

After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate-of-increase for each expenditure category. As we proposed, in this final rule, we used the same price proxies for the FY 2006-based CIPI that were used in the FY 2002-based CIPI, with the exception of the Boeckh Construction Index (74 FR 24164). We replaced the Boeckh Construction Index with BEA's chained price index for nonresidential construction for hospitals and special care facilities. The BEA index represents construction of facilities such as hospitals, nursing homes, hospices, and rehabilitation centers. Although these price indices move similarly over time, we believe that it is more technically appropriate to use an index that is more specific to the hospital industry. We believe these are the most appropriate proxies for hospital capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability. The rationale for selecting the price

proxies, excluding the building and fixed equipment price proxy, was explained more fully in the FY 1997 IPPS final rule (61 FR 46196).

The price proxies are presented in Chart 7.

Chart 9 below compares both the historical and forecasted percent changes in the FY 2002-based CIPI and the FY 2006-based CIPI.

CHART 9—COMPARISON OF FY 2002-BASED AND FY 2006-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, FY 2004 THROUGH FY 2012

Fiscal year	CIPI, FY 2002-based	CIPI, FY 2006-based
FY 2004	0.5	0.8
FY 2005	0.6	0.9
FY 2006	0.9	1.1
FY 2007	1.2	1.3
FY 2008	1.4	1.4
Forecast:		
FY 2009	1.7	1.5
FY 2010	1.5	1.2

CHART 9—COMPARISON OF FY 2002-BASED AND FY 2006-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, FY 2004 THROUGH FY 2012—Continued

Fiscal year	CIPI, FY 2002-based	CIPI, FY 2006-based
FY 2011	1.4	1.3
FY 2012	1.6	1.4
Average:		
FYs 2004–2008	0.9	1.1
FYs 2009–2012	1.6	1.4

Source: IHS Global Insight, Inc, 2nd Quarter 2009; USMACRO/CONTROL0609@CISSIM/TL0509.SIM.

IHS Global Insight, Inc. forecasts a 1.2 percent increase in the FY 2006-based CIPI for FY 2010, as shown in Chart 9. The underlying vintage-weighted price increases for depreciation (including building and fixed equipment and movable equipment) and interest (including government/nonprofit and for-profit) are included in Chart 10.

CHART 10—CMS CAPITAL INPUT PRICE INDEX PERCENT CHANGES, TOTAL AND DEPRECIATION AND INTEREST COMPONENTS, FYS 2004 THROUGH 2012

Fiscal year	Total	Depreciation	Interest
FY 2004	0.8	1.5	-2.6
FY 2005	0.9	1.7	-3.1
FY 2006	1.1	2.0	-3.2
FY 2007	1.3	2.1	-3.4
FY 2008	1.4	2.1	-2.6
Forecast:			
FY 2009	1.5	2.1	-2.0
FY 2010	1.2	1.8	-2.1
FY 2011	1.3	1.7	-1.4
FY 2012	1.4	1.7	-0.7

Source: IHS Global Insight, Inc, 2nd Quarter 2009; USMACRO/CONTROL0609@CISSIM/TL0509.SIM.

Rebasing the CIPI from FY 2002 to FY 2006 decreased the percent change in the FY 2010 forecast by 0.3 percentage point, from 1.5 to 1.2, as shown in Chart 9. The difference in the forecast of the FY 2010 market basket increase is primarily due to the proposed change in the price proxy for building and fixed equipment as well as the proposed change in the vintage weights applied to the price proxy for interest. As mentioned above, we are changing the price proxy used for building and fixed equipment to BEA's chained price index for nonresidential construction for hospitals and special care facilities. We believe this change represents a technical improvement as the BEA price index is an index that is more representative of the hospital industry. For the FY 2010 update, the result of this change is a forecasted price change in total depreciation of 1.8 percent in

the FY 2006-based CIPI compared to 2.0 percent in the FY 2002-based CIPI. The other primary factor contributing to the difference is the change in the vintage weights used to calculate the vintage-weighted price proxy for interest. The forecasted price change in total interest is -2.1 percent in the FY 2006-based CIPI compared to -1.5 percent in the FY 2002-based CIPI. This is a result of changing the expected life of hospital debt instruments from 23 years to 25 years. We did not receive any public comments on our proposed methodological changes to the capital input price index published in the FY 2010 IPPS/RV 2010 LTCH PPS proposed rule (74 FR 24154). Therefore, we are adopting as final, without modification, the proposed FY 2006-based CIPI for FY 2010 in this final rule.

