail to meet the equal-spacing property. In particular, if we revised the scale along the lines suggested by the commenters, the interval of scores needed to receive one point would be only half as large as the remaining eight intervals. As a result, the number of hospitals receiving one point would be reduced and our ability to distinguish among hospitals on the lower end of the scale would also be reduced.

Regarding the specific comment that the scoring scale starts with only 0.5, we note that, in fact, hospitals scoring within the achievement range start with a score of ''round (.5).'' The ''round'' function is part of the formula and cannot be ignored without significantly altering the resulting calculations, which would prevent us from implementing equal spacing within the achievement and improvement ranges as described above. We note that within the formula, any value that ends in .5 rounds to the next higher integer, so ''round(.5)'' equals 1 and a hospital scoring at the achievement threshold receives 1 point on that measure. Likewise, a score of 4.5 rounds to 5, and so on.

The formula for improvement points is similar except that it divides the range between the hospital's baseline score and the benchmark into 9 equally-spaced intervals and awards a hospital a score between 0 and 9 improvement points. Again, the round function is part of the formula and needs to be acknowledged (with the similar stipulation that values ending in .5 round to the next higher integer). Thus, a hospital with a score exactly equal to its improvement threshold receives a score of round (−.5), which would equal 0 points.

Comment: One commenter recommended that the point conversions and reconversion steps be removed from the mathematical calculations, and that CMS develop a more direct calculation method rather than scoring hospitals with points based on measure rates and later converting point totals into domain scores.

Response: The point calculations used to score hospitals on performance measures reflect our intent to provide a more[?] robust measure scoring methodology than[?] is possible with a more direct score calculation. We believe that the point conversions from raw measure scores to the 0–10 and 0–9 achievement and improvement ranges, respectively, enable us to more clearly communicate assessments of hospital performance to hospitals and the public. We note that the point calculations allow us to easily calculate and combine points earned for both achievement and improvement, as well as compare hospitals earning points on different measures in cases when the relevant achievement ranges may differ substantially. We will evaluate the impact of the scoring methodology and will continue to examine alternative scoring methodologies for future years of the program.

Comment: Some commenters suggested that the proposed scoring methodology undervalues improvement, and that establishing a lower "improvement benchmark" would be more appropriate so that the improvement range is the same for every hospital.

Response: We believe establishing a lower benchmark would undervalue achievement by lowering the standard by which hospitals may achieve 10 points as well as the importance of improving to the highest level of care. Setting a separate, lower benchmark for the improvement range might also encourage higher achieving hospitals to underperform, as they would be rewarded more highly for achieving a lower level of improvement. A higher benchmark also allows every hospital to improve as much as possible and to the highest level of care.

Comment: Some commenters agreed with our proposal to exclude the "Would You Recommend" item in the HCAHPS performance score and to include only the Overall Rating because they believe that "recommend" is properly characterized as a measure of expectations. Other commenters thought both the Overall Rating and "Would You Recommend" should be included. One commenter thought the Overall Rating should receive more weight than the other HCAHPS dimensions because the commenter viewed it as an outcome measure.

Response: We decided to include only the Overall Rating and not the "Would You Recommend" item in the HCAHPS measure because the two global ratings are highly correlated and the "Would You Recommend" item is more likely to measure expectations and other factors rather than the actual patient experience. It is important to note that, while there is a high correlation between these items overall, there can still be divergence for some hospitals. Thus for purposes of the Hospital IQR program, these two dimensions will be reported separately.

With regard to giving greater weight to the Overall Rating item, we believe that the Overall Rating item is no more of an outcome than the other HCAHPS items, so it has been given the same weight as the other HCAHPS dimensions in the Hospital VBP scoring formula. Compared to the other HCAHPS dimensions, the Overall Rating focuses on the overall experience, while the other dimensions focus on specific aspects of the hospital stay.

As discussed above, we are finalizing an HCAHPS scoring approach that does not use percentiles, and instead will adopt an approach that uses the percentage of top-box scores for scoring a hospital's HCAHPS calculations. We believe that this change will both simplify the calculation of HCAHPS scores and will make the HCAHPS scoring more comparable to that of the clinical process of care and outcome measures.

Accordingly, after considering public comments, we are finalizing the scoring methodology as follows:

Hospitals will receive an achievement and improvement score for each of the clinical process of care and outcome measures that apply to them, and for each HCAHPS dimension. Hospital will earn between 0–10 points for achievement based on where its performance for the measure falls relative to the achievement threshold and the benchmark according to the following formula:

[9 * ((Hospital's performance period score − achievement threshold)/(benchmark − achievement threshold))] + .5, where the hospital performance period score falls in the range from the achievement threshold to the benchmark

All achievement points will be rounded to the nearest whole number (for example, an achievement score of 4.5 would be rounded to 5). If a hospital's score is:

- Equal to or greater than the benchmark, the hospital will receive 10 points for achievement.
- Equal to or greater than the achievement threshold (but below the benchmark), the hospital will receive a score of 1–9 based on a linear scale established for the achievement range

(which distributes all points proportionately between the achievement threshold and the benchmark so that the interval in performance between the score needed to receive a given number of achievement points and one additional achievement point is the same throughout the range of performance from the achievement threshold to the benchmark).

• Less than the achievement threshold (that is, the lower bound of the achievement range), the hospital will receive 0 points for achievement.

Hospitals will earn between 0–9 points based on how much their performance on the measure during the performance period improves from their performance on the measure during the baseline period according to the following formula:

[10 * ((Hospital performance period score − Hospital baseline period score)/(Benchmark − Hospital baseline period score))] − .5, where the hospital performance score falls in the range from the hospital's baseline period score to the benchmark

All improvement points will be rounded to the nearest whole number.

If a hospital's score on the measure during the performance period is:

• Greater than its baseline period score but below the benchmark (within the improvement range), the hospital will receive a score of 0–9 based on the linear scale that defines the improvement range.

• Equal to or lower than its baseline period score on the measure, the hospital will receive 0 points for improvement.

Hospitals will earn between 0–20 consistency points on the HCAHPS measure based on the lowest of its 8 HCAHPS dimension scores.

A hospital will receive 0 consistency points if its performance on one or more HCAHPS dimensions during the performance period is at least as poor as the worst-performing hospital's performance on that dimension during the baseline period. A hospital will receive a maximum score of 20 consistency points if its performance on all 8 HCAHPS dimensions is at or above the achievement threshold.

Based on comments discussed above, consistency points will be awarded proportionately based on the single lowest of a hospital's 8 HCAHPS dimension scores during the performance period compared to the achievement threshold (the 50th percentile of the baseline performance score) for that specific HCAHPS dimension. If the lowest score is less than the achievement threshold, then the score is based on the distance between the achievement threshold (50th percentile of baseline) and the floor (0th percentile of baseline). If all 8 of a hospital's dimension scores during the performance period are at or above the achievement threshold (50th percentile of hospital performance in the baseline period), then that hospital will earn all 20 consistency points. (That is, if the lowest of a hospital's eight HCAHPS dimension scores is at or above the 50th percentile of hospital performance on that dimension during the baseline period, then that hospital will earn the maximum of 20 consistency points). If the lowest score a hospital receives on an HCAHPS dimension is at or below the floor of hospital performance on that dimension during the baseline period, then 0 consistency points will be awarded to that hospital. Otherwise, consistency points will be awarded proportionately according to the distance of the performance period score for that dimension between the floor and the achievement threshold.

We define the *lowest dimension score* as the lowest value across the eight HCAHPS dimensions using the following formula:

((Hospital's performance period score—floor)/(achievement threshold—floor)).

The formula for the HCAHPS consistency points score is as follows:

(20 * (lowest dimension score) − 0.5), rounded to the nearest whole number, with a minimum of zero and a maximum of 20 consistency points.

Consistency points will be rounded to the nearest whole number (for example, 9.5 consistency points would be rounded to 10 points).

Table 9 below displays floors, achievement thresholds, and benchmarks for HCAHPS consistency points applicable to FY 2013 using a baseline period of July 1, 2009–March 31, 2010.

TABLE 9—HCAHPS [1] TOP-BOX SCORES [2] REPRESENTING THE FLOOR (MINIMUM), ACHIEVEMENT THRESHOLD (50TH PERCENTILE) AND BENCHMARK (MEAN OF TOP DECILE) FOR HOSPITAL VALUE-BASED PURCHASING: BASELINE PERIOD (JULY 1, 2009–MARCH 31, 2010)

HCAHPS dimension	Floor (minimum)	Achievement threshold (50th percentile)	Benchmark (mean of top decile)
Communication with Nurses	38.98	75.18	84.70
Communication with Doctors	51.51	79.42	88.95
Responsiveness of Hospital Staff	30.25	61.82	77.69
Pain Management	34.76	68.75	77.90
Communication about Medicines	29.27	59.28	70.42
Hospital Cleanliness & Quietness	36.88	62.80	77.64
Discharge Information	50.47	81.93	89.09
Overall Rating of Hospital	29.32	66.02	82.52

[1] Includes IPPS hospitals with 100+ completed surveys from patients discharged between July 2009 and March 2010 (3,211 hospitals). Scores have been adjusted for survey mode and patient-mix.

[2] "Top-box" score is the percentage of patients who chose the most positive response to HCAHPS survey items.

As stated above, we also note that, to achieve greater uniformity of scoring for all of the domains, we are finalizing the definition of the benchmark as the mean of the top decile of performance on the HCAHPS dimensions, rather than the 95th percentile of performance as we had proposed.

We have provided three examples describing how the clinical process of care and outcome measures will be scored. These examples are similar to those that were provided in the Hospital Inpatient VBP proposed rule (76 FR 2467–2470), but illustrate scoring on a different measure since PN–2, used in the proposed rule, is now topped-out. Three more examples illustrate how the

finalized scoring methodology will be applied to the HCAHPS dimensions. The clinical process of care examples use AMI–7a "Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival," while the HCAHPS examples are based on the "Doctor Communication" dimension.

Figure 1 shows measure scoring for Hospital B. The benchmark calculated for AMI–7a in this case was 0.9191 (the mean value of the top decile during the baseline period), and the achievement threshold was 0.6548 (the performance of the median or the 50th percentile hospital during the baseline period). Hospital B's performance rate of 0.93 during the performance period for this measure exceeds the benchmark, so Hospital B would earn 10 points (the maximum) for achievement. The hospital's performance rate on a measure is expressed as a decimal. In the illustration, Hospital B's performance rate of 0.93 means that 93 percent of applicable patients received Fibrinolytic Therapy within 30 minutes of arrival. (Because Hospital B has earned the maximum number of points possible for this measure, its improvement score would be irrelevant.)

Figure 1. Example of Hospital Earning Points by Exceeding Benchmark, Clinical Process of Care and Outcome Measure Scoring Under Three-Domain Performance Scoring Model

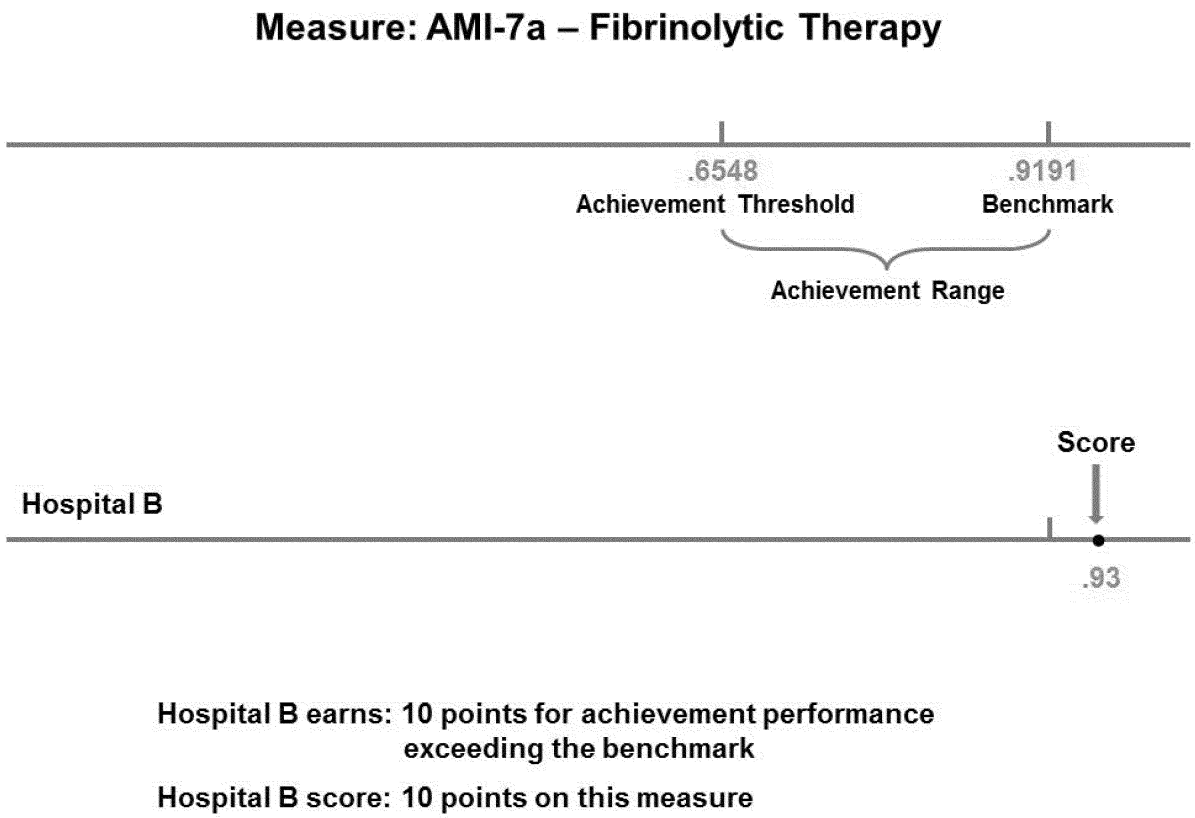


Figure 2 shows the scoring for another hospital, Hospital I. As can be seen below, the hospital's performance on this measure went from 0.4297 (below the achievement threshold) in the baseline period to 0.8163 (above the achievement threshold) in the performance period. Applying the achievement formula, Hospital I would earn 6 points for this measure, calculated as follows:

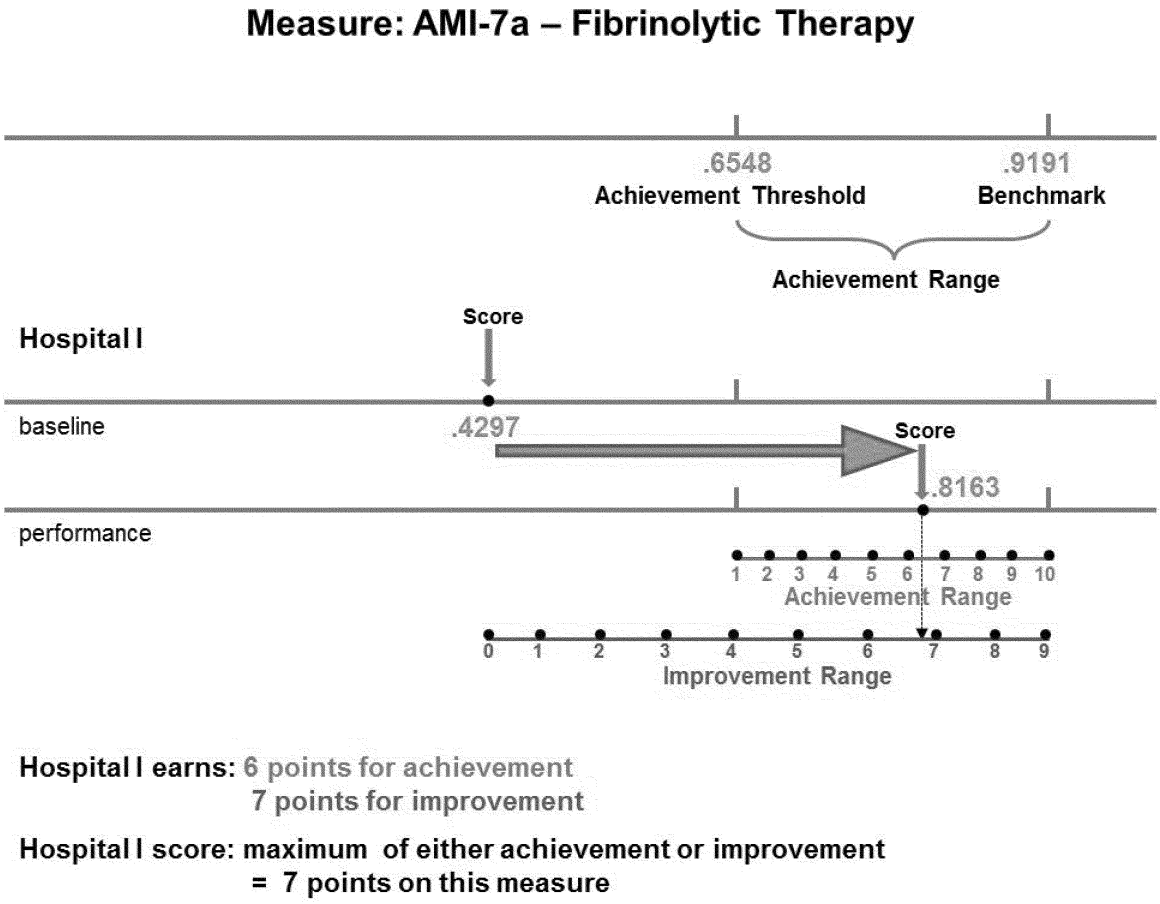
$[9 * ((0.8163 - 0.6548)/(0.9191 - 0.6548))] + 0.5 = 5.5 + 0.5 = 6$ points.

However, because Hospital I's performance during the performance period is also greater than its performance during the baseline period, it would be scored based on improvement as well. According to the improvement formula, based on Hospital I's period-to-period improvement, from 0.4297 to 0.8163, Hospital I would earn 7 points, calculated as follows:

$[10 * ((0.8163 - 0.4297)/(0.9191 - 0.4297))] - 0.5 = 7.9 - 0.5 = 7.4$, rounded to 7 points.

Because the higher of the two scores is used for determining the measure score, Hospital I would receive 7 points for this measure (rounded to the nearest whole number).

Figure 2. Example of Hospital Earning Points by Achievement or Improvement, Clinical Process of Care and Outcome Measure Scoring Under Three-Domain Performance Scoring Model



In Figure 3 shown below, Hospital L's performance on AMI–7a drops from 0.72 to 0.64 (a decline of 0.08 points). Because this hospital's performance during the performance period is lower than the achievement threshold of 0.6548, it receives 0 points based on achievement. It would also receive 0 points for improvement, because its performance during the performance period is lower than its performance during the baseline period. In this example, Hospital L would receive 0 points for the measure.

Figure 3. Example of Hospital Earning No Points, Clinical Process of Care and Outcome Measure Scoring Under Three-Domain Performance Scoring Model

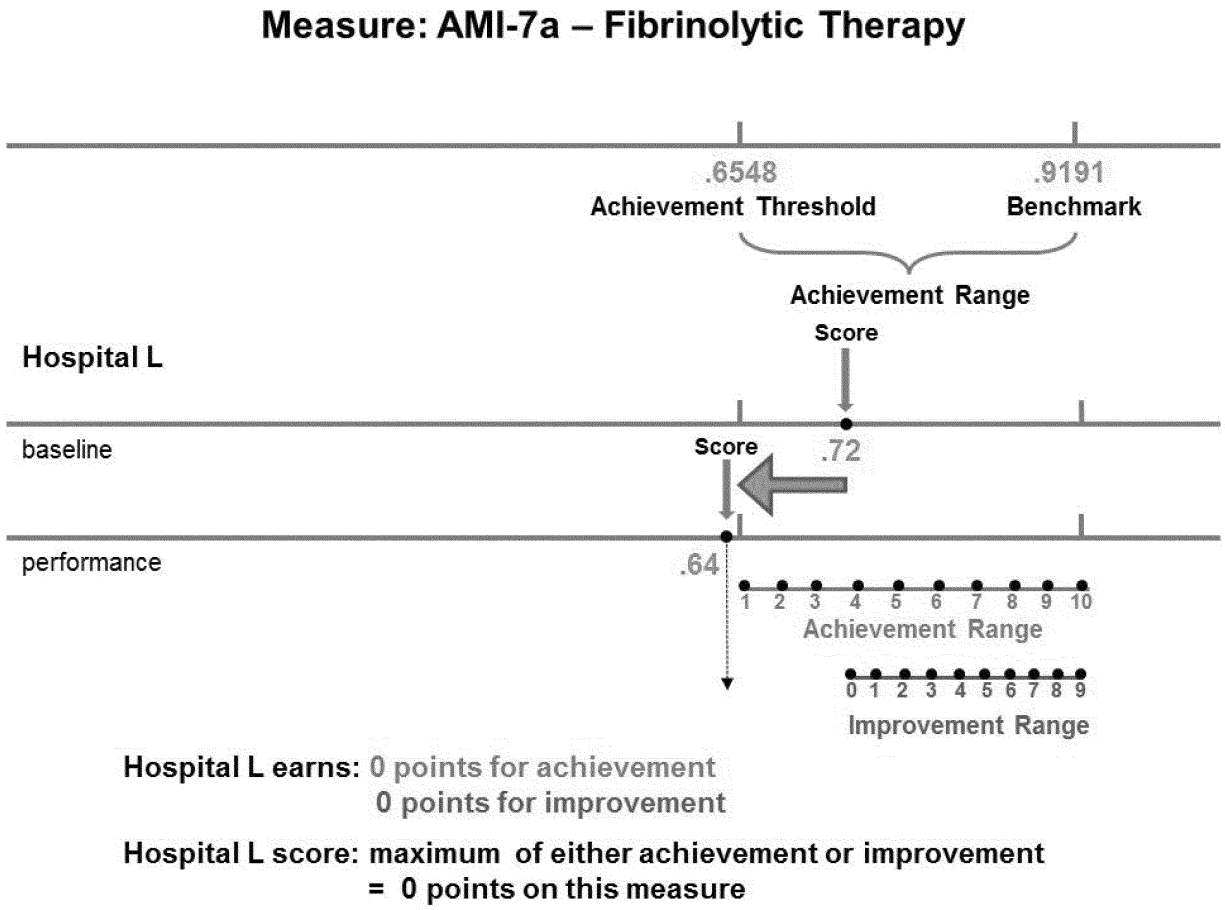


Figure 4 shows Hospital B's scoring on the doctor communication dimension. It scores a 90 percent, which exceeded the benchmark. Thus, Hospital B would earn the maximum of 10 points for achievement. Because this is the highest number of achievement points the hospital could attain for this dimension, its improvement from its baseline period score on this measure would not be relevant.

Figure 4. Example of Hospital Earning Points by Exceeding Benchmark, HCAHPS Measure Scoring Under the Three-Domain Performance Scoring Model

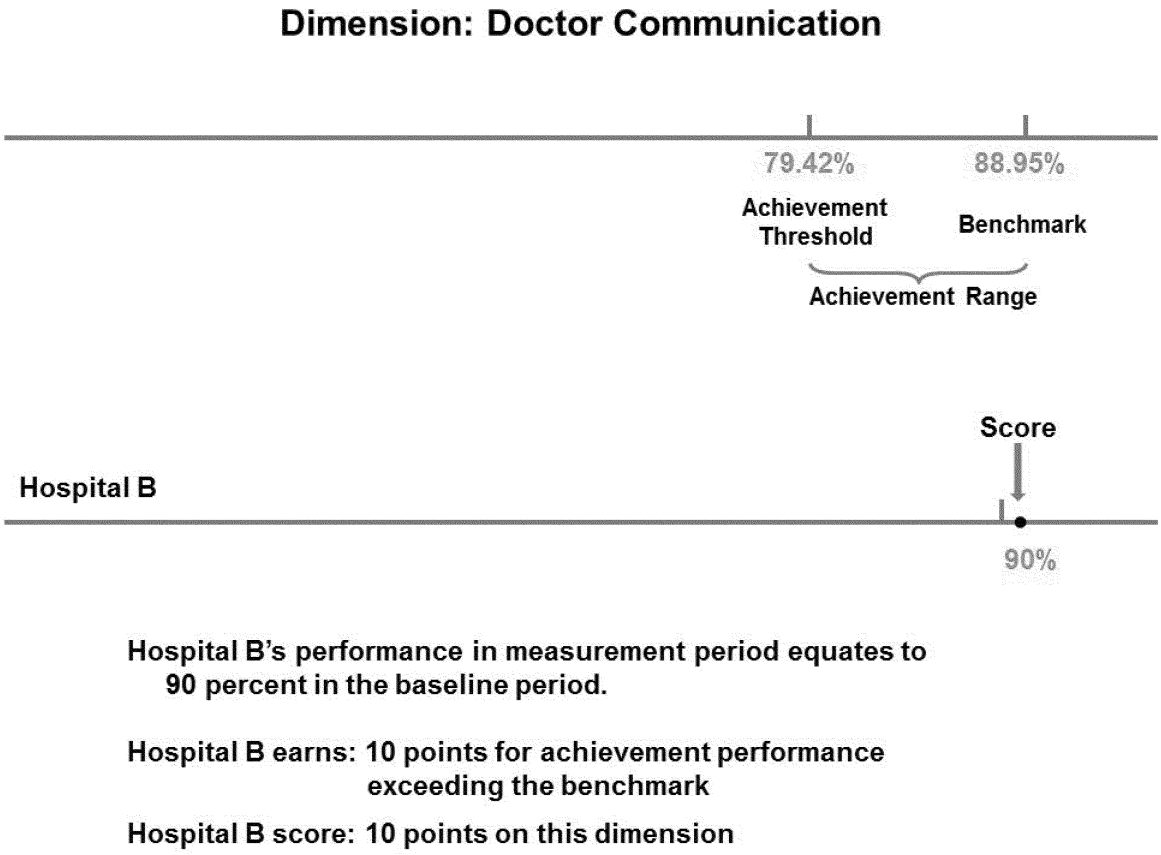


Figure 5 shows that Hospital I's performance on the doctor communication dimension rose from 77.19 percent during the baseline period to 82.07 percent during the performance period. Because Hospital I's performance during the performance period exceeds the achievement threshold of 79.42 percent, Hospital I's score would fall within the achievement range. According to the achievement scale, Hospital I would earn 3 achievement points, calculated as follows:

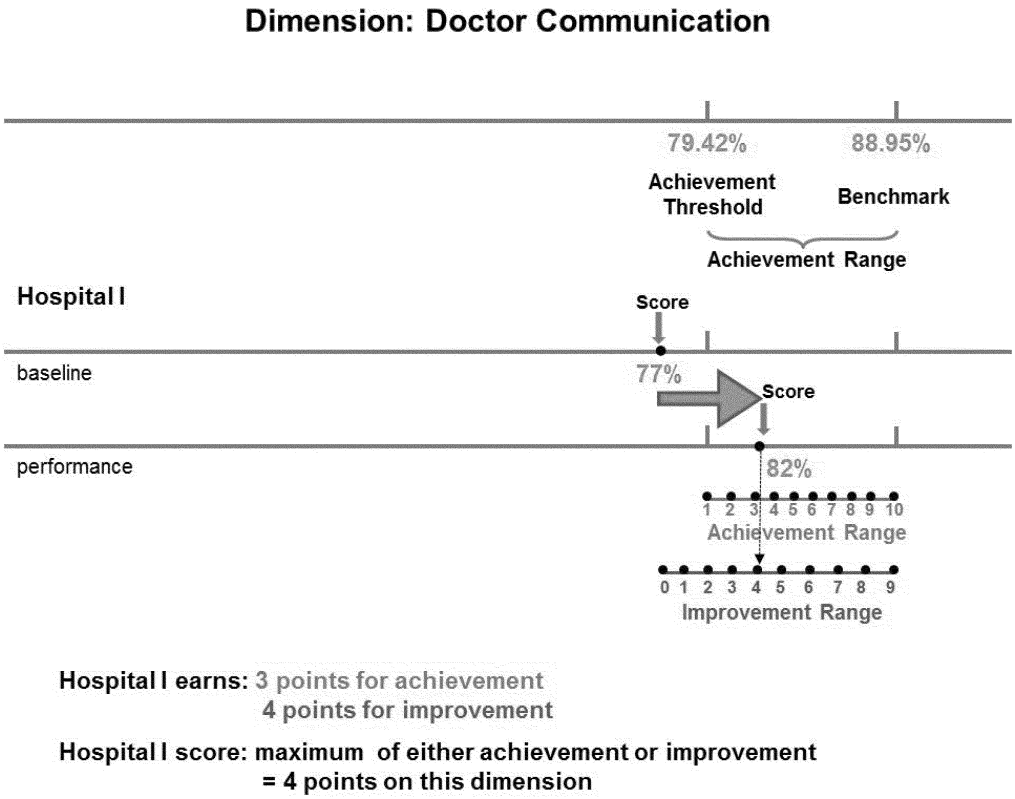
$$[9 * ((82.07 - 79.42)/(88.95 - 79.42))] + 0.5 = 2.5 + 0.5 = 3$$

However, in this case, the hospital's performance in the performance period has improved from its performance during the baseline period, so Hospital I would be scored based on improvement as well as achievement. Applying the improvement scale, Hospital I's period-to-period improvement from 77.19 percent to 82.07 percent would earn 3.65 improvement points, which would be rounded to 4 points calculated as follows:

$$[10 * ((82.07 - 77.19)/(88.95 - 77.19))] - 0.5 = 3.65$$

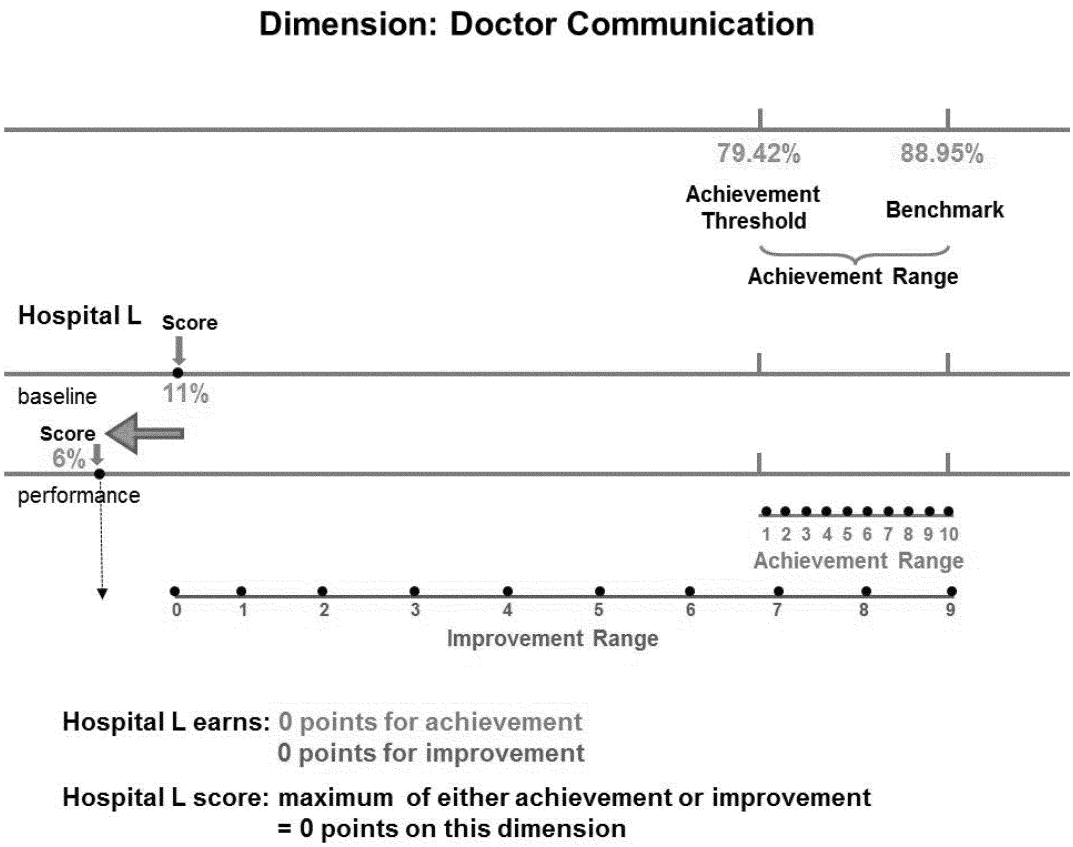
Using the greater of the two scores, Hospital I would receive 4 points for this dimension (rounded to the nearest whole number).

Figure 5. Example of Hospital Earning Points By Achievement or Improvement, HCAHPS Measure Scoring Under the Three-Domain Performance Scoring Model



In Figure 6, Hospital L's performance in the baseline period was at 11 percent, and its performance declined in the performance period to 6 percent. Because Hospital L's performance during the performance period is lower than the achievement threshold of 79.42 percent, it would receive 0 points based on achievement. Hospital L would also receive 0 points for improvement because its performance during the performance period is lower than its performance during the baseline period.

Figure 6. Example of Hospital Earning Zero Points, HCAHPS Measure Scoring Under the Three-Domain Performance Scoring Model



c. The Total Domain Score and the Total Performance Score

We proposed to group the measures for the Hospital VBP program into domains, which we proposed to define as categories of measures by measure type. Because the clinical process of care and outcome measure performance scores will be based only on the measures that apply to the hospital, we proposed to normalize the domain scores across hospitals by converting the points earned for each domain to a percentage of total points. We proposed that the points earned for each measure that applies to the hospital would be summed (weighted equally) to determine the total earned points for the domain.

For purposes of the Hospital VBP program in FY 2013, we also proposed that only two domains will be scored, the clinical process of care and patient experience of care. In determining how to appropriately weight quality measure domains, we considered a number of criteria. Specifically, we considered the number of measures that we proposed to include in each domain and the reliability of individual measure data. We also considered the systematic effects of alternative weighting schemes on hospitals according to their location and characteristics (for example, by region, size, and teaching status) and Departmental quality improvement priorities. We strongly believe that outcome measures are important in assessing the overall quality of care provided by hospitals. However, for reasons outlined in the Hospital Inpatient VBP Program proposed rule (76 FR 2461), we did not propose to include outcome measures in the FY 2013 Hospital VBP program. Taking all of these considerations into account, we proposed the use of a 70 percent clinical process of care and 30 percent patient experience of care (HCAHPS) weighting scheme for the FY 2013 Hospital VBP program. We proposed this weighting scheme because the proposed clinical process of care measures comprise all but one of the measures we proposed to include in the FY 2013 Hospital VBP program. We believe assigning a 30 percent weight to the patient experience of care domain is appropriate because the HCAHPS measure is comprised of eight dimensions that address different aspects of patient satisfaction.

We solicited public comment on the domain weighting approach and calculation of the total performance score, as well as the utility and appropriateness of alternative methods.