V. Other Decisions and Changes to the IPPS for Operating Costs and GME Costs

A. Reporting of Hospital Quality Data for Annual Hospital Payment Update

1. Background

a. Overview

CMS is seeking to promote higher quality and more efficient health care for Medicare beneficiaries. This effort is supported by the adoption of an increasing number of widely-agreed upon quality measures. CMS has worked with relevant stakeholders to define measures of quality in almost every setting and currently measures some aspect of care for almost all Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and, increasingly, outcomes.

CMS has implemented quality measure reporting programs for multiple settings of care. The Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program implements a quality reporting program for hospital inpatient services. In addition, CMS has implemented quality reporting programs for hospital outpatient services, the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), and for physicians and other eligible professionals, the Physician Quality Reporting Initiative (PQRI). CMS has also implemented quality reporting programs for home health agencies and skilled nursing facilities that are based on conditions of participation, and an end-stage renal disease quality reporting program that is based on conditions for coverage.

b. Hospital 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 authority for the RHQDAPU program and revised the mechanism used to update the standardized payment amount for inpatient hospital operating costs. Specifically, section 1886(b)(3)(B)(vii)(I) of the Act, before it was amended by section 5001(a) of Public Law 109–171, provided for a reduction of 0.4 percentage points to the update percentage increase (also known as the market basket update) for FY 2005 through FY 2007 for any subsection (d) hospital that did not submit data on a set of 10 quality indicators established by the Secretary as of November 1, 2003. It also provides that any reduction would apply 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 IPPS hospitals to submit data on the quality measures established by the Secretary, and also built upon the previously established Voluntary Hospital Quality Data Reporting Program that we described in the FY 2009 IPPS final rule (73 FR 48598).

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 change in § 412.64(d) of our regulations. We adopted additional requirements under the RHQDAPU program in the FY 2006 IPPS final rule (70 FR 47420).

c. Hospital Quality Data Reporting under Section 5001(a) of Public Law 109–171

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 revise the mechanism used to update the standardized payment amount for hospital inpatient operating costs, in particular, by adding new section 1886(b)(3)(B)(viii) to the Act. Specifically, sections 1886(b)(3)(B)(viii)(I) and (II) of the Act provide that the payment update for FY 2007 and each subsequent fiscal year be reduced by 2.0 percentage points for any 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 provides that any reduction in a hospital's payment update 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 in the payment update for FY 2007 and subsequent fiscal years for subsection (d) hospitals that do not comply with requirements for reporting quality data, as provided for under section 1886(b)(3)(B)(viii) of the Act.

(1) Quality Measures

Section 1886(b)(3)(B)(viii)(III) of the Act requires that the Secretary expand the “starter set” of 10 quality measures that was established by the Secretary as of November 1, 2003, as the Secretary determines to be appropriate for the measurement of the quality of care furnished by a hospital in inpatient settings. In expanding this set of measures, section 1886(b)(3)(B)(viii)(IV) of the Act requires that, effective for payments beginning with FY 2007, the Secretary begin to adopt the baseline set of performance measures as set forth in a report issued by the Institute of Medicine (IOM) of the National Academy of Sciences under section 238(b) of Public Law 108–173.⁸

The IOM measures include: 21 Hospital Quality Alliance (HQA) quality measures (including the “starter set” of

10 quality measures); the Hospital Consumer Assessment of Health Providers and Systems (HCAHPS) patient experience of care survey; and 3 structural measures.⁹ The structural measures are: (1) Adoption of computerized provider order entry for prescriptions; (2) staffing of intensive care units with intensivists; and (3) evidence-based hospital referrals. These structural measures constitute the Leapfrog Group's original “three leaps,” and are part of the National Quality Forum's (NQF's) 30 Safe Practices for Better Healthcare. The HCAHPS survey is part of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) program, which develops and supports the use of a comprehensive and evolving family of standardized surveys that ask consumers and patients to report on and evaluate their experiences with health care. These surveys cover topics that are important to consumers, such as the communication skills of providers and the accessibility of services. CAHPS originally stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans, the name has evolved as well to capture the full range of survey products and tools.

Section 1886(b)(3)(B)(viii)(V) of the Act requires that, effective for payments beginning with FY 2008, the Secretary add other quality 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 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. 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 through public comment.