Comment: Some commenters suggested that we weight Total Performance scores by "opportunities to provide care," rather than equally weighting each measure within each domain.

Response: We thank commenters for their suggestion. However, we believe that weighting each measure within a domain equally will encourage hospitals to consider each of them equally in their quality improvement initiatives. We also believe that weighting by the number of opportunities, the suggested alternative, would overemphasize the SCIP measures, which often have opportunity counts that are much larger than the corresponding counts for measures related to other topics or conditions.

Comment: Many commenters opposed our proposal to weight the patient experience of care domain at 30 percent, arguing that the HCAHPS survey composing the domain is subjective, and is not sufficiently risk adjusted for

patient characteristics or other factors. Those commenters suggested various proposed weights but generally called on us to lower the patient experience of care domain weight. One commenter suggested that we weight the patient experience of care domain higher than 30 percent of the Total Performance Score. A few commenters supported our proposal.

Response: We appreciate the commenters' suggestions. However, we disagree with weighting the patient experience of care domain either higher or lower than proposed. As we detailed in the Hospital Inpatient VBP Program proposed rule (76 FR 2475), we considered many factors when determining the appropriate domain weights for the FY 2013 program, including the number of measures in each domain, the reliability of individual measure data, systematic effects of alternative weighting schemes on hospitals according to their location and characteristics, and Departmental quality improvement priorities. We also believe that delivery of high-quality, patient-centered care requires us to carefully consider the patient's experience in the hospital inpatient setting.

Comment: Some commenters suggested that CMS should convene focus groups of Medicare beneficiaries to determine the relative importance of clinical process of care and patient experience of care domains for weighting.

Response: We believe that we have received significant public input to inform our approach for weighing each domain. Many public comments on the proposed rule discussed the weighing and relative importance of the domains, and supported the proposed weighting distribution. We will, however, continue to monitor the weighing distribution between domains and will consider commenters' suggestions as the program goes forward and new measures and domains are added.

Comment: Commenters suggested that we place greater weight on outcome measures compared to clinical process of care measures and that we emphasize overall rating dimensions of the HCAHPS survey over other dimensions.

Response: We will take the commenters' suggestion to weight the outcome domain more heavily than the clinical process of care domain as we develop our weighting proposals for the FY2014 Hospital VBP program. However, as we stated earlier, we believe that all measures within a domain should be weighted equally in order to encourage hospitals to improve their performance on all of them.

Based on the comments we received, we are finalizing the calculation of the clinical process of care and outcome domain scores as follows:

1. For each domain:

Total earned points for domain = Sum of points earned for all applicable domain measures

2. Each hospital also has a corresponding universe of total possible points for each of the clinical process and outcome domains calculated as follows:

Total possible points for domain = Total number of domain measures that apply to the hospital multiplied by 10 points

3. For each domain, the total domain score would be calculated as a percentage, as follows:

Domain score = Total earned points for domain divided by Total possible points for domain multiplied by 100 percent.

We are also finalizing the calculation of the patient experience of care domain score as follows:

1. For each of the eight dimensions, determine the larger of the 0–10 achievement score and the 0–9 improvement score;

2. Sum these 8 values to arrive at a 0–80 HCAHPS base score;

3. Calculate the 0–20 HCAHPS consistency score;

4. To arrive at the HCAHPS total earned points, or HCAHPS overall score, sum the HCAHPS base score and the consistency score.

In summary, the overall HCAHPS performance score is calculated as follows:

HCAHPS total earned points = HCAHPS base score + consistency score.

After consideration of public comments, we are finalizing the calculation of a hospital's Total Performance Score as follows:

Multiply the hospital's performance score for each domain by the weight for that domain (70 percent clinical process of care, 30 percent patient experience of care), and add those weighted scores together.

d. Alternative Performance Scoring Models

We discussed our analysis of several alternative performance scoring models in addition to the model proposed (76 FR 2476–2478). We solicited public comments on the proposed model as well as the other potential performance scoring models. The comments we received on these models and our responses are set forth below.

Comment: While agreeing with the analysis of scoring models considered in the proposed rule, one commenter asked that CMS consider including aspects of the Appropriate Care Model (ACM) in the Hospital VBP program scoring methodology, perhaps by creating a hybrid model in which a portion of the overall performance score is determined by an ACM-like measure of patient-level appropriate care.

Response: The ACM, also referred to as the "all-or-none" model, is intended to be a more patient-centric method of assessing hospital performance on the clinical process of care measures (see 76 FR 2476–2478).

The ACM creates sub-domains by topic for the clinical process measures and is distinguished from the other two models described in the Hospital Inpatient VBP Program proposed rule (namely, the Three-Domain Performance Scoring Model and the Six-Domain Performance Scoring Model) in that it requires complete mastery for each topic area ("all-or-none") in the clinical process of care domain at the patient level.

Under the ACM, the patient encounter, rather than the clinical process of care measure itself, becomes the scored "event," with a hospital receiving 1 point if it successfully provides to a patient the applicable processes under all of the measures within an applicable topic area, or 0 points if it fails to furnish one or more of the applicable processes. The hospital's condition-specific ACM score is the proportion of patients with the condition who receive the appropriate care as captured by the process measures that fall within the topic area. As discussed in the proposed rule, in the Three-Domain Performance Scoring Model, the scoring of the clinical process of care measures in a single clinical process of care domain is consistent with the current level of precision on the measures.

We believe that given the current set of measures available for adoption into the Hospital VBP program at this time, the intermediate scores created at the condition or topic level under the ACM would convey a false sense of precision about the quality of care provided for that condition. The ACM sets a high bar for quality improvement and sends a strong signal about complete mastery for each individual topic area ("all-or-none") at the patient level.

On the other hand, we stated our belief that for complex patients or patients for whom one or more processes are not needed, the ACM model may provide a disincentive to providing quality care. The ACM is considered to be "patient focused" rather than "opportunity focused." Due

to its all-or-nothing scoring approach, the ACM loses patient information that would have some effect on the total performance score under the Three-Domain Performance Scoring Model, under which hospitals would receive credit for all of the measures for which it met the performance standard. Furthermore, as a result of all-or-nothing scoring, the ACM approach captures whether a patient received appropriate care, but it does not describe the extent of lacking care. Since the unit of scoring is the patient encounter, and the hospital earns a clinical process of care domain score of zero for a patient if the hospital fails to provide any of the applicable processes covered by the measures in the applicable topic area, we believe that the hospital is likely to become aware of all of the processes the patient requires in order to treat the condition, rather than thinking in terms of individual opportunities.

We will continue analyzing alternative performance scoring models, including the ACM, and will consider proposing to implement scoring models other than the Three-Domain Performance Scoring Model in the future. As the industry continues to develop sets of measures that capture many aspects of quality for various conditions, we will seek to examine more patient-centered scoring methodologies and measures, and will certainly consider hybrid models such as the one described by the commenter.

G. Applicability of the Value-Based Purchasing Program to Hospitals

Section 1886(o)(1)(C) of the Act specifies how the value-based purchasing program applies to hospitals. For purposes of the Hospital VBP program, the term "hospital" is defined under section 1886(o)(1)(C)(i) as a "subsection (d) hospital," (as defined in section 1886(d)(1)(B) of the Act). Section 1886(d)(1)(B) of the Act defines a "subsection (d) hospital" as a "hospital located in one of the fifty States or the District of Columbia." The term therefore does not include hospitals located in the territories or hospitals located in Puerto Rico. Section 1886(d)(9)(A) of the Act separately defines a "subsection (d) Puerto Rico hospital" as a hospital that is located in Puerto Rico and that "would be a subsection (d) hospital if it were located in one of the 50 states." Therefore, because 1886(o)(1)(C) does not refer to "subsection (d) Puerto Rico hospitals," the Hospital VBP program would not apply to hospitals located in Puerto Rico. The statutory definition of a subsection (d) hospital under section 1886(d)(1)(B), however, does include inpatient, acute care hospitals located in the State of Maryland. These hospitals are not currently paid under the IPPS in accordance with a special waiver provided by section 1814(b)(3) of the Act. Despite this waiver, the Maryland hospitals continue to meet the definition of a "subsection (d) hospital" because they are hospitals located in one of the 50 states. Therefore we proposed that the Hospital VBP program will apply to acute care hospitals located in the State of Maryland unless the Secretary exercises discretion pursuant to 1886(o)(1)(C)(iv), which states that "the Secretary may exempt such hospitals from the application of this subsection if the State which is paid under such section submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection."

The statutory definition of a subsection (d) hospital also does not apply to hospitals and hospital units excluded from the IPPS under section 1886(d)(1)(B) of the Act, such as psychiatric, rehabilitation, long term care, children's, and cancer hospitals. In order to identify hospitals, we proposed that, for purposes of this provision, we would adjust payments to hospitals as they are distinguished by provider number in hospital cost reports. We proposed that payment adjustments for hospitals be calculated based on the provider number used for cost reporting purposes, which is the CMS Certification Number (CCN) of the main provider (also referred to as OSCAR number). Payments to hospitals are made to each provider of record.

Comment: Several commenters, including national and state hospital associations, expressed their support of our proposal to apply the Hospital VBP program to subsection (d) hospitals in accordance with the statutory requirement. Clarification was requested regarding whether critical access hospitals (CAHs) and subsection (d) hospitals that are in CMS demonstrations for their inpatient payment, such as the Rural Community Hospital Demonstration Program, are to be included in the Hospital VBP program.

Response: For purposes of the Hospital VBP program, the term "hospital" is defined under section 1886(o)(1)(C)(i) as a "subsection (d) hospital," (as defined in section 1886(d)(1)(B) of the Act). Section 1886(d)(1)(B) of the Act defines a "subsection (d) hospital" as a "hospital located in one of the fifty States or the District of Columbia." This does not include IPPS hospitals in Puerto Rico. We are finalizing that we shall identify these hospitals by the CMS Certification Number (CCN) of the main Provider (also referred to as OSCAR number), calculate, and make the payment adjustments based on this identification.

CAHs are designated under section 1820(c); therefore, consistent with section 1886(o)(1)(C)(i), which limits participation in the Hospital VBP program to subsection (d) hospitals, they are ineligible to participate in the Hospital VBP program.

Hospitals that participate in the Rural Community Hospital Demonstration Program are subsection (d) hospitals; therefore, the Hospital VBP program would apply to them. To the extent there are other demonstrations involving subsection (d) hospitals, we will need to evaluate each individual demonstration to determine how it might potentially overlap with the Hospital VBP program.

Comment: Several commenters requested that CMS exempt hospitals in Maryland from the Hospital VBP program. Commenters described current quality efforts in Maryland relating to quality reporting, hospital-acquired conditions, and readmissions. Some stated that "requiring Maryland to comply with the federal program in addition to the existing State programs would be burdensome and duplicative." Several commenters noted that the State intended to submit a report pursuant to section 1886(o)(1)(C)(iv).

Response: Our proposal was to apply the Hospital VBP program to acute care hospitals in Maryland paid under the 1814(b)(3) waiver unless the Secretary exercised her discretion to exempt these hospitals. We intend to make this the subject of future rulemaking.

Inpatient acute care hospitals located in the State of Maryland are not currently paid under the IPPS in accordance with a special waiver provided by section 1814(b)(3) of the Act. Despite this waiver, Maryland hospitals continue to meet the definition of a "subsection (d) hospital" under section 1886(d)(1)(B) of the Act because they are hospitals located in one of the 50 states. While these hospitals are not subject to the payment reduction under the Hospital IQR program, all or nearly all of them submit data to *Hospital Compare* on a voluntary basis. Therefore, we do not believe that requiring these hospitals to participate in the Hospital VBP program would create an additional or duplicative burden for them. Section

1886(o)(1)(C)(iv) of the Act grants the Secretary discretion to exempt hospitals paid under section 1814(b)(3) from the Hospital VBP program, but only if the State which is paid under such section submits "an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection." To facilitate future rulemaking on this topic, we believe that this report should be received prior to the Secretary's consideration of whether to exercise discretion under section 1886(o)(1)(C)(iv) of the Act.

According to section 1886(o)(1)(B) of the Act, the Hospital VBP program applies to discharges occurring on or after October 1, 2012. Therefore, in response to public comment, we are adopting the following procedure for submission of the state report in order for a hospital within the state to be exempt from the Hospital VBP program: a State shall submit, in writing and electronically, a report pursuant to section 1886(o)(1)(C)(iv) in a timeframe such that allows it to be received no later than October 1, 2011, which is the beginning of the fiscal year prior to the beginning of FY 2013. The statute requires the report to describe how a "similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings." We request that the report be as specific as possible in describing the quality (and other) measures included and in describing the results achieved over an applicable time period, noting that for the initial report the applicable time period would likely be before and after implementation of the State program. In response to commenters' discussion of readmissions-related quality efforts in Maryland, we point out that 1886(o)(2)(A) specifically excludes measures of readmissions from the Hospital VBP program.

Section 1886(o)(1)(C)(ii) sets forth a number of exclusions to the definition of the term "hospital." First, under section 1886(o)(1)(C)(ii)(I), a hospital is excluded if it is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) (the Hospital IQR program) for the applicable fiscal year. Therefore, any hospital that is subject to the Hospital IQR program payment reduction because it does not meet the requirements for the Hospital IQR program will be excluded from the Hospital VBP program for such fiscal year. We are concerned about the possibility of hospitals deciding to "opt out" of the Hospital VBP program by choosing to not submit data under the Hospital IQR program, thereby avoiding both the base operating DRG payment reduction and the possibility to receive a value-based incentive payment, although we recognize that these hospitals would still be subject to the Hospital IQR program reduction to their applicable percentage increase for the fiscal year. We intend to track hospital participation in the Hospital IQR program and welcome public input on this issue.

With respect to hospitals for which we have measure data from the performance period but no measure data from the baseline period (perhaps because these hospitals were either not open during the baseline period or otherwise did not participate in the Hospital IQR program during that period), we proposed that these hospitals will still be included in the Hospital VBP program, but that they will be scored based only on achievement. We invited public comments on this approach and requested input on how to score hospitals without baseline performance data using this and other approaches.

Under section 1886(o)(1)(C)(ii)(II), a hospital is excluded if it has been cited by the Secretary for deficiencies during the performance period that pose immediate jeopardy to the health or safety of patients. We proposed to interpret this provision to mean that any hospital that is cited by CMS through the Medicare State Survey and Certification process for deficiencies during the performance period (for purposes of the FY 2013 Hospital VBP program, the performance period is July 1, 2011–March 31, 2012) that pose immediate jeopardy to patients will be excluded from the Hospital VBP program for the fiscal year. We also proposed to use the definition of the term "immediate jeopardy" that appears in 42 CFR 489.3.

Section 1886(o)(1)(C)(ii)(III) requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year.

Section 1886(o)(1)(C)(ii)(IV) requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year.

In determining the minimum number of reported measures and cases under sections 1886(o)(1)(C)(ii)(III) and (IV), the statute requires the Secretary to conduct an independent analysis of what minimum numbers would be appropriate. To fulfill this requirement, we commissioned Brandeis University to perform an independent analysis that examined technical issues concerning the minimum number of cases per measure and the minimum number of measures per hospital needed to derive reliable performance scores. This analysis examined hospital performance scores using data from 2007 through 2008 and 2008 through 2009. The researchers tested different minimum numbers of cases and measures and concluded that the most important factor in setting minimum thresholds for the Hospital VBP program is to determine a combination of thresholds that allows the maximum number of hospitals to be scored reliably. We note that such reliability depends on the combination of the two thresholds. For example, if we allowed the number of cases per measure to be small (for example, 5 cases), we might still have reliable overall scores if there were a sufficiently large number of measures.

The independent analysis indicated that a smaller number of cases would yield less reliable results for any given measure, ultimately affecting results, when the measures were combined to create the domain scores. Because the finalized Hospital VBP program scoring methodology aggregates information across all of the measures, the analysis considered various thresholds for the minimum number of cases to include in a measure. We recognized that lowering the minimum number of cases required for each measure would allow a greater number of hospitals to participate in the Hospital VBP program. The analysis explored whether a lower threshold for each individual measure might be sufficient to make composite measures (that is, measures based on aggregations of individual measures), more statistically reliable.

Brandeis researchers checked the reliability of the total performance score for hospitals with only 4 measures. One approach was to randomly select 4, 6, 10, or 14 measures and to compare the reliabilities that are determined using these different sets of measures per hospitals. The research found that using 4 randomly selected measures per hospital did not greatly reduce between-hospital reliability (particularly in terms of rank ordering) from what would have been determined using 10 or 14 measures. Examining hospitals with at least 10 cases for each clinical process measure, the analysis compared the reliability of clinical process measure scores for hospitals according to the

number of such measures reported. Whisker plots and reliability scores revealed comparable levels of variation in the process scores for hospitals reporting even a small number of measures as long as the minimum of 10 cases per clinical process measure was met. Based on this analysis, we proposed to establish the minimum number of cases required for each measure under the proposed Three Domain Performance Scoring Model at 10, which we believe will allow us to include more hospitals in the Hospital VBP program.

When examining the minimum number of measures necessary to derive reliable performance scores, the independent analysis revealed that the distribution of performance scores varied depending on the number of measures reported per hospital. The whisker plots and reliability scores demonstrated a clear difference in the distribution of scores for hospitals reporting 4 or more measures compared with those reporting fewer than 4 measures.

We believe that setting the minimum number of measures and cases as low as is reasonable is an essential component of implementing the Hospital VBP program and will help to minimize the number of hospitals unable to participate due to not having the minimum number of cases for a measure or the minimum number of measures. Therefore, as we stated above, we proposed to exclude from hospitals' Total Performance Score calculation any measures on which they report fewer than 10 cases. We also proposed to exclude from the Hospital VBP program any hospitals to which less than 4 of the measures apply.

We also proposed that, for inclusion in the Hospital VBP program for FY 2013, hospitals must report a minimum of 100 HCAHPS surveys during the performance period. The reliability of HCAHPS scores was determined through statistical analyses conducted by RAND, the statistical consultant for HCAHPS. RAND's analysis indicates that HCAHPS data does not achieve adequate reliability with a sample of less than 100 completed surveys to ensure that true hospital performance rather than random "noise" is measured. RAND's analysis indicates that HCAHPS data are significantly below 85 percent reliability levels across all HCAHPS dimensions with a sample of less than 100 completed surveys.

As proposed in the Hospital Inpatient VBP Program proposed rule (76 FR 2481), hospitals reporting insufficient data to receive a score on either the clinical process of care or HCAHPS domains will not receive a Total Performance Score for the FY 2013 Hospital VBP program.

We solicited public comments on our proposals regarding the minimum numbers of cases and measures necessary for hospitals' inclusion in the Hospital VBP program. We note that hospitals excluded from the Hospital VBP program will be exempt from the base operating DRG payment reduction required under section 1886(o)(7) as well as the possibility for value-based incentive payments.

We also note that the independent analysis conducted by Brandeis only looked at clinical process of care measures and for that reason, we intended that our proposal for the 10 case and 4 measure minimums apply only to those measures. We intend to make a separate proposal on what specific minimum numbers of cases and measures should apply to the outcome domain in future rulemaking. To the extent that the comments to the Hospital Inpatient VBP proposed rule pertained to what specific minimums would be appropriate for the outcome domain, we will take them into consideration as we develop our proposal. We will address the comments in this final rule insofar as they relate to what minimum numbers would be appropriate for the clinical process of care and patient experience of care domains.

Comment: Some commenters asked if very small hospitals will be subjected to the 1.0 percent reduction in base operating DRG amounts without being eligible for value-based incentive payments.

Response: Hospitals to which the Hospital VBP program does not apply will not receive a reduction to their base operating DRG amounts.

Comment: Many commenters asked that new hospitals not be included in the Hospital VBP program until they have sufficient time to implement all of their quality initiatives and begin meeting the requirements under the Hospital IQR program, and that new hospitals be given the opportunity to be scored on improvement during their first year of participation in the Hospital VBP program. Several other commenters objected to the inclusion of any hospitals that did not have sufficient measure data from the baseline period with which to calculate improvement scores, claiming that it would be unfair to deny these hospitals the opportunity to receive potentially higher scores based on improvement points. One commenter asked whether a hospital assigned a CCN in January 2010 would be scored based on a shorter baseline period or scored based only on achievement.

Response: We recognize the commenters' concerns regarding the fair treatment of all hospitals in the Hospital VBP program and the desire that all hospitals be given the opportunity to earn improvement points. However, we do not believe that we have authority to exclude these hospitals from the Hospital VBP program; section 1886(o)(1)(C)(ii) of the Act sets forth specific exclusions to the term "hospital" for purposes of the program, and none of these exclusions relate to hospitals that do not have baseline performance measure data. If a hospital does not have a minimum number of cases on a given measure in the baseline period, then we interpret the hospital to have "no measure data from the baseline period" with which to calculate an improvement threshold. In such a case, the hospital would not be scored on improvement for that measure. If, however, a hospital reports the minimum number of cases during the applicable baseline period on a given measure—whether such data was obtained throughout the entire baseline period or only over a portion of such period—then the hospital's data during the performance period would be compared to its baseline period performance for the purpose of determining improvement points for that measure. Hospitals not scored on improvement for a given measure will still have the opportunity to score up to 10 achievement points on that measure. As noted above, we believe it is important to include as many hospitals as possible in order to successfully implement the Hospital VBP program and succeed in achieving the Hospital VBP program goals. Thus, the program will apply to hospitals, as that term is defined in section 1886(o)(1)(C)(i), and provided that none of the exclusions in section 1886(o)(1)(C)(ii) apply.

Comment: Commenters suggested that CMS should develop a new value-based purchasing program specific to cancer centers. Other commenters suggested that CMS consider promoting disease-specific quality programs across all care settings.

Response: We thank the commenters for their input. We will certainly take their suggestions under advisement for future quality improvement efforts. We note that the Affordable Care Act requires the Secretary to implement a number of new value-based purchasing and quality reporting initiatives across various health care settings, including quality reporting programs for cancer care hospitals and psychiatric hospitals, as well as to develop plans for value-

based purchasing efforts in the home health and skilled nursing settings.

Comment: Several commenters requested improvements to or clarification of the Medicare State Survey and Certification Process prior to its use in the Hospital VBP program.

Response: We proposed to interpret the statutory exclusion at Section 1886(o)(1)(C)(ii)(II) to mean that any hospital that is cited by CMS through the Medicare State Survey and Certification process for deficiencies during the performance period that pose immediate jeopardy to patients will be excluded from the Hospital VBP program for the fiscal year. We proposed to use the definition of the term "immediate jeopardy" that appears in 42 CFR § 489.3. We intend to further evaluate the application of this definition to the Hospital VBP context and may make additional proposals related to the "immediate jeopardy" exclusion in section 1886(o)(1)(C)(ii)(II) in future rulemaking.

Comment: Many commenters suggested different numbers of minimum cases for hospitals to be included in Hospital VBP, arguing that 10 cases per clinical process measure are insufficient to produce reliable measure scores. A number of commenters argued that CMS should use the same reliability criteria it uses for purposes of displaying measure information on *Hospital Compare* for purposes of defining the minimum case threshold for the Hospital VBP program.

Response: There are currently no minimum case thresholds for the clinical process of care measures reported on *Hospital Compare,* and all clinical process of care data, regardless of sample size, are made publicly available. We recognize that there is currently a footnote added where the Hospital IQR reported clinical process of care measure rates are based on less than 25 cases, and we note that we originally believed that this footnote was appropriate based on the work we did in developing the Hospital Compare display parameters for Hospital IQR data. However, the more recent independent analysis that was completed as part of the development of the Hospital Inpatient VBP proposed rule indicates that the clinical process of care measure data is reliable with fewer than 25 cases, and we plan to revise the footnote on Hospital Compare.

Comment: Many commenters called on us to publish the independent analysis we used to determine the appropriate minimum numbers of cases and measures for the Hospital VBP program.

Response: To the extent that these analyses are not subject to privilege, we will make available additional information, including the study results and methods, and will inform the public when such information is available.

Comment: One commenter asked whether we had considered the impacts of the proposed measure and case minimums on hospitals' ability to compete for value-based incentive payments.

Response: As detailed in the Hospital Inpatient VBP proposed rule (76 FR 2480), we considered many factors when developing the measure and case minimums, including the reliability of Total Performance Scores, the number of hospitals included in the program, and the impact on small hospitals under various scenarios. We believe that reliable clinical process of care and patient experience of care domain scores can be generated based on the proposed minimum numbers of cases, measures, and completed HCAHPS surveys, and that hospitals will be able to fairly compete for value-based incentive payments.

Comment: Some commenters suggested that we should consider other performance measures for hospitals with few cases.

Response: We note that section 3001(b)(2) of the Affordable Care Act requires the Secretary to establish a value-based purchasing demonstration program for hospitals that are excluded from the Hospital VBP program because they do not have the minimum number of cases or measures.

Comment: One commenter suggested that CMS require hospitals to submit a minimum of 300 HCAHPS surveys per year in order to be included in Hospital VBP; another commenter questioned whether 100 completed HCAHPS surveys will still be the minimum number required in the future should Hospital VBP move to a 12-month performance period rather than the 9-month performance period finalized for the FY 2013 Hospital VBP program. Another commenter was concerned that the HCAHPS exclusion of patients discharged to a nursing home would not permit hospitals to achieve a sufficient number of completed surveys.

Response: Because of reliability concerns, if a hospital has less than 100 completed surveys, we will not calculate an HCAHPS performance score for the Hospital VBP program (and thus will exclude the hospital from the Hospital VBP program). The requirement for 100 completed surveys pertains to both the 9 month and 12 month performance periods as the 100 survey requirement is based upon the reliability of the data, not the number of calendar quarters. In either time period, we want to ensure that we have reliable data to measure performance. Using statistical measures of reliability that calculate the proportion of the variance in reported hospital scores that is due to true variation between hospitals, rather than within hospital variation that reflects limited sample size, HCAHPS data have been found to be unreliable when a hospital achieves under 100 survey completes.

Patients that are discharged to nursing homes are excluded from the survey due to numerous problems that have been encountered by HCAHPS survey vendors and self-administering hospitals in contacting nursing home patients. We have also found, based on our own research on this topic, that the response rate for nursing home residents is extremely low. By increasing their sampling of patients not discharged to nursing homes, hospitals can achieve a sufficient number of completed surveys.

Based on the comments we received, we are finalizing our proposals regarding the applicability of the Hospital VBP program to hospitals, including calculating and making payment adjustments for this provision using the CCN of the main provider and making payments to each provider of record. Further, we adopt the procedures noted above for submission of the report required under section 1886(o)(1)(C)(iv) and note that we intend to make the question of whether to exempt Maryland hospitals from the Hospital VBP program the subject of future rulemaking.

We are also finalizing a policy to exclude from a hospital's total performance score its score on any clinical process measure for which it reports fewer than 10 cases, and to exclude from the Hospital VBP program any hospital to which less than 4 of the clinical process measures apply. We are also finalizing our proposal to exclude from the FY 2013 Hospital VBP program a hospital that reports fewer than 100 HCAHPS surveys during the performance period. Finally, we are finalizing our proposal to score hospitals only based on achievement if we have measure data from the performance period but no measure data from the baseline period. However, as discussed above, we will interpret "no measure data from the baseline period" to include data that does not meet the minimum measure and case thresholds that we are adopting in this final rule for the clinical process of care and patient experience of care domains. We believe that calculating an improvement threshold requires at least as much data

as is required for calculating measure scores during the performance period in order to ensure valid comparisons between the two periods. We further believe that the analyses we commissioned to determine the minimum number of cases, measures, and completed HCAHPS surveys during the performance period can be appropriately applied to requiring these minimums in the baseline period to create an improvement threshold.

H. The Exchange Function

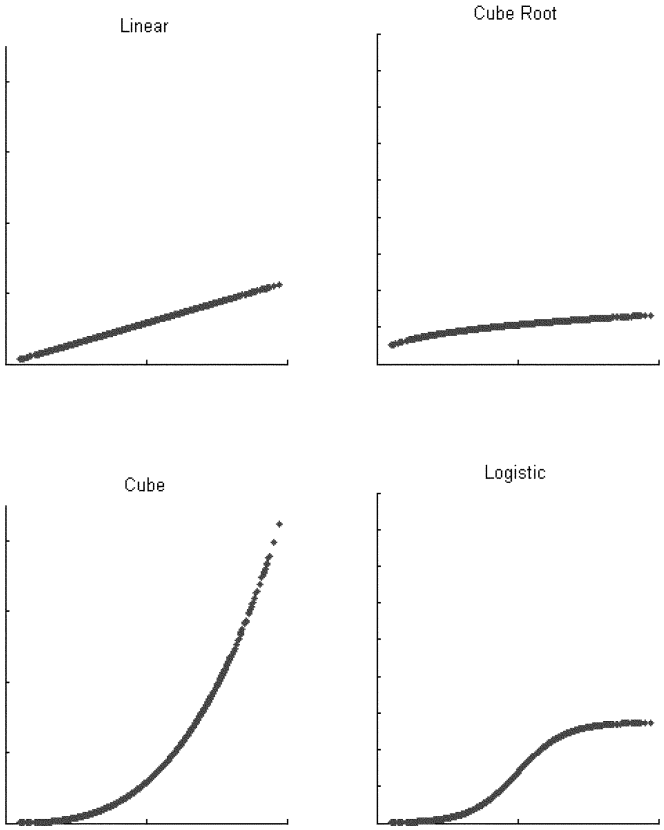
Section 1886(o)(6) of the Act governs the calculation of value-based incentive payments under the Hospital VBP program. Specifically, section 1886(o)(6)(A) requires that in the case of a hospital that meets or exceeds the performance standards for the performance period for a fiscal year, the Secretary shall increase the base operating DRG payment amount (as defined in section 1886(o)(7)(D)), as determined after application of a payment adjustment described in section 1886(o)(7)(B)(i), for a hospital for each discharge occurring in the fiscal year by the value-based incentive payment amount. Section 1886(o)(6)(B) defines the value-based incentive payment amount for each discharge in a fiscal year as the product of (1) the base operating DRG payment amount for the discharge for the hospital for such fiscal year, and (2) the value-based incentive payment percentage for the hospital for such fiscal year. Section 1886(o)(6)(C)(i) provides that the Secretary must specify a value-based incentive payment percentage for each hospital for a fiscal year, and section 1886(o)(6)(C)(ii) provides that in specifying the value-based incentive payment percentage, the Secretary must ensure (1) that the percentage is based on the hospital's performance score, and (2) that the total amount of value-based incentive payments to all hospitals in a fiscal year is equal to the total amount available for value-based incentive payments for such fiscal year under section 1886(o)(7)(A), as specified by the Secretary.

Section 1886(o)(7) of the Act describes how the value-based incentive payments are to be funded. Under section 1886(o)(7)(A), the total amount available for value-based incentive payments for all hospitals for a fiscal year must be equal to the total amount of reduced payments for all hospitals under section 1886(o)(7)(B), as estimated by the Secretary. Section 1886(o)(7)(B)(i) requires the Secretary to adjust the base operating DRG payment amount for each hospital for each discharge in a fiscal year by an amount equal to the applicable percent of the base operating DRG payment amount for the discharge for the hospital for such fiscal year, and further requires that the Secretary make these reductions for all hospitals in the fiscal year involved, regardless of whether or not the hospital has been determined to have earned a value-based incentive payment for the fiscal year. With respect to FY 2013, the term "applicable percent" is defined as 1.0 percent, but the amount gradually rises to 2.0 percent by FY 2017 (section 1886(o)(7)(C)).

The 2007 Report to Congress introduced the exchange function as the means to translate a hospital's total performance score into the percentage of the value-based incentive payment earned by the hospital. We believe that the selection of the exact form and slope of the exchange function is of critical importance to how the incentive payments reward performance and encourage hospitals to improve the quality of care they provide.

As illustrated in Figure 7, we considered four mathematical exchange function options: straight line (linear); concave curve (cube root function); convex curve (cube function); and S-shape (logistic function).

Figure 7. Exchange Function Options.



In determining which of these exchange functions would be most appropriate for translating a hospital's Total Performance Score into a value-based incentive payment percentage, we carefully considered four aspects of each option.

First, we considered how each option would distribute the value-based incentive payments among hospitals. Under section 1886(o)(7)(A) of the Act, the total amount available for value-based incentive payments for all hospitals for a fiscal year must be equal to the total amount of reduced payments for all hospitals for such fiscal year, as estimated by the Secretary. We interpreted this section to mean that the redistribution of a portion of the IPPS payments to all hospitals under the Hospital VBP program must be accomplished in a way that is estimated to be budget neutral, without increasing or decreasing the aggregate overall IPPS payments made to all hospitals. As a result, if we award higher value-based incentive payments to higher performing hospitals, less money is available to make value-based incentive payments to lower performing hospitals. The reverse is also true. If we give higher value-based incentive payments to lower performing hospitals, less money is available to reward higher performing hospitals. The form and slope of each exchange function also affects the level of value-based incentive payments available to hospitals at various performance levels. Under both the cube and logistic functions, lower incentive payments are available to lower performing hospitals and aggressively higher payments are available for higher performing hospitals. These functions therefore distribute more incentive payments to higher performing hospitals. Under the cube root function, payments stay at relatively lower levels for higher performing hospitals; this function distributes more incentive payments to lower performing hospitals. The linear function moves more aggressively to higher levels for higher performing hospitals than the cube root function, but not as aggressively as the logistic and cube functions. It therefore distributes more incentive payments to higher performing hospitals than the cube root function, but not as aggressively as the logistic and cube functions.

Second, we considered the potential differences between the value-based incentive payment amounts for hospitals that do poorly and hospitals that do very well. Due to the fact that the cube root function distributes lower payment amounts to higher performing hospitals, the cube root function creates the narrowest distribution of incentive payments across hospitals. The linear is next, followed by the logistic. The cube function, which most aggressively moves to higher payment levels for higher performing hospitals, creates the widest distribution.

Third, we considered the different marginal incentives created by the different exchange function shapes. In the case of the linear shape, the marginal incentive does not vary for higher or lower performing hospitals. The slope of the linear function is constant, so any hospital with a Total Performance Score that is 0.1 higher than another hospital would receive the same increase in its value-based incentive payment across the entire Total Performance Score range. For the other shapes, the slope of the exchange function creates a higher or lower marginal incentive for higher or lower performing hospitals. Steeper slopes at any given point on the function indicate greater marginal incentives for hospitals

to improve scores and obtain higher payments at that point, while flatter slopes indicate smaller marginal incentives. If the slope is steeper at the low end of performance scores than at the high end, as with the cube root function, hospitals at the low end have a higher marginal incentive to improve than hospitals at the high end. If the slope is steeper at the high end, as with the cube function, hospitals have a higher marginal incentive to improve at the high end than they do at the low end.