Section 1886(b)(3)(B)(viii)(VI) of the Act authorizes the Secretary to replace any quality measures or indicators in

⁸ Institute of Medicine, “Performance Measurement: Accelerating Improvement,” December 1, 2005, available at: <http://www.iom.edu/CMS/3809/19805/31310.aspx>. IOM set forth these baseline measures in a November 2005 report. However, the IOM report was not released until December 1, 2005 on the IOM Web site.

⁹ Structural measures assess characteristics linked to the capacity of the provider to deliver quality healthcare. Institute of Medicine: Division of Health Care Services. Measuring the Quality of Health Care: A Statement by the National Roundtable on Healthcare Quality. National Academy Press; Washington, DC 1999.

appropriate cases, such as where 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. Thus, the Secretary is granted broad discretion to replace measures that are no longer appropriate for the RHQDAPU program.

In the FY 2007 IPPS final rule, we began to expand the RHQDAPU program measures by adding 11 quality measures to the 10-measure starter set to establish an expanded set of 21 quality measures for the FY 2007 payment determination (71 FR 48033 through 48037, 48045).

In the CY 2007 OPPTS/ASC final rule (71 FR 68201), we adopted six additional quality measures for the FY 2008 payment determination, for a total of 27 measures. Two of these measures (30-Day Risk Standardized Mortality Rates for Heart Failure and 30-Day Risk Standardized Mortality Rates for AMI) were calculated using existing administrative Medicare claims data; thus, no additional data submission by hospitals was required for these two measures. The measures used for the FY

2008 payment determination included, for the first time, the HCAHPS patient experience of care survey.

In the FY 2008 IPPS final rule (72 FR 47348 through 47358) and the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66875 through 66877), we added three additional process measures to the RHQDAPU program measure set. (These three measures are SCIP-Infection-4: Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose, SCIP-Infection-6: Surgery Patients with Appropriate Hair Removal, and Pneumonia 30-day mortality (Medicare patients).) The addition of these 3 measures brought the total number of RHQDAPU program measures to be used for the FY 2009 payment determination to 30 (72 FR 66876). The 30 measures used for the FY 2009 annual payment determination are listed in the FY 2009 IPPS final rule (73 FR 48600 through 48601).

For the FY 2010 payment determination, we added 15 new measures to the RHQDAPU program measure set and retired one. Of the new measures, 13 were adopted in the FY

2009 IPPS final rule (73 FR 48602 through 48611) and two additional measures were finalized in the CY 2009 OPPTS/ASC final rule with comment period (73 FR 68780 through 68781). This resulted in an expansion of the RHQDAPU program measures from 30 measures for the FY 2009 payment determination to 44 measures for the FY 2010 payment determination. The RHQDAPU program measures for the FY 2010 payment determination consist of: 26 chart-abstracted process measures, which measure care provided for Acute Myocardial Infarction (AMI), Heart Failure (HF), Pneumonia (PN), or Surgical Care Improvement (SCIP); 6 claims-based measures, which evaluate 30-day mortality or 30-day readmission rates for AMI, HF, or PN; 9 AHRQ claims-based patient safety/inpatient quality indicator measures; 1 claims-based nursing sensitive measure; 1 structural measure that assesses participation in a systematic database for cardiac surgery; and the HCAHPS patient experience of care survey. The measures are listed below.

Topic	RHQDAPU program quality measures for the FY 2010 payment determination
Acute Myocardial Infarction (AMI)	<ul style="list-style-type: none"> • AMI-1 Aspirin at arrival. • AMI-2 Aspirin prescribed at discharge. • AMI-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction. • AMI-4 Adult smoking cessation advice/counseling. • AMI-5 Beta blocker prescribed at discharge. • AMI-6 Beta blocker at arrival. • AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival. • AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI).
Heart Failure (HF)	<ul style="list-style-type: none"> • HF-1 Discharge instructions. • HF-2 Left ventricular function assessment. • HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction.
Pneumonia (PN)	<ul style="list-style-type: none"> • HF-4 Adult smoking cessation advice/counseling. • PN-2 Pneumococcal vaccination status. • PN-3b Blood culture performed before first antibiotic received in hospital. • PN-4 Adult smoking cessation advice/counseling. • PN-5c Timing of receipt of initial antibiotic following hospital arrival. • PN-6 Appropriate initial antibiotic selection. • PN-7 Influenza vaccination status.
Surgical Care Improvement Project (SCIP)	<ul style="list-style-type: none"> • SCIP-1 Prophylactic antibiotic received within 1 hour prior to surgical incision. • SCIP-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time. • SCIP-VTE-1: Venous thromboembolism (VTE) prophylaxis ordered for surgery patients. • SCIP-VTE-2: VTE prophylaxis within 24 hours pre/post surgery. • SCIP-Infection-2: Prophylactic antibiotic selection for surgical patients. • SCIP-Infection-4: Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose. • SCIP-Infection-6: Surgery Patients with Appropriate Hair Removal.