Fourth, we weighed the relative importance of having the exchange function be as simple and straightforward as possible.

Taking all of these factors into account, we proposed to adopt a linear exchange function for the purpose of calculating the percentage of the value-based incentive payment earned by each hospital under the Hospital VBP program. The linear function is the simplest and most straightforward of the mathematical exchange functions discussed above. The linear function provides all hospitals the same marginal incentive to continually improve. The linear function rewards higher performing hospitals more aggressively than the cube root function, but not as aggressively as the logistic and cube functions. We proposed the function's intercept at zero, meaning that hospitals with scores of zero will not receive any incentive payment. Payment for each hospital with a score above zero will be determined by the slope of the linear exchange function, which will be set to meet the budget neutrality requirement of section 1886(o)(6)(C)(ii)(II) of the Act, that the total amount of value-based incentive payments equal the estimated amount available under section 1886(o)(7)(A). In other words, we proposed to set the slope of the linear exchange function for FY 2013 so that the estimated aggregate value-based incentive payments for FY 2013 are equal to 1.0 percent of the estimated aggregate base operating DRG payment amounts for FY 2013. We proposed that analogous estimates will be done for subsequent fiscal years.

We believe that our proposed linear exchange function ensures that all hospitals have strong incentives to continually improve the quality of care they provide to their patients. We may revisit the issue of the most appropriate exchange function in future rulemaking as we gain more experience under the Hospital VBP program. We solicited public comments on our exchange function and the resulting distribution of value-based incentive payments.

We noted in the Hospital Inpatient VBP Program proposed rule that, in order evaluate the different exchange functions, we needed to estimate the value-based incentive payment amount. As stated above, section 1886(o)(6)(B) of the Act defines the value-based incentive payment amount as equal to the product of the base operating DRG payment amount for each discharge for the hospital for the fiscal year and the value-based incentive payment percentage specified by the Secretary for the hospital for the fiscal year. Section 1886(o)(7)(D)(i) defines the base operating DRG payment with respect to a hospital for a fiscal year as, unless certain special rules apply, "the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (q)) for a discharge if [subsection (o)] did not apply; reduced by any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F) and (12) of subsection (d); and such other payments under subsection (d) determined appropriate by the Secretary." Therefore, for estimation purposes, to calculate base operating DRG payments, we estimated the total payments using Medicare Part A claims data and subtracted from this number the estimates of payments made as outlier payments (authorized under section 1886(d)(5)(A)), indirect medical education payments (authorized under section 1886(d)(5)(B)), disproportionate share hospital payments (authorized under section 1886(d)(5)(F)), and low-volume hospital adjustment payments (authorized under section 1886(d)(12)). We note that this approximation of base operating DRG payments made for the purpose of estimating the value-based payment amount to evaluate the different exchange functions is not a policy proposal. We will propose a definition of the term "base operating DRG payment amount" under section 1886(o)(7)(D), as well as how we would implement the special rules for certain hospitals described in section 1886(o)(7)(D)(ii), in future rulemaking. We solicited public comment to inform our intended future policymaking on this issue.

Furthermore, section 1886(o)(7)(A) states that the total amount available for value-based incentive payments for all hospitals for a fiscal year shall be equal to the total amount of reduced payments for all hospitals for such fiscal year. To calculate the total amount of reduced payments, section 1886(o)(7)(B) states that the base operating DRG payment amount shall be reduced by an applicable percent as defined under section 1886(o)(7)(C). This applicable percent is 1.0 percent for FY 2013, 1.25 percent for FY 2014, 1.5 percent for FY 2015, 1.75 percent for FY 2016, and 2.0 percent for FY 2017 and subsequent years. To develop an estimation of the value-based incentive payment amount for the purposes of evaluating the different exchange functions, we used the FY 2013 1.0 percent as the applicable percent. We multiplied an estimate (described above) of the total aggregate base operating DRG payments for hospitals as defined under section 1886(o)(1)(C) by 1.0 percent in order to derive the total amount available for value-based incentive payments that was used in the evaluation of the four exchange functions.

The comments we received on this proposal and our responses are set forth below.

Comment: The majority of commenters, including MedPAC, expressed support for our proposed linear exchange function with an intercept of zero during the initial years of the Hospital VBP program. The reasons cited by these commenters included that a linear exchange function appropriately incentivizes both high- and low-performing hospitals; it is more straightforward than the alternative functional forms discussed in the Hospital Inpatient VBP Program proposed rule (that is cube, cube root, and logistic); and it provides a relatively more even distribution of incentive payments. Many commenters indicated that we should consider revisiting the issue of the exchange function once we have actual data and experience under an implemented Hospital VBP program. Some of these commenters, including MedPAC, suggested that over time we could consider providing stronger incentives to lower performing hospitals depending on the initial experience and data.

A few commenters did not support the use of the linear exchange function with an intercept of zero. These commenters indicated that we need to provide greater incentives to lower performing hospitals in the initial implementation, such as through the use of a cube root exchange function.

Commenters also requested transparency with respect to the slope of the linear exchange function for FY 2013 and the associated issues of budget neutrality, payment impacts, and the maximum performance-based payment adjustment that can be made to a hospital's base operating DRG payment amount. They also requested additional operational detail on how CMS will distribute the incentive payment

amounts to the hospitals once they have been determined.

Response: We agree with the commenters who supported our proposed linear exchange function. It provides all hospitals with the same marginal incentive to continually improve. It more aggressively rewards higher performing hospitals than the cube root function, but not as aggressively as the logistic and cube functions. It is also the simplest and most straightforward of the mathematical exchange functions discussed in the Hospital Inpatient VBP Program proposed rule.

We disagree with the commenters who stated that we need to provide greater incentives to lower performing hospitals in the initial implementation of the Hospital VBP program, such as through the use of a cube root exchange function. At this time we believe it would be prudent to examine the experience and data from the initial implementation of the program before considering increasing the incentives to lower performing hospitals. We note that increasing the incentives to lower performing hospitals would result in decreased incentives for higher performing hospitals due to the requirement in section 1886(o)(6)(C)(ii)(II) of the Act that the total amount available for value-based incentive payments under section 1886(o)(6) for all hospitals for a fiscal year be equal to the total amount of reduced payments for all hospitals under section 1886(o)(7)(B) for such fiscal year, as estimated by the Secretary.

With respect to the slope of the linear exchange function for FY 2013, we fully intend to provide the final exchange function slope once our actuaries have the data necessary to calculate it. As noted in the Hospital Inpatient VBP Program proposed rule (76 FR 2483), our actuaries will calculate the slope of the linear exchange function for FY 2013 so that the estimated aggregate value-based incentive payments for FY 2013 are equal to 1.0 percent of the estimated aggregate base operating DRG payment amounts for FY 2013. It is not possible for our actuaries to calculate the final slope of the linear exchange function until we have the data from the performance period.

As we have indicated previously, we intend to propose a definition of the base operating DRG payment amount in future rulemaking. We also intend to provide additional operational detail concerning how hospitals will receive the value-based incentive payments in a future rule.

As requested by many commenters, we would consider revisiting the issue of the exchange function depending on the actual data and experience under the implemented Hospital VBP program.

Comment: One commenter argued that an increasing proportion of hospital payments should be tied to performance, eventually even above the 2.0 percent margin.

Response: Section 1886(o)(7)(C) of the Act provides for an annual increase in the funding for available value-based incentive payments from FY 2013 to FY 2017, adjusting the applicable percent of base operating DRG payments available for value-based incentive payments as follows: with respect to FY 2013, 1.0 percent; with respect to FY 2014, 1.25 percent; with respect to FY 2015, 1.5 percent; with respect to FY 2016, 1.75 percent; and with respect to FY 2017 and succeeding fiscal years, 2 percent. In effect, this will tie an increasing proportion of hospital payments to performance on quality measures. CMS does not have authority to increase the base DRG operating payment withhold amount above 2.0 percent.

After considering the public comments, we are finalizing the exchange function as proposed.

I. Hospital Notification and Review Procedures

Section 1886(o)(8) of the Act requires the Secretary to inform each hospital of the adjustments to payments to the hospital for discharges occurring in a fiscal year as a result of the calculation of the value-based incentive payment amount (section 1886(o)(6)) and the reduction of the base operating DRG payment amount (section 1886(o)(7)(B)(i)) not later than 60 days prior to the fiscal year involved. We proposed to notify hospitals of the 1.0 percent reduction to their respective FY 2013 base operating DRG payments for each discharge in the FY 2013 IPPS rule, which will be finalized at least 60 days prior to the beginning of FY 2013. We expect to propose to incorporate this reduction into our claims processing system in January 2013, which will allow the 1.0 percent reduction to be applied to the FY 2013 discharges, including those that have occurred beginning on October 1, 2012. We will address the operational aspects of the reduction as part of the FY 2013 IPPS rule.

Because the performance period would end only six months prior to the beginning of FY 2013, CMS will not know each hospital's exact Total Performance Score or final value-based incentive payment adjustment 60 days prior to the start of the 2013 fiscal year on October 1, 2012. Therefore, we proposed to inform each hospital through its QualityNet account at least 60 days prior to October 1, 2012 of the estimated amount of its value-based incentive payment for FY 2013 discharges based on estimated performance scoring and value-based incentive payment amounts, which will be derived from the most recently available data. We also proposed that each hospital participating in the Hospital VBP program establish a QualityNet account if it does not already have one for purposes of the Hospital IQR program. We further proposed to notify each hospital of the exact amount of its value-based incentive payment adjustment for FY 2013 discharges on November 1, 2012. The value-based incentive payment adjustment would be incorporated into our claims processing system in January 2013, which will allow the value-based incentive payment adjustment to be applied to the FY 2013 discharges, including those that have occurred beginning on October 1, 2012.

Section 1886(o)(10)(A)(i) of the Act requires the Secretary to make information available to the public regarding individual hospital performance in the Hospital VBP program, including: (1) hospital performance on each measure that applies to the hospital; (2) the performance of the hospital with respect to each condition or procedure; and (3) the hospital's Total Performance Score. To meet this requirement, we proposed to publish hospital scores with respect to each measure, each hospital's condition-specific score (that is, the performance score with respect to each condition or procedure, for example, AMI, HF, PN, SCIP, HAI), each hospital's domain-specific score, and each hospital's Total Performance Score on the *Hospital Compare* Web site. We note that we did not propose to use a hospital's condition-specific score for purposes of calculating its Total Performance Score under the Three-Domain Performance Scoring Model.

Section 1886(o)(10)(A)(ii) of the Act requires the Secretary to ensure that each hospital has the opportunity to review and submit corrections related to the information to be made public with respect to the hospital under section 1886(o)(10)(A)(i) prior to such information being made public. As stated above, we proposed to derive the Hospital VBP measures data directly from measure data submitted by each hospital under the Hospital IQR program. We proposed that the procedures we adopt for the Hospital IQR program will also be the procedures

that hospitals must follow in terms of reviewing and submitting corrections related to the information to be made public under section 1886(o)(10) of the Act.

With respect to the FY 2013 Hospital VBP program, we proposed to make each hospital's Hospital VBP performance measure score, condition-specific score, domain-specific score, and Total Performance Score available on the hospital's QualityNet account on November 1, 2012. We proposed to remind each hospital via the hospital's secure QualityNet account of the availability of its performance information under the Hospital VBP program on this date. Pursuant to section 1886(o)(10)(A)(ii), we proposed to provide hospitals with 30 calendar days to review and submit corrections related to their performance measure scores, condition-specific scores, domain-specific scores and Total Performance Score.

Section 1886(o)(10)(B) requires the Secretary to periodically post on the *Hospital Compare* Web site aggregate information on the Hospital VBP program, including: (1) the number of hospitals receiving value-based incentive payments under the program as well as the range and total amount of such value-based incentive payments; and (2) the number of hospitals receiving less than the maximum value-based incentive payment available for the fiscal year involved and the range and amount of such payments. We proposed to post aggregate Hospital VBP information on the *Hospital Compare* Web site in accordance with Section 1886(o)(10)(B) of the Act. We will provide further details on reporting aggregated information in the future.

The comments we received on this proposal and our responses are set forth below.

Comment: Some commenters expressed general support for our proposals to display hospital's Hospital VBP performance measure score, condition-specific score, domain-specific score, and Total Performance Score available on the hospital's QualityNet account on November 1, 2012 for the FY 2013 Hospital VBP program, specifically noting time limitations in the statutory timeline.

Response: We thank commenters for their support.

Comment: Some commenters called on CMS to translate hospitals' Total Performance Scores into publicly reported data that is meaningful to consumers and those employers sponsoring health care coverage for their employees, specifically by listing data not only for Medicare patients but for all patients. One commenter additionally requested that hospitals' performance be evaluated and reported on an individual basis, even if hospitals are commonly owned and operating upon one license, and, therefore, reporting as one entity. One commenter asked if CMS will publish hospital-specific incentive payment percentages or amounts.

Response: As discussed in the Hospital Inpatient VBP Program proposed rule (76 FR 2484), section 1886(o)(10)(A)(i) of the Act requires the Secretary to make information available to the public regarding individual hospital performance in the Hospital VBP program. We proposed to publish hospital scores with respect to each measure, each hospital's condition-specific score, each hospital's domain-specific score, and each hospital's Total Performance Score on the *Hospital Compare* Web site. We will make every effort to make the information presented as usable and clear for public use as possible. However, we do not plan at this point to make public hospital-specific incentive payment percentages or amounts because we believe that the information required to be publicly reported adequately describes each hospital's individual performance under the program. With respect to the request that we report performance information for individual hospitals that are commonly owned, CMS currently receives and displays data under the Hospital IQR program by CCN number. One CCN number can apply to multiple campuses of one hospital. Although hospital owners have chosen to enroll these campuses in the Medicare program as one integrated hospital rather than as separate hospitals, we are aware that members of the public tend to view them as separate hospitals. CMS is currently exploring best methods to make data publicly available for each campus of multi-campus hospitals operating under one CCN number and will take this comment into consideration as it seeks to improve transparency of hospital performance for consumers.

Comment: One commenter suggested that we develop a composite quality measurement system for the *Hospital Compare* Web site similar to the Society of Thoracic Surgeons' Adult Cardiac Surgery Database.

Response: We thank the commenter for the suggestion. We are continuing to look for ways to decrease the reporting burden to hospitals and make the information that we include on *Hospital Compare* meaningful for consumers. We will take the suggestion under advisement.

Comment: Commenters questioned how the Hospital VBP program would ease reporting burdens and aid consumers if, although hospitals are required to report measure data, some of the data reported would not be made publicly available on *Hospital Compare.*

Response: We note that all data used to evaluate hospital performance in Hospital VBP will also be submitted by hospitals under the Hospital IQR program. Accordingly, the Hospital VBP program does not impose reporting requirements on hospitals in addition to or different from those imposed by the Hospital IQR program. We believe that the data as reported on *Hospital Compare* adequately reflects each hospital's performance without miring the consumer in too much detail. As discussed above, consumers will be able to see each hospital's score with respect to each measure, each hospital's condition-specific score, each hospital's domain-specific score, and each hospital's Total Performance Score on the *Hospital Compare* Web site. We are aware that the score for a measure for purposes of the Hospital VBP program might differ from the rate we display for that measure for purposes of the Hospital IQR program based on differing date ranges used for each program and the fact that the Hospital VBP data will reflect a hospital's performance score on the measure. We will make every effort to ensure that these differences are clearly explained to the public.

Comment: Many commenters asked that frequently updated calculations be provided for each hospital. Some commenters specifically asked for quarterly hospital preview reports with a percentile ranking for each hospital. Other commenters suggested CMS make available a report through QualityNet that would provide constant updates and status about value-based purchasing scoring calculations and each hospital's individual and up-to-date scores.

Response: We believe that yearly updates of Hospital VBP performance information will provide the most simplicity and clarity for hospitals, although we will certainly consider commenters' suggestions as the program moves forward. We note that Total Performance Scores are based on measure data from the entirety of the performance period, not any subset. We are concerned that providing hospitals with a calculation of their scores based on only a portion of the performance period would be misleading because the scores would be based on insufficient data and could be significantly different from the hospitals' Total Performance Scores, which will be based on data from entire performance periods. For

these reasons, we believe calculating Hospital VBP scores based on the data from the entire performance period will provide hospitals with the best and most reliable information for their use.

Comment: Some commenters asked CMS to provide the final, adjusted DRG payments 30 days before October 1, 2012 to avoid claims reprocessing for the value-based incentive payments.

Response: Section 1886(o)(8) requires the Secretary to inform each hospital of the adjustments to payments to the hospital for discharges occurring in a fiscal year as a result of the calculation of the value-based incentive payment amount (section 1886(o)(6)) and the reduction of the base operating diagnosis-related group (DRG) payment amount (section 1886(o)(7)(B)(i)), not later than 60 days prior to the fiscal year involved. We proposed to notify hospitals of the 1.0 percent reduction to their FY 2013 base operating DRG payments for each discharge in the FY 2013 IPPS rule, which will be finalized at least 60 days prior to the beginning of the 2013 fiscal year. We expect to propose to incorporate this reduction into our claims processing system in January 2013, which will allow the 1.0 percent reduction to be applied to the FY 2013 discharges, including those that have occurred beginning on October 1, 2012. We will address the operational aspects of the reduction as part of the FY 2013 IPPS rule.

Because the finalized nine-month performance period will end only six months prior to the beginning of FY 2013, we will not have enough time to calculate each hospital's exact total performance score or final value-based incentive payment adjustment 60 days prior to the start of the 2013 fiscal year on October 1, 2012. Therefore, we proposed to inform each hospital through its QualityNet account at least 60 days prior to October 1, 2012 of the estimated amount of its value-based incentive payment for FY 2013 discharges based on estimated performance scoring and value-based incentive payment amounts, which will be derived from the most recently available data. We also proposed that each hospital participating in the Hospital VBP program establish a QualityNet account if it does not already have one for purposes of the Hospital IQR program.

We further proposed to notify each hospital of the exact amount of its value-based incentive payment adjustment for FY 2013 discharges on November 1, 2012. The value-based incentive payment adjustment would be incorporated into our claims processing system in January 2013, which will allow the value-based incentive payment adjustment to be applied to the FY 2013 discharges, including those that have occurred beginning on October 1, 2012.

We made these notification proposals because we concluded that using a full year as the FY 2013 performance period would not give us sufficient time to calculate the total performance scores and value-based incentive payments, notify hospitals regarding their payment adjustments, and implement the payment adjustments.

While we generally agree with commenters' suggestion, we believe our finalized performance period and notification policies outlined above appropriately balance the need for a robust FY 2013 performance period with hospitals' desire to receive value-based incentive payments as quickly as possible.

Comment: One commenter asked how often the rankings for each hospital, based on individual Total Performance Scores, will be updated. The commenter also asked if there will be a data backlog for such rankings, and, if so, how great.

Response: We have not proposed to provide "rankings" of hospitals based on their Total Performance Scores. Rather, the hospitals' Total Performance Scores will be calculated annually at least 60 days prior to the beginning of the fiscal year. As stated above, because the Total Performance Scores depend on the entirety of hospitals' data submitted during the performance period, we do not believe that providing more frequent updates to the Total Performance Scores than on an annual basis would be helpful to providers or the public.

While there is a delay between the conclusion of the performance period and the beginning of the fiscal year in which the corresponding value-based incentive payments will be made, this time period is necessary for hospitals to submit the required data, for that data to be validated, for hospitals to review and submit corrections to information that will be made public, and for us to calculate Total Performance Scores. We do not view this delay as a "backlog," which we would interpret in this context as an extraordinary delay in data submission, validation, processing and notifications to hospitals.

As noted above, we will provide further details on information to be made public with respect to hospitals' performance scores in the future. We will consider the commenter's implicit suggestion that we should provide rankings in the future.

After considering the public comments, we are finalizing the notification and review provisions of the Hospital Inpatient VBP Program proposed rule as proposed.

J. Reconsideration and Appeal Procedures

Section 1886(o)(11)(A) of the Act requires the Secretary to establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards (section 1886(o)(3)(A)) and the hospital performance score (section 1886(o)(5)). Under section 1886(o)(11)(B) of the Act, there is no administrative or judicial review under section 1869, section 1878, or otherwise of the following: (1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) and the determination of such amount; (2) the determination of the amount of funding available for the value-based incentive payments under section 1886(o)(7)(A) and payment reduction under section 1886(o)(7)(B)(i); (3) the establishment of the performance standards under section 1886(o)(3) and the performance period under section 1886(o)(4); (4) the measures specified under section 1886(b)(3)(B)(viii) and the measures selected under section 1886(o)(2); (5) the methodology developed under section 1886(o)(5) that is used to calculate hospital performance scores and the calculation of such scores; or (6) the validation methodology specified in section 1886(b)(3)(B)(viii)(XI).

We solicited public comment, in general, on the structure and procedure of an appropriate appeals process. Specifically, we solicited comment on the appropriateness of a process that would establish an agency-level appeals process under which CMS personnel having appropriate expertise in the Hospital VBP program would decide the appeal. We sought insight on what qualifications such personnel should hold. We solicited comment on how the appeals process should be structured. Finally, we solicited public input on the timeframe in which these appeals should be resolved.

The comments we received on this proposal and our response are set forth below.

Comment: Many commenters called on us to establish an appeals process as soon as possible or prior to FY 2012. Others provided suggestions on the proper form of an appeals process, including a peer-reviewed process similar to QIOs or an informal dispute resolution process such as that outlined in the CMS State Operations Manual, 7212.

Response: We thank commenters for their input. These comments will inform future rulemaking on this issue.

K. FY 2013 Validation Requirements for Hospital Value-Based Purchasing

In the FY 2011 Inpatient Prospective Payment System (IPPS) final rule (75 FR 50225 through 50230), we adopted a validation process for the FY 2013 Hospital IQR program. We proposed that this validation process will also apply to the FY 2013 Hospital VBP program. We believe that using this process for both the Hospital IQR program and the Hospital VBP program is beneficial for both hospitals and CMS because no additional burden will be placed on hospitals to separately return requested medical records for the Hospital VBP program. Because the measure data we are using for the Hospital VBP program is the same as, or a subset of, the data we collect for the Hospital IQR program, we believe that we can ensure that the Hospital VBP program measure data are accurate through the Hospital IQR program validation process.

We note that we recently proposed to shorten the timeframe for submitting medical records for purposes of validation under the Hospital IQR program from 45 days to 30 days. Details regarding that proposal can be found in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011.

The comments we received on this proposal and our responses are set forth below.

Comment: A number of commenters expressed support for our proposal on data validation.

Response: We thank the commenters for their input.

Comment: Some commenters requested information on how the data validation processes for Hospital VBP would be run and, if issues regarding validation arose, how such problems would be addressed.

Response: We interpret the comments to request more information on validation scoring, sample selection, medical record request deadlines, and measures included in the validation process. Details regarding the validation process that we have adopted for the FY 2013 Hospital IQR program, as well as the change that we recently proposed to adopt for that process, can be found in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225 through 50230) and in the FY 2012 IPPS/LTCH PPS proposed rule scheduled for publication on May 5, 2011. The public section of the QualityNet Web site (*http://www.qualitynet.org*) also contains additional technical information about the validation process. As we stated in the Hospital Inpatient VBP Program proposed rule, we believe that using this process for both the Hospital IQR program and the Hospital VBP program will be beneficial for both hospitals and CMS because no additional burden will be placed on hospitals to separately return requested medical records for the Hospital VBP program. Because the measure data we are using for the Hospital VBP program is the same or a subset of the data we collect for the Hospital IQR program, we believe that we can ensure that the Hospital VBP program measure data are accurate through the Hospital IQR program validation process. The data validation for the proposed baseline period was completed at the end of January 2011.

Comment: Some commenters suggested that CMS should conduct targeted validation, studying the overall accuracy of hospitals' calculation of measure performance rather than assessing accuracy of every data element.

Response: As we explain in the FY 2011 IPPS/LTCH PPS Final Rule (75 FR 50225 through 50230), the validation process we have adopted for the Hospital IQR Program uses every data element used to calculate chart abstracted quality measures to assess overall measure accuracy. We interpret the comment to request that we target hospitals for validation that have attained high measure rates, high performance scores, and/or a very high number of improvement points as part of their Hospital VBP total performance score calculation. We believe that targeting validation on the subset of hospitals achieving high performance scores and the highest performance score changes from previous performance periods would improve the data accuracy under the Hospital VBP program. We will consider this suggestion for future rulemaking.

Comment: A commenter asked how we will validate data submitted from hospitals during the initial baseline period.

Response: We interpret this comment to question our validation process for the FY 2013 proposed baseline period for chart abstracted clinical process of care measure data from July 1, 2009 to March 31, 2010. We validated the Hospital IQR data for the 3rd calendar quarter 2009 discharges using the validation process that we adopted in the FY 2010 IPPS final rule (73 FR 43882 through 43889) for the FY 2011 payment determination and for 1st calendar quarter 2010 discharges using the validation process that we adopted in the FY 2011 IPPS final rule (75 FR 50225 through 50229) for the FY 2012 payment determination. The 4th calendar quarter of 2009 was not among the quarters of data that were used for validation of the FY 2011 or FY 2012 payment determinations. Accordingly, we used the process that we adopted for the FY 2012 payment determination to validate data from this calendar quarter. We completed validation of these data in January 2011.

Comment: A number of commenters suggested that we consider the impact of the ICD–10–CM/PCS reporting implementation on the Hospital VBP program, measure rates, and quality improvement efforts.

Response: We interpret the comment to request additional information on the impact of ICD–10/CM/PCS implementation on Hospital VBP measure populations changing from ICD–9 codes to using ICD–10 codes. While the change in codes used for measure calculation may have some impact on measure rates, this will not happen until the transition to ICD–10 on October 1, 2013. We have not modeled this impact on Hospital VBP measures using statistical analysis at the present time. We will closely monitor the impact of ICD–10 implementation on the Hospital VBP program measure achievement and improvement trends and consider this information in future rulemaking. We agree that this fundamental change in categorizing diagnoses and procedures could potentially impact Hospital VBP performance scores through changes in measure rates due to measure population definition changes and coding definition changes. Additional information regarding ICD–10 implementation can be found at: *http://www.cms.gov/ICD10.*

Comment: Some commenters argued that the proliferation of different electronic reporting requirements and programs and differing chart-abstraction practices may result in inconsistent data collection by hospitals.

Response: We appreciate the comment and understand that differences in abstraction practices and increased use of electronic health records may result in inconsistent interpretations of measure instructions among hospitals in terms of data collection. A principal goal of our validation requirement is to ensure consistency and accuracy in hospital reported measures. We currently validate the accuracy of chart-abstracted measure data reported for the Hospital IQR program and, as explained above, will use this validation process to

ensure the accuracy of the Hospital VBP chart-abstracted measure data.

After considering the public comments, we are finalizing our proposal to use the validation process we use for the FY 2013 Hospital IQR program to ensure that data for the FY 2013 Hospital VBP program are accurate.

L. Additional Information

1. Monitoring and Evaluation. As part of our ongoing effort to ensure that Medicare beneficiaries receive high-quality inpatient care, CMS plans to monitor and evaluate the new Hospital VBP program. Monitoring will focus on whether, following implementation of the Hospital VBP program, we observe changes in access to and the quality of care furnished to beneficiaries, especially within vulnerable populations. We will also evaluate the effects of the new Hospital VBP program in areas such as:

- Access to care for beneficiaries, including categories or subgroups of beneficiaries.
- Changes in care practices that might adversely impact the quality of care furnished to beneficiaries.
- Patterns of care suggesting particular effects of the Hospital VBP program (such as whether there are changes in the percentage of patients receiving appropriate care for conditions covered by the measures); or a change in the rate of hospital acquired conditions.
- Best practices of high-performing hospitals that might be adopted by other hospitals. We currently collect data on readmission rates for beneficiaries diagnosed with myocardial infarction, heart failure, and pneumonia. We also collect chart abstracted data on a variety of quality of care indicators related to myocardial infarction, heart failure, pneumonia, and surgical care improvement. These sources and other available data will provide the basis for early examination of trends in care delivery, access, and quality. Assessment of the early experience with the Hospital VBP program will allow us to create an active learning system, building the evidence base essential for guiding the design of future Hospital VBP programs and enabling us to address any disruptions in access or quality that may arise. These ongoing monitoring and evaluation efforts will be part of our larger efforts to promote improvements in quality and efficiency, both within CMS and between CMS and hospitals in the Hospital VBP program.

2. Electronic Health Records (EHRs)

a. Background

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of electronic health records (EHRs, also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from the EHRs directly to a CMS data repository (70 FR 47420 through 47421). We encouraged hospitals that are implementing, upgrading, or developing EHR systems to ensure that the technology obtained, upgraded, or developed conforms to standards adopted by HHS. We suggested that hospitals also take due care and diligence to ensure that the EHR systems accurately capture quality data and that, ideally, such systems provide point of care decision support that promotes optimal levels of clinical performance.

We also continue to work with standard-setting organizations and other entities to explore processes through which EHRs could speed the collection of data and minimize the resources necessary for quality reporting as we have done in the past.

We note that we have initiated work directed toward enabling EHR submission of quality measures through EHR standards development and adoption. We have sponsored the creation of electronic specifications for quality measures for the hospital inpatient setting, and will also work toward electronically specifying measures selected for the Hospital IQR program and the Hospital VBP program.

b. HITECH Act EHR Provisions

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes payment incentives under Medicare for the adoption and use of certified EHR technology beginning in FY 2011. Hospitals are eligible for these payment incentives if they meet requirements for meaningful use of certified EHR technology, which include reporting on quality measures using certified EHR technology. With respect to the selection of quality measures for this purpose, under section 1886(n)(3)(A)(iii) of the Act, as added by section 4102 of the HITECH Act, the Secretary shall select measures, including clinical quality measures, that hospitals must provide to CMS in order to be eligible for the EHR incentive payments. With respect to the clinical quality measures, section 1886(n)(3)(B)(i) of the Act requires the Secretary to give preference to those clinical quality measures that have been selected for the Hospital IQR program under section 1886(b)(3)(B)(viii) of the Act or that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. All clinical quality measures selected for the EHR Incentive Program for eligible hospitals must be proposed for public comment prior to their selection, except in the case of measures previously selected for the Hospital IQR program under section 1886(b)(3)(B)(viii) of the Act. The final rule for the Medicare and Medicaid EHR Incentive Programs includes 15 clinical quality measures for eligible hospitals and critical access hospitals (75 FR 44418), two of which have been selected for the Hospital IQR program under section 1886(b)(3)(B)(viii) of the Act for the FY 2014 payment determination (75 FR 50210 through 75 FR 50211).

Thus, the Hospital IQR and Hospital VBP programs have important areas of overlap and synergy with respect to the EHR-based reporting of quality measures under the HITECH Act. We believe the financial incentives under the HITECH Act for the adoption and meaningful use of certified EHR technology by hospitals will encourage greater EHR-based reporting of clinical quality measures under the Hospital IQR program which are subsequently used for the Hospital VBP Program.

We note that the provisions in this final rule do not implicate or implement any HITECH statutory provisions. Those provisions are the subject of separate rulemaking and public comment.

The comments we received on this proposal and our responses are set forth below.

Comment: Many commenters expressed support or encouragement of EHR use for quality improvement efforts.

Response: We thank commenters for their support.

Comment: Some commenters argued that EHR use in hospitals does not mean that quality of care is improving.

Response: We thank commenters for their input. We agree with commenters' point that possessing electronic health records alone does not constitute quality improvement. However, the criteria for "meaningful use" certified EHR technology are intended to encourage actual improvements in medical care quality associated with health information technology rather than simple possession of new systems. As stated in the Hospital Inpatient VBP proposed rule (76 FR 2485), we believe that electronic reporting of measure information is a necessary step towards a more integrated health care system

and one we intend to encourage in future Hospital VBP rulemaking.

Comment: Some commenters requested clarification on the interaction of the Hospital VBP program initiatives with the EHR incentive programs.

Response: We appreciate the commenters' request. We are actively planning to synchronize the various reporting programs in order to ensure harmony amongst measures across various settings. We hope to have all measure data submitted via EHRs in the future.

Comment: One commenter suggested that CMS ensure that value-based purchasing initiatives foster innovative, quality care with an adequate level of reimbursement for innovative medical technologies.

Response: We thank the commenter for this observation and believe that the Hospital VBP program will drive high quality care for Medicare beneficiaries, including through the provision of innovative technologies and EHRs. As stated above, we will closely monitor the Hospital VBP program for effects on the provision of medical care and on changes to medical practices, including the appropriate use of medical technologies.

Comment: Many commenters suggested that CMS coordinate with the Office of the National Coordinator for Health IT (ONC) so that quality reporting and value-based purchasing data can be collected from certified EHR technology and related health information systems rather than manually extracted from medical records and submitted through a CMS Web site. Many commenters suggested that the first steps in coordination between CMS and ONC should be to clarify the goals and harmonize the measure specifications between CMS quality reporting and value-based purchasing efforts and "meaningful use."

Response: We believe that using the same specifications for similarly-constructed measures for "meaningful use" and value-based purchasing initiatives would reduce confusion from multiple overlapping measures, reduce the costs of developing measures and could potentially address the limitations of CMS data collection methods that impact the ability to risk-adjust measures and distinguish outcomes that are present on admission.

We agree that data required for quality reporting and value-based purchasing should be collected primarily from certified EHR technology rather than manually extracted from medical records when at all possible. We believe that collecting and transmitting data in this fashion will, in the long term, reduce provider reporting burden, as well as improve the reliability of the data used for public reporting and value-based purchasing. In achieving this objective, we will continue to engage the ONC on a myriad of operational issues and challenges that will need to be addressed when aligning value-based purchasing and "meaningful use," including harmonizing the specifications of overlapping measures between "meaningful use" and value-based purchasing programs and considering developing new policies to protect patient privacy when accessing EHR data.

M. QIO Quality Data Access

In the proposed rule (76 FR 2485), we explained the various changes that have occurred since the QIO program regulations were first issued in 1985 (see 50 FR 15347, April 17, 1985). These include the significant technological changes that have occurred in the last 25 years; the addition of new responsibilities performed by QIOs; changes in the way QIOs— and CMS—conduct business; the establishment of new laws to protect data and information, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Federal Information Security and Management Act (FISMA); the need for improved transparency and focus on quality health care and patient safety; and the realization that CMS needs improved access to better manage and oversee the QIOs. We also noted that these same regulations govern data and information held by End Stage Renal Disease Networks in accordance with section 1881(c)(8) of the Act.