Topic	RHQDAPU program quality measures for the FY 2010 payment determination
Mortality Measures (Medicare Patients)	<ul style="list-style-type: none"> • SCIP—Cardiovascular-2: Surgery Patients on a Beta Blocker Prior to Arrival Who Received a Beta Blocker During the Perioperative Period.
Patients' Experience of Care	<ul style="list-style-type: none"> • MORT—30—AMI: Acute Myocardial Infarction 30-day mortality—Medicare patients.
Readmission Measures (Medicare Patients)	<ul style="list-style-type: none"> • MORT—30—HF: Heart Failure 30-day mortality—Medicare patients. • MORT—30—PN: Pneumonia 30-day mortality —Medicare patients. • HCAHPS survey. • READ—30—HF: Heart Failure 30-Day Risk Standardized Readmission Measure (Medicare patients). • READ—30—AMI: Acute Myocardial Infarction 30-Day Risk Standardized Readmission Measure (Medicare patients). • READ—30—PN: Pneumonia 30-Day Risk Standardized Readmission Measure (Medicare patients).
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures.	<ul style="list-style-type: none"> • PSI 04: Death among surgical patients with treatable serious complications. • PSI 06: Iatrogenic pneumothorax, adult. • PSI 14: Postoperative wound dehiscence. • PSI 15: Accidental puncture or laceration. • IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume). • IQI 19: Hip fracture mortality rate. • Mortality for selected surgical procedures (composite). • Complication/patient safety for selected indicators (composite). • Mortality for selected medical conditions (composite). • Failure to Rescue (Medicare claims only). • Participation in a Systematic Database for Cardiac Surgery.
Nursing Sensitive	
Cardiac Surgery	

On December 31, 2008, CMS advised hospitals that they would no longer be required to submit data for the RHQDAPU program measure AMI-6—Beta blocker at arrival, beginning with discharges occurring on April 1, 2009. This change was based on the evolving evidence regarding AMI patient care, as well as changes in the American College of Cardiology/American Heart Association (ACC/AHA) practice guidelines for ST-segment elevation myocardial infarction and non-ST segment elevation myocardial infarction, upon which AMI-6 is based. The new guideline recommends that early intravenous beta-blockers specifically should be avoided in certain patient populations due to increased mortality risk. These patients are identified by a complex set of contraindications that we believe would make revision of the measure impractical and might result in unintended consequences, including harm to patients based on misinterpretation of an overly complex measure in the clinical setting. Based on the new studies, the ACC/AHA Task Force on Performance Measures removed this measure from the set of AMI performance measures as of November 10, 2008, and did not replace the measure. CMS took action to remove the measure from reporting initiatives based on the lack of support by the measure developer and the considerations identified above.

We discussed considerations relating to retiring or replacing measures in the FY 2008 IPPS final rule with comment period and the FY 2009 IPPS final rule, including the “topping out” of hospitals’ performance under a measure (72 FR 47358 through 47359 and 73 FR 48603 through 48604, respectively). However, in this instance, the measure no longer “represent[s] the best clinical practice,” an additional basis under section 1886(b)(3)(B)(viii)(VI) of the Act for retiring a measure. For the FY 2010 payment determination and subsequent payment determinations, we have formally retired the AMI-6 measure from the RHQDAPU program. Therefore, hospitals participating in the RHQDAPU program are not required to submit data on the AMI-6 measure beginning with discharges occurring on April 1, 2009. However, in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24167), we sought public comment on the retirement of the AMI-6 measure.

Comment: Many commenters supported immediate retirement of quality measures, including AMI-6, for which evolving clinical evidence suggests potential patient safety concerns. Other commenters suggested that CMS seek public input when it is considering immediate retirement of a measure. These commenters also indicated that measure retirement for other reasons should be conducted through the rulemaking process. One commenter indicated that formal retirement through rulemaking

following immediate retirement is confusing.

Response: We believe that immediate retirement of quality measures should occur when the clinical evidence suggests that continued collection of the data may result in harm to patients. Under such circumstances, we may not be able to wait until the annual rulemaking cycle or until we have had the opportunity to obtain input from the public to retire the measure because of the necessity to discourage potentially harmful practices which may result from continued collection of the measure. We agree with the commenters that retirement of measures for reasons other than potential patient safety concerns should occur through the rulemaking process allowing for public comment. Because we generally adopt and retire RHQDAPU program quality measures through the rulemaking process (except for the immediate retirement exception we are adopting in this final rule), we believe that it is appropriate to use the rulemaking process to confirm the retirement of measures that were the subject of recent immediate retirement activity.

(2) Maintenance of Technical Specifications for Quality Measures

The technical specifications for each RHQDAPU program measure are listed 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. In the FY 2010 IPPS/RV 2010 LTCH PPS proposed rule (74 FR 24167), we invited public comment on our process of notifying the public about the technical specifications for RHQDAPU program quality measures and whether it can be improved to enable more meaningful public comment on our proposed measures. We also invited public comment on whether the information posted on the <https://www.QualityNet.org> Web site, including the frequency with which this information is updated, provides hospitals enough information and time to implement the collection of data necessary for these required quality measures.

Comment: Commenters agreed that timely updates to quality measures are necessary for maintaining comparable and credible measurement results and supported our process for posting changes to the Specifications Manual on the QualityNet Web site, and issuing notifications regarding updates issued. Some commenters suggested adding other methods to notify stakeholders as to technical specifications updates. These suggestions included utilizing a Real Simple Syndication (RSS) to send e-mail alerts to stakeholders, providing links to specifications not on the QualityNet Web site, listserv notifications, sharing the draft technical specifications with hospitals and data vendors 30 days prior to their release so that errors and omissions can be identified and corrected before the final version of the specifications is released, and not releasing the Specifications Manual until all revisions and updates are complete, thereby reducing the number of addenda. One commenter requested that the Specifications Manual be released with all relevant changes once a year.

Response: We will consider these suggestions for other methods to notify stakeholders as to technical specifications updates. The Specifications Manual is updated in two scheduled releases a year occurring at 6 month intervals in order to incorporate updates to the code sets used in the measure specifications, add or remove measures, and to provide vendors with adequate notice of changes. The Specifications Manual contains

specifications for measures that have been adopted into the RHQDAPU program. However, we may include specifications for some of the proposed measures or measures under consideration for preview purposes only. Specifications for measures that are under development are not included in the Specifications Manual.

(3) Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act requires that the Secretary establish procedures for making quality data available to the public after ensuring that a hospital has the opportunity to review its data before these data are made public. Data from the RHQDAPU program are included on the *Hospital Compare* Web site, <https://www.hospitalcompare.hhs.gov>. The RHQDAPU program currently includes process of care measures, risk adjusted outcome measures, the HCAHPS patient experience of care survey, and a structural measure regarding cardiac surgery registry participation. This Web site assists beneficiaries and the general public by providing information on hospital quality of care to consumers who need to select a hospital. It further serves to encourage consumers 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.

Comment: Several commenters submitted suggestions for improving public reporting of RHQDAPU program measures on the *Hospital Compare* Web site. A number of commenters stated that the *Hospital Compare* Web site is cumbersome to navigate and that data are displayed in a rigid fashion. The commenters suggested that CMS give end users the flexibility to create customized reports or tailor the data display to the end user's needs. Some commenters also suggested that hospitals would benefit from examining how well they are performing if they had access to reports that show performance on the care processes that take place during discharge. Other commenters stated that the display of data on the *Hospital Compare* Web site for the public may be interpreted as encouraging performance at 100 percent on the measures even though lower levels of performance on measures may be appropriate, and requested that CMS remove the current wording under the "*Learn how to use the information from this site*" link on the *Hospital Compare* Web site because it misrepresents to the public what the appropriate quality benchmarks are for certain measures.

Several commenters supported the adoption of a more consumer-friendly star rating system for hospitals that would allow consumers to make decisions about where to receive care based on a composite "score" for the facility, rather than minor performance differences on individual measures. Another commenter disagreed with posting results on the *Hospital Compare* Web site when a hospital has fewer than 25 eligible cases in a reporting period for a measure, stating that the results may not be statistically valid or understood by most health care consumers. Another commenter stated that all reporting formats should be tested with consumers before being publicly displayed.

Response: Section 1886(b)(3)(B)(viii)(VII) of the Act requires that the Secretary establish procedures for making the data reported under the RHQDAPU program available to the public. We appreciate these suggestions regarding potential improvements to the *Hospital Compare* Web site. We continue to conduct consumer focus groups and work to identify areas for improvement, and will make changes that we believe are beneficial. In terms of a report that focuses upon care provided at discharge, hospitals can use their quarterly *Hospital Compare* preview reports, the downloadable *Hospital Compare* data sets, and other QualityNet reports to examine their performance on measures that relate to care provided at discharge. Although we do not believe that the current wording in the "*Learn how to use the information from this site*" is misleading, we will re-examine the language and determine whether it would be appropriate to make changes. We are also working on condition-specific (AMI, HF, PN, SCIP and HCAHPS) composites for the *Hospital Compare* Web site in the future to make it more consumer-friendly.

On the *Hospital Compare* Web site, we employ a footnote for rates based upon fewer than 25 cases: "The number of cases is too small (<25) to reliably tell how well a hospital is performing," but display the rate so that consumers can decide whether and how to consider the information.

2. Retirement of RHQDAPU Program Measures

As stated above, we retired the AMI-6 measure from the RHQDAPU program measure set beginning with discharges occurring on April 1, 2009, because we believed, based on new evidence, that the continued use of the measure raised specific patient safety concerns. In situations such as this, we do not

believe that it is appropriate to wait for the annual rulemaking cycle. Rather, in the FY 2010 IPPS/RV 2010 LTCH PPS proposed rule (74 FR 24168), we proposed to promptly retire the measure and 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 RHQDAPU program, which include e-mail blasts to hospitals and the dissemination of Standard Data Processing System (SDPS) memoranda to QIOs, as well as posting the information on the QualityNet Web site. We proposed to confirm the retirement of the measure in the next IPPS rulemaking. In other circumstances where we do not believe that continued use of a measure raises specific patient safety concerns, we intend to use the regular rulemaking process to retire a measure.

We invited public comment on whether any other RHQDAPU program measures should be retired from the RHQDAPU program, as well as on the criteria that should be used in retiring measures. To the extent that performance has improved because of the collection and public display of quality measures, we also invited public comment on how performance could be maintained on the “topped out” measures once they are retired. We note that many of the measures in the existing program have experienced improved performance rates over the years. On our Web site, <https://www.cms.hhs.gov/HospitalQualityInits/>, we have posted the performance rates for the existing measures over the years that they have been collected through the RHQDAPU program. However, thus far, only one measure, the pneumonia oxygenation assessment measure, has reached such a high level of compliance (nearly 100 percent for the vast majority of hospitals) that we retired the measure.

Comment: Some commenters recommended 11 measures for retirement for varying reasons. Seven of these measures were recommended for retirement based on their performance being uniformly high nationwide, with little variability among hospitals. These seven measures are:

- AMI-1 Aspirin at arrival
- AMI-3 ACEI/ARB for left ventricular systolic dysfunction
- AMI-4 Adult smoking cessation advice/counseling
- AMI-5 Beta-blocker prescribed at discharge
- HF-4 Adult smoking cessation advice/counseling
- PN-4 Adult smoking cessation advice/counseling

- SCIP-Infection-6: Surgery patients with appropriate hair removal

Commenters also recommended that CMS implement an ongoing surveillance mechanism for measures that are retired due to unvarying high performance rates nationwide in order to prevent deterioration of performance.

Four of the 11 measures recommended for retirement from the RHQDAPU program were recommended for reasons other than high unvarying performance. These four measures are:

- HF-1 Discharge instructions
- PN-3b Blood culture performed before first antibiotic received in hospital
- SCIP-Infection-2: Prophylactic antibiotic selection for surgical patients
- SCIP-Infection-4: Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose

With regard to the HF-1 Discharge instructions measure, a commenter stated that while high quality discharge instructions are important for better outcomes, this measure neither measures nor affects the quality of the discharge instruction. Another commenter stated that the complexity of the data collection guidelines for this measure outweighs its value.

Several commenters recommended retirement of measure PN-3b, Blood culture performed before first antibiotic received in hospital, because they believe that it does not align with current clinical guidelines.

Some commenters also suggested retirement of the SCIP-Infection-2: Prophylactic antibiotic selection for surgical patients measure because the measure is overly complicated and confusing, and the SCIP-Infection-4: Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose measure because of a perceived risk of complications due to extended insulin drips. Several commenters suggested that CMS develop a process for determining when process measures should be retired to accommodate the inclusion of broad outcome measures on a topic, and that CMS retire measures when negative unintended consequences result.

Response: We will consider these suggestions for measures to retire in a future rulemaking. We note that we will continue to retire measures based on reasons other than potential harm to patients by using the rulemaking process, and we believe it is important to weigh all relevant factors and consequences related to retirement