In light of the above, we proposed several changes to the QIO regulations. Specifically, we proposed amending the definition of the QIO review system in § 480.101(b) to include CMS; modifying § 480.130 to clarify the Department's general right to access non-QRS confidential and non-confidential information; removing the onsite limitation placed on CMS' access to QIO internal deliberations in § 480.139(a); and similarly modifying § 480.140 to eliminate the onsite restriction to CMS' access to Quality Review study (QRS) data. We also proposed making corresponding changes in § 422.153 to ensure consistency with § 480.140. In addition, we asked for comments regarding whether the "onsite" restriction should be eliminated entirely from subparagraph (a) of section 480.140 so that other entities who already have access to this information can obtain it without going to the QIO's site. We also asked for comments on whether researchers should be allowed access to QIO information and the process, including criteria, which should be used to approve or deny these requests.

The comments we received on these changes and our responses are set forth below.

Comment: We received comments expressing concern that the changes to the QIO confidentiality regulations strip many of the confidentiality safeguards and go against Congress' original intent in establishing the confidentiality requirements contained in section 1160 of the Social Security Act. These comments included concerns that making CMS part of the review system and providing CMS with access to confidential QIO deliberations and QRS information would make the information subject to the Freedom of Information Act (FOIA); would not provide "adequate protection" as required by section 1160; would violate other laws, such as the Health Insurance Portability and Accountability Act (HIPAA); and may result in patient, physician, and provider information being released much more broadly than Congress intended, including potential releases of information during discovery in civil proceedings. Other commenters believed that there could be serious unintended consequences for patients, physicians, and providers, including damage to professional reputations.

Response: We thank the commenters for their concerns. While section 1160 does provide a general framework for maintaining the confidentiality of data or information acquired by QIOs, the section gives the Secretary broad discretion on when disclosures are necessary and appropriate. Paragraph (a)(1) provides that disclosures can be made "to the extent that may be necessary to carry out the purposes of [the QIO statute], * * *" Paragraph (a)(2) gives the Secretary authority to allow disclosures in such cases and under such circumstances as the Secretary provides for in regulations to assure the adequate protection of the rights and interests of patients, physicians and providers. As we discussed in the proposed rule, the initial regulatory framework was developed at a time when computers were in their infancy and the work of the QIOs was performed onsite at provider and physician facilities. However, as technology has advanced and the QIOs' workload has expanded, what was deemed "adequate" 25 years ago is no longer the case. CMS has

weighed the concerns of the commenters against the needs of the QIO program, as well as other benefits CMS will gain from these changes. We have determined that the benefits resulting from these changes are extremely important at this time. We believe that these changes are necessary to modernize the regulations to equate with the manner in which QIOs carry out their work. In addition, these changes take into account the increased focus on medical errors and patient safety, which continue to be a major focus of the QIO program and of CMS. These changes, particularly the expanded definition of "QIO review system," acknowledge the key role CMS plays in quality improvement, including CMS' role in the Hospital Value Based Purchasing Program, the Hospital Inpatient Quality Reporting Program, and the Hospital Outpatient Quality Data Reporting Program. We also recognize that conveying additional kinds of QIO confidential information to CMS will result in the information being subject to the Freedom of Information Act (FOIA); however, protections remain within FOIA for protecting certain kinds of confidential information from further disclosure. In obtaining any information, CMS strives to adhere to all legal requirements, including those specified in HIPAA and in the Federal Information Security and Management Act (FISMA). Our goals are, among others, to achieve improved management and oversight of the QIO program and greater transparency of physician and provider care. We recognize that these goals must be accomplished while continuing to ensure that QIOs are able to effectively develop reliable methods for identifying medical errors and attain overall improvement in the quality of health care provided to patients.

Comment: Several commenters expressed concerns regarding the negative impact the changes to the confidentiality regulations, and in particular CMS' expanded access to QIO information, could have on the QIO program. Some commenters suggested that the changes could place the entire QIO review process—and the QIO program—in jeopardy. Some believed that the changes are not in line with the original intent of the confidentiality provisions, which was to ensure "frank and open communication" and that the ability of the QIOs to attain quality improvement would be undermined. Others believed that the changes could create an environment where every discussion between the QIO and a provider or physician would take place in the presence of the provider's or practitioner's legal counsel in an attempt to ensure that the provider or practitioner does not reveal potentially damaging information. Still others believed the changes could result in attorneys using the QIO process as a "screening" tool, gaining access to QIO information to decide whether a lawsuit against an individual or entity identified in the information might be appropriate, or whether the information might bolster an existing suit. The commenters also mentioned that access to QIO information might subject QIO staff to a lawsuit when a jury's decision ultimately differs from that of the QIO. In addition, QIOs attempting to mediate and/or resolve concerns or complaints could see less willingness by beneficiaries, physicians, and providers to engage in these discussions in light of concerns that information and outcomes may become discoverable and that this could ultimately impact patient safety. In fact, at least one commenter suggested that providers and physicians could be less likely to participate in programs associated with other Federal agencies, such as the Center for Disease Control, and Prevention's work associated with Healthcare Acquired Infections. Concerns were also raised regarding the ability of QIOs to hire physician reviewers should the names of physician reviewers and their conclusions about the quality of care provided by other physicians and providers become discoverable and that this could drive up costs associated with hiring these physician reviewers.

Response: QIOs perform numerous reviews through their contracts with CMS, including quality of care reviews, medical necessity reviews, readmission reviews, higher-weighted diagnosis related group reviews, appropriateness of settings reviews, admission reviews, as well as appeals of beneficiary discharges from a variety of provider settings. In carrying out these reviews, the QIOs rely on medical and other relevant information supplied by providers, physicians and beneficiaries, and these providers and physicians are required by law to provide QIOs with relevant information upon request. In fact, the QIO regulations at § 480.130 already provide, without any amendments, that the Department of Health and Human Services (including CMS) has full access to all QIO confidential information—except information that qualifies as QRS data and internal deliberations. As such, we do not anticipate that QIO core review operations will be impacted in any significant way through the changes to the confidentiality regulations. Moreover, while reference was made to a potential negative impact on participation in other Federal programs, the exact nature of this impact was not clear and again, in light of the Department's existing access, we do not believe that the commenters' concern is likely. Quality Review Studies is the one area in which the changes could potentially have an impact on provider and physician participation; however, we do not believe that the changes will have the profound impact envisioned by these commenters. In light of CMS' role in paying claims and the substantial amount of claims data already in CMS' possession, requestors can already obtain certain information from CMS's Privacy Act Systems of Records related to providers and physicians from which conclusions about their performance could be gleaned. This is in addition to the performance information that is already made available on providers and physicians through the various quality reporting programs. CMS' goal is not to serve as the repository of all QIO data and information. We recognize that responsibility is best left to the QIOs, and we are cognizant of the concerns expressed by the commenters. To the extent that we are going to collect information that will be retrieved by an individual's personal identifier including name, social security number, etc., we will publish a CMS Privacy Act System of Record notice in the **Federal Register**. However, at this time we have not identified such a need. Additionally, CMS does not disclose patient identifiable data to third party FOIA requesters and will protect this information to the extent allowed by Federal law. As we have noted, one of our major goals is to improve the management and oversight of the QIOs. We do not intend to interfere in the relationships between the QIOs and physicians, providers, etc.

Although providers and physicians could conceivably engage legal counsel, this does not appear likely, particularly given the nature of the review process as detailed below. Providers and physicians have always had the right to consult with their counsel but have not routinely enlisted such assistance. We believe that this is because of the QIOs' statutory right to medical information, which is normally maintained in the medical records. Moreover, while the impact of the changes will place more emphasis on information in CMS' possession, section 1157(b) of the QIO statute protects the QIO and its employees from being held to have violated a criminal law or be civilly

liable for performing its statutory and contractual responsibilities, provided due care was exercised. Additionally, while the changes provide CMS with the right to obtain more data off-site, they do not mandate that CMS receive every piece of information in the QIOs' possession, and we will make determinations regarding information needed in line with our stated goals, as articulated above. As such, we do not anticipate routinely obtaining the names of physician reviewers or other information associated with QIO deliberations unless that information is pertinent to a specific identifiable performance initiative.

Comment: Some commenters expressed concern that there could be a lack of control over disclosures once confidential information is provided to other Federal and state agencies and that robust systems are needed to prevent inherent dangers associated with multiple "hand-offs" of information from agency to agency so that the necessary level of responsibility and oversight is maintained and information is not lost, misused or inappropriately disclosed. In addition, a concern was raised that QIO information represents only a subset of all data and information and that CMS and other agencies must consider that the information does not represent the "norm." In particular, commenters raised concerns that the expanded access to quality improvement review activity would allow CMS to use QIO data to determine new methodologies to reduce or deny payments for other initiatives, such as the expansion of the Recovery Audit Program.

Response: We appreciate the comments regarding the need for internal controls related to information provided to other Federal and state agencies. However, QIOs already have the authority to release confidential information to Federal and state agencies in certain instances as defined by the QIO confidentiality regulations in Part 480 (for example, the Office of Inspector General, Federal and State fraud and abuse agencies, and Federal and State agencies responsible for risks to the public health), and necessary controls are already in place to effectuate these provisions and ensure the data is appropriately protected. We believe that any additional controls associated with the potential increased access by Federal and state agencies can be handled through the development of additional program instructions and policy statements. Moreover, CMS already has a well-defined process in place to ensure protection of various types of information, including limited data sets, identifiable data, and claims data in general, and this includes adherence to specific information technology requirements, as well as HIPAA and FISMA. As we have noted, our goal in expanding the access is, in part, to ensure appropriate oversight and management of the QIO program. However, we recognize that access to this information could have additional benefits and improve our understanding of payment related problems. This includes the ability to use QIO data to determine new methodologies to reduce or deny payments for other initiatives, such as recovery audits. In utilizing the data, we also recognize that careful analysis will need to be conducted to ensure that the scope of the data is clearly recognized so that inaccurate conclusions are not drawn based on the particular "subset" of data being used.

Comment: We received comments advising that making confidential QIO information available to researchers would undermine the QIO program and could drive Hospitals to cease participating in QIO activities. Some commenters recognized that while sharing this data may be beneficial and increase opportunities for improvement within our health care systems, the data and process for obtaining the data could be easily mismanaged if well-defined parameters are not put into place for approving these requests, including the establishment of detailed criteria that ensures the research has value to CMS' and is in line with CMS' goals, and that the research be conducted by credible research entities. Still others commented that QIOs should share only aggregate level data or de-identified data and that rigorous assurances and safeguards be put in place to ensure patient privacy and confidentiality.

Response: We appreciate the comments and suggestions regarding the release of information to researchers. As discussed previously, QIOs perform numerous reviews through their contracts with CMS, including quality of care reviews, medical necessity reviews, readmission reviews, higher-weighted diagnosis related group reviews, appropriateness of settings reviews, admission reviews, as well as appeals of beneficiary discharges from a variety of provider settings. In carrying out these reviews, the QIOs rely on medical and other relevant information supplied by Medicare providers, physicians and beneficiaries, and these providers and physicians are required by law to provide QIOs with medical and other relevant information upon request. As such, we do not anticipate that most QIO core review operations will be negatively impacted through the changes to the confidentiality regulations. As previously mentioned, although there could be some potential impact on participation in Quality Review Studies, our hope is that the focus will remain on the patients and the quality improvements that can be achieved through these studies. Additionally, the potential benefits attained through the efforts of researchers are significant, particularly as we aim to improve patient safety by reducing medical errors. We recognize that these requests should be thoroughly evaluated, with the release of information based on well-defined criteria. CMS already employs the CMS Privacy Board to review researchers' requests for CMS claims data. The Board reviews the request, and ensures that the request would comply with applicable privacy and security laws and CMS policies governing data disclosure. Only after an affirmative finding is the data released to the researcher. We believe that we should use the CMS Privacy Board to process research requests for QIO data as well. After consideration of the public comments, we have added § 480.144 to allow CMS to approve requests from researchers for access to QIO confidential information.

Furthermore, even after the Board determines that the disclosure would comply with applicable laws and CMS' policies, data is only released upon execution of a data use agreement (DUA). These agreements spell out the expectations on data transmission, storage, access, use, re-use and disclosure to downstream entities. CMS conditions research data disclosures on the researchers' acceptance of these terms. DUAs therefore provide ongoing protection of the data after it is released.

Moreover, in order to fully leverage the capabilities of these researchers, it is imperative that full access be given in those situations in which the CMS Privacy Board deems warranted. Our goal will be to develop sub-regulatory requirements, including any additional criteria and requirements necessary to properly evaluate these requests to coincide with the effectuation of this Final Rule.

Comment: We received comments in support of CMS's proposed changes to the regulations governing QIOs, including those providing CMS with broader access to QIO data and the deletion of the "onsite" requirement for CMS and other Federal and state agencies having the right to access the data. These commenters believed that any entity that is entitled to have access to QIO information should be able to get the information without going onsite to

the QIO. The commenters considered the technological advances since 1985 considerable and that new Federal legislation, including HIPAA and FISMA, have made the "on-site" requirement obsolete. Others supported making CMS an identified part of the definition of a "QIO review system" because this would assist CMS in becoming more efficient in exchanging data and enable CMS to better manage and respond to new information. These comments also supported CMS' modification of § 480.139 and § 480.140 to facilitate CMS' communication with, and awareness of, QIO activities needed to improve the proper oversight and management of QIOs and the timely access to information.

Response: We thank these commenters for the support. The changes are designed to improve our oversight and management of the QIOs while also better utilizing available data to oversee patient care, and where feasible the Medicare program. We see the recognition of CMS' role in the QIO review system as an important step towards achieving this goal. Moreover, as we conveyed in the Hospital Inpatient VBP Program proposed rule, the current state of technology, the use of electronic exchanges of data and information, and the speed at which data must be exchanged to ensure accomplishment of our work warrants the elimination of the restriction that data can only be accessed onsite at the QIO by CMS in sections 480.139 and 480.140. For the same reasons, we believe that the onsite restriction should be eliminated for all Federal and state agencies having access to QIO data as specified in section 480.140. In implementing these changes and allowing improved access to this information, CMS will ensure adherence to all legal requirements, including HIPAA and FISMA, and we will establish policies and procedures to ensure appropriate protections are in place in response to the deletion of the onsite requirement from sections 480.139 and 480.140.

Comment: We received several comments in support of giving researchers access to QIO confidential information. Many believed this access would enable researchers to study quality issues and obtain needed insights into ways health care quality could be improved. Commenters also supported leveraging the current CMS Privacy Board structure to evaluate these requests. Others suggested that the process for accessing QIO data be given free of lengthy delays or cumbersome process requirements for approval of these requests. It was also suggested that an expedited process be created that would grant individual QIOs with the authority to independently assess and release information, would incorporate tightly managed data use agreements and would also allow requestors to appeal declinations to the CMS Privacy Board. Alternatively, comments were received suggesting that CMS utilize a review process similar to "investigational review boards" or the "Limited Data Set Date process."

Response: We appreciate these comments and agree with the positive insights that could be attained by allowing researcher access to QIO data as well as the benefits of using the already established CMS Privacy Board. Although we have considered other options for evaluating these requests, we believe that using the existing CMS Privacy Board gives us the best opportunity to ensure that all requests are appropriately evaluated in a timely fashion. As necessary, we will consider potential modifications to the specific criteria and processes employed by the CMS Privacy Board should circumstances warrant such changes. Moreover, with regard to the suggestion that QIOs be used to evaluate these requests, we believe that this would create a substantial workload burden for QIOs and could potentially result in different decisions on similar requests, along with the potential for "forum-shopping" for those who have had their requests denied by individual QIOs. While we recognize that other models may exist to evaluate these data requests, we believe the use of the CMS Privacy Board represents the best opportunity to ensure requests are properly and uniformly adjudicated, without placing an undue burden on individual QIOs.

Comment: One commenter requested a change to the QIO confidentiality regulations related to the right of an attending physician to unilaterally decide not to release individual case review results to beneficiaries if the attending physician determines the results could "harm" the beneficiary. The commenter suggested that the regulatory requirement be changed to allow providers to comment on these determinations and that the QIO "finding" be available to the beneficiary in all circumstances and that these changes are important for improvements to the patient, physician and provider relationships.

Response: While we appreciate this suggestion, we believe that it is outside the scope of this Final Rule. As such, we are not taking any action at this time. However, we reserve the right to consider this issue in future rulemaking.

After consideration of the public comments, we are finalizing the proposed changes to the QIO program regulations. In addition, we are eliminating the "onsite" restriction on Quality Review Study information in § 480.140(a) so that all of the entities and individuals listed in that provision are no longer subject to it. We are also establishing regulations governing the ability of researchers to request access to QIO confidential information.

III. Collection of Information Requirements

We will submit a revised information collection and recordkeeping requirements to incorporate CMS access of information from QIOs. CMS intends to modify existing information collection requirements approved on behalf of the Hospital IQR program data collection (OMB 0938–1022) and supporting the Hospital Value Based Purchasing Program, and the QIO quality of care complaint form (OMB 0938–1102) to QIO program confidentiality regulation modification. We estimate that the 53 QIOs will each require approximately 120 hours per QIO per year to modify information technology systems necessary to grant CMS access to the requested information, or a total of 6,360 burden hours per year. We believe that no additional information will be collected from providers and Beneficiaries as a result of this information collection.

IV. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of

quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an "economically" significant rule, under section 3(f)(1) of Executive Order 12866, and a major rule under the Congressional Review Act. Accordingly, the rule has been reviewed by the Office of Management and Budget.

2. Statement of Need

The objectives of the Hospital VBP program include to transform how Medicare pays for care and to encourage hospitals to continually improve the quality of care they provide. In accordance with section 1886(o) of the Act, we will accomplish these goals by providing incentive payments based on hospital performance on measures. This final rule was developed based on extensive research we conducted on hospital value-based purchasing, some of which formed the basis of the 2007 Report to Congress, as well as extensive stakeholder and public input. The approach reflects the statutory requirements and the intent of Congress to promote increased quality of hospital care for Medicare beneficiaries by aligning a portion of hospital payments with performance.

3. Summary of Impacts

To provide funding for value-based incentive payments, beginning in fiscal year 2013 and in each succeeding fiscal year, section 1886(o)(7) of the Act governs the funding for the value-based incentive payments and requires the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an amount equal to the applicable percent of the base operating DRG payment amount for the discharge for the hospital for such fiscal year. We anticipate defining the term "base operating DRG payment amount" in future rulemaking. For purposes of this final rule, we have limited our analysis of the economic impacts to the value-based incentive payments. As required by section 1886(o)(7)(A), total reductions for hospitals under section 1886(o)(7)(B) must be equal to the amount available for value-based incentive payments under section 1886(o)(6), as estimated by the Secretary, resulting in a net budget-neutral impact. Overall, the distributive impact of this final rule is estimated at $850 million for FY 2013.

The objectives of the Hospital VBP program include to transform how Medicare pays for care and to encourage hospitals to continually improve the quality of care they provide. In accordance with section 1886(o) of the Act, we will accomplish these goals by providing incentive payments based on hospital performance on measures. This final rule was developed based on extensive research we conducted on hospital value-based purchasing, some of which formed the basis of the 2007 Report to Congress, as well as extensive stakeholder and public input. The approach reflects the statutory requirements and the intent of Congress to promote increased quality of hospital care for Medicare beneficiaries by aligning a portion of hospital payments with performance.

4. Detailed Economic Analysis

Table 10 displays our analysis of the distribution of possible total performance scores based on 2009 data, providing information on the estimated impact of this final rule. Value-based incentive payments for the estimated 3,092 hospitals that would participate in Hospital VBP are stratified by hospital characteristic, including geographic region, urban/rural designation, capacity (number of beds), and percentage of Medicare utilization. For example, row 8 of Table 10 shows the estimated value-based incentive payments for the East South Central region, which includes the states of Alabama, Kentucky, Mississippi, and Tennessee. Column 2 relates that, of the 3,092 participating hospitals, 301 are located in the East South Central region. Column 3 provides the estimated mean value-based incentive payment to those hospitals, which is 1.021 percent. The next columns provide the distribution of scores by percentile; we see that the value-based incentive percentage payments for hospitals in the East South Central region range from 0.550 at the 5th percentile to 1.482 at the 95th percentile, while the value-based incentive payment at the 50th percentile is 1.023 percent.

TABLE 10—TWO-DOMAIN IMPACT (CLINICAL PROCESS AND HCAHPS): ESTIMATED INCENTIVE RATES BY HOSPITAL CHARACTERISTIC †

Hospital characteristic			Percentile						
	N = 3,092	Mean	5th	10th	25th	50th	75th	90th	95th
Region									
New England	138	1.083	0.660	0.751	0.935	1.088	1.276	1.391	1.434
Middle Atlantic	370	0.955	0.542	0.619	0.766	0.963	1.152	1.288	1.352
South Atlantic	518	1.041	0.551	0.661	0.822	1.039	1.255	1.420	1.499
East North Central	475	1.022	0.555	0.652	0.840	1.025	1.214	1.380	1.472
East South Central	301	1.021	0.550	0.634	0.810	1.023	1.235	1.413	1.482
West North Central	248	1.083	0.638	0.721	0.866	1.075	1.283	1.470	1.567
West South Central	457	1.014	0.477	0.597	0.784	0.997	1.248	1.432	1.563
Mountain	201	0.980	0.584	0.650	0.822	0.986	1.159	1.336	1.396
Pacific	384	0.935	0.434	0.551	0.755	0.951	1.126	1.290	1.383
Urban/Rural									
Large Urban	1,199	1.008	0.552	0.646	0.815	1.014	1.206	1.370	1.449
Other Urban	1,010	1.016	0.551	0.646	0.817	1.015	1.209	1.379	1.484
Rural	883	1.007	0.487	0.607	0.788	1.009	1.239	1.398	1.499
Capacity (by # beds)									
1 to 99 beds	1,045	1.044	0.491	0.617	0.814	1.047	1.284	1.456	1.575
100 to 199 beds	939	1.002	0.500	0.598	0.815	1.015	1.201	1.360	1.452
200 to 299 beds	481	0.989	0.586	0.662	0.803	0.996	1.175	1.323	1.392
300 to 399 beds	279	0.995	0.577	0.668	0.821	1.022	1.167	1.293	1.379

TABLE 10—TWO-DOMAIN IMPACT (CLINICAL PROCESS AND HCAHPS): ESTIMATED INCENTIVE RATES BY HOSPITAL CHARACTERISTIC †—Continued

Hospital characteristic			Percentile						
	N = 3,092	Mean	5th	10th	25th	50th	75th	90th	95th
400 to 499 beds	151	0.985	0.575	0.700	0.837	0.982	1.135	1.307	1.414
500+ beds	197	0.960	0.562	0.652	0.766	0.960	1.146	1.265	1.314
Medicare Utilization									
0 to 25%	237	0.990	0.542	0.639	0.798	1.012	1.164	1.352	1.451
> 25% to 50%	1,508	1.016	0.528	0.642	0.818	1.020	1.224	1.381	1.459
> 50% to 65%	1,148	1.005	0.524	0.637	0.804	1.008	1.206	1.381	1.482
> 65%	196	1.02	0.52	0.60	0.80	1.02	1.28	1.42	1.53

† Note: Because sufficient 2009 data was not available at the time of publication of this final rule, the measures SCIP–Card–2 and SCIP–Inf–4 were not included in the calculation of estimated incentive rates. However, we believe that no significant change in estimated incentive rates results from the omission of these measures.

Table 11 below shows the estimated percent distribution by hospital characteristic of the 1 percent reduction ($850 million) in the base operating DRG payment for fiscal year 2013.

TABLE 11—AVERAGE ESTIMATED PERCENTAGE WITHHOLD AMOUNT (AS REQUIRED BY SECTION 1886(O)(7) OF THE SOCIAL SECURITY ACT) BY HOSPITAL CHARACTERISTIC

Hospital characteristic	N = 3,092	Estimated percent withhold amount
Region:		
New England	138	5.9
Middle Atlantic	370	15.9
South Atlantic	518	19.5
East North Central	475	17.5
East South Central	301	7.8
West North Central	248	7.2
West South Central	457	10.3
Mountain	201	4.8
Pacific	384	11.2
Urban/Rural:		
Large Urban	1,199	49.8
Other Urban	1,010	38.2
Rural	883	11.1
Capacity (by # beds):		
1 to 99 beds	1,045	8.1
100 to 199 beds	939	21.2
200 to 299 beds	481	20.5
300 to 399 beds	279	16.9
400 to 499 beds	151	11.0
500+ beds	197	23.4
Medicare Utilization:		
0 to 25%	237	3.9
> 25% to 50%	1,508	60.0
> 50% to 65%	1,148	32.8
> 65%	196	3.2

We also analyzed the characteristics of hospitals not receiving a Hospital VBP score based on the program requirements, which is shown below in Table 12. We estimate that 353 hospitals will not receive a Hospital VBP score in fiscal year 2013. We note that these hospitals will not be impacted by the reductions in base DRG operating payments under section 1886(o)(7). Hospitals not included in this analysis were excluded due to the complete absence of cases applicable to the measures included, or due to the absence of a sufficient number of cases to reliably assess the measure.

As might be expected, a significant portion of hospitals not receiving a Hospital VBP score are small providers because such entities are more likely to lack the minimum number of cases or measures required to participate in the Hospital VBP program. We anticipate conducting future research on methods to include small hospitals in the Hospital VBP program.

TABLE 12—PROJECTED NUMBER OF HOSPITALS NOT RECEIVING A HOSPITAL VBP SCORE IN FY 2013, BY HOSPITAL CHARACTERISTIC

Hospital characteristic	Number of hospitals not receiving hospital VBP score (N = 353)
Region:	
New England	6

TABLE 12—PROJECTED NUMBER OF HOSPITALS NOT RECEIVING A HOSPITAL VBP SCORE IN FY 2013, BY HOSPITAL CHARACTERISTIC—Continued

Hospital characteristic	Number of hospitals not receiving hospital VBP score (N = 353)
Middle Atlantic	18
South Atlantic	14
East North Central	31
East South Central	26
West North Central	17
West South Central	85
Mountain	25
Pacific	26
Puerto Rico	34
Missing Region	71
Urban/Rural:	
Large Urban	116
Other Urban	83
Rural	83
Missing Urban/Rural	71
Capacity (by # beds):	
1 to 99 beds	213
100 to 199 beds	47
200 to 299 beds	11
300 to 399 beds	8
400 to 499 beds	2
500+ beds	0
Missing Capacity	72
Medicare Utilization:	
0 to 25%	78
> 25% to 50%	75
> 50% to 65%	43
> 65%	28
Missing Medicare Utilization	129

We note that a number of hospitals were missing hospital characteristic data, including region, urban/rural classification, size, and Medicare utilization. All 353 hospitals included in Table 9, including those with missing hospital characteristic data, lacked sufficient clinical process of care data or HCAHPS data needed to calculate a total performance score.

5. Alternatives Considered

The major alternative performance scoring models considered for this final rule were the Six-Domain Performance Scoring Model and the Appropriate Care Model, and both of these models were discussed at length in the proposed rule (76 FR 2476 through 2478).

The Appropriate Care Model (ACM) creates sub-domains by topic for the clinical process of care measures and is distinguished from the Three-Domain Performance Scoring Model in that it requires complete mastery for each topic area ("all-or-none") in the clinical process of care domain at the patient level. Under the ACM, the patient encounter is the scored "event," with a hospital receiving 1 point if it successfully provides to a patient the applicable processes under all of the measures within an applicable topic area, or 0 points if it fails to furnish one or more of the applicable processes. The hospital's condition-specific ACM score is the proportion of patients with the condition who receive the appropriate care as captured by the process measures that fall within the topic area.

The Six-Domain Performance Scoring Model, like the ACM, would create and separately score individual sub-domains at the topic level for the clinical process measures. In other words, the clinical process of care domain would be further broken down into sub-domains characterized by condition. We would assign intermediate scores to each hospital for each of the clinical process sub-domains. Like the Three-Domain Performance Scoring Model, hospitals would be scored on each measure in the sub-domain and individual measures would still be weighted equally within a sub-domain. Scores across the topic area sub-domains would then be equally weighted and combined to create an overall clinical process score. The total performance score would be computed as an average across domains, calculated by weighting the scores for each of the three domains.

Examining these alternative performance scoring models, our analyses showed only modest differences in financial reimbursements across the separate models considered by the various characteristics listed above. We believe that these observed transfers are within the limits of expected variation and do not reflect significant differences in financial reimbursements between the performance scoring models considered.

6. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), we have prepared an accounting statement showing the classification of the impacts associated with the provisions of this final rule.

As required by section 1886(o)(7)(A), total reductions for hospitals under section 1886(o)(7)(B) must be equal to the amount available for value-based incentive payments under section 1886(o)(6), resulting in a net budget-neutral impact. Overall, the distributive impacts of this final rule, resulting from the incentive payments and the 1 percent reduction (withhold) in the base operating DRG payment for fiscal year 2013, are estimated at $850 million for fiscal year 2013 (reflected in 2010 dollars).

TABLE 13—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR FY 2013

Category	Transfers
Annualized Monetized Transfers	$0 (Distributive impacts resulting from the incentive payments and the 1 percent reduction (withhold) in the base operating DRG payment are estimated at $850 million.)
From Whom To Whom?	Federal Government to Hospitals.

B. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that the great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business having revenues of $7.0 million to $34.5 million or less in any 1 year. For purposes of the RFA, among the 3,092 hospitals that would be participating in the Hospital VBP program, we estimate that percent increases in payments resulting from this final rule will range from 0.0236 percent for the lowest-scoring hospital to 1.817 percent for the highest-scoring hospital. When the reduction to base operating DRG payments required under section 1886(o)(7) (one percent in FY 2013, gradually rising to 2 percent by FY 2017) is taken into account, roughly half of participating hospitals will receive a net increase in payments and half will receive a net decrease in payments. However, we estimate that no participating hospital will receive more than a net 1 percent increase or decrease in total Medicare payments. This falls well below the threshold for economic significance established by HHS for requiring a more detailed impact assessment under the RFA. Thus, we are

not preparing an analysis under the RFA because the Secretary has determined that this final rule would 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 regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. We did not prepare an analysis under section 1102(b) of the Act because the Secretary has determined that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Comment: One commenter disagreed with our analysis, which concluded that the proposed rule will not have an impact on a substantial number of small, rural hospitals. The commenter argued that quality improvement efforts are more costly for small hospitals and was also concerned about the program's reliability in low volume situations.

Response: As discussed throughout the various sections of this Regulatory Impact Analysis, including the discussions of the RFA and section 1102(b), and based on the concluding economic impact findings and tables presented, we believe there will not be a significant impact on the operations of a substantial number of small rural hospitals. Absent any new data, commenters may reference the upcoming demonstration projects such as those required under section 3001(b) of the Affordable Care Act as a tool for better understanding any new economic impacts, including those of small rural hospitals. As described in section II. G. of this Final Rule, we believe that the measure and case minimums allow us to include as many hospitals as possible while calculating reliable Total Performance Scores.

Comment: Another commenter asked for more detail in Table 10, including data to offer a rationale for the incentive rates identified. This commenter stated that the "weights have not been defined or modeled within the rule to allow hospitals to make projections with budgeting and other operational issues." This commenter recommended that CMS provide additional information so that hospitals can replicate the process and calculations for planning purposes.

Response: We believe the data on the two-domain impact of the Hospital VBP program provided in Table 10 are as detailed as possible, along with the accompanying narrative and analysis provide a description of the number of affected entities and the size of the economic impacts of this final rule, as well as the justification for the Secretary's certification that this final rule will not have a significant economic impact on a substantial number of small entities. We will take the commenter's suggestions for providing additional data under advisement should additional or more detailed data become available and as we continue public outreach and education efforts for the Hospital VBP program.

C. Unfunded Mandates Reform Act Analysis

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 would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

V. Federalism Analysis

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. As stated above, this final rule would not have a substantial effect on State and local governments.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 480

Health care, Health professions, Health records, Peer Review Organizations (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 continues to read as follows:

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

Subpart D—Quality Improvement

■ 2. Section 422.153 is revised to read as follows:

§ 422.153 Use of quality improvement organization review information.

CMS will acquire from quality improvement organizations (QIOs) as defined in part 475 of this chapter data collected under section 1886(b)(3)(B)(viii) of the Act and subject to the requirements in § 480.140(g). CMS will acquire this information, as needed, and may use it for the following functions:

(a) Enable beneficiaries to compare health coverage options and select among them.

(b) Evaluate plan performance.

(c) Ensure compliance with plan requirements under this part.

(d) Develop payment models.

(e) Other purposes related to MA plans as specified by CMS.

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE OF QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

■ 3. The authority citation for part 480 continues to read as follows:

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

Subpart B—Utilization and Quality Control Quality Improvement Organizations (QIOs)

■ 4. Section 480.101(b) is amended by revising the definition of "QIO review system" to read as follows:

§ 480.101 Scope and definitions.

* * * * *

(b) * * *

QIO review system means the QIO and those organizations and individuals who either assist the QIO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes—

(1) The QIO and its officers, members and employees;

(2) QIO subcontractors;

(3) Health care institutions and practitioners whose services are reviewed;

(4) QIO reviewers and supporting staff;

(5) Data support organizations; and

(6) CMS.

* * * * *

■ 5. Section 480.130 is revised to read as follows:

§ 480.130 Disclosure to the Department.

Except as limited by § 480.139(a) and § 480.140 of this subpart, QIOs must disclose to the Department all information requested by the Department in the manner and form requested. The information can include confidential and non-confidential information and requests can include those made by any component of the Department, such as CMS.

■ 6. Section 480.139 is amended by revising paragraph (a)(1) to read as follows:

§ 480.139 Disclosure of QIO deliberations and decisions.

(a) * * *

(1) A QIO must not disclose its deliberations except to—

(i) CMS; or

(ii) The Office of the Inspector General, and the Government Accountability Office as necessary to carry out statutory responsibilities.

* * * * *

■ 7. Section 480.140 is amended by revising paragraphs (a) introductory text, (a)(1) and paragraph (g) to read as follows:

§ 480.140 Disclosure of quality review study information.

(a) A QIO must disclose quality review study information with identifiers of patients, practitioners or institutions to—

(1) Representatives of authorized licensure, accreditation or certification agencies as is required by the agencies in carrying out functions which are within the jurisdiction of such agencies under state law; to Federal and State agencies responsible for identifying risks to the public health when there is substantial risk to the public health; or to Federal and State fraud and abuse enforcement agencies;

* * * * *

(g) A QIO must disclose quality review study information to CMS with identifiers of patients, practitioners or institutions—

(1) For purposes of quality improvement. Activities include, but are not limited to, data validation, measurement, reporting, and evaluation.

(2) As requested by CMS when CMS deems it necessary for purposes of overseeing and planning QIO program activities.

■ 8. Section 480.144 is added to read as follows:

§ 480.144 Access to QIO Data and Information.

CMS may approve the requests of researchers for access to QIO confidential information not already authorized by other provisions in 42 CFR part 480.

Authority: Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: April 14, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: April 26, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–10568 Filed 4–29–11; 8:45 am]

BILLING CODE 4120–01–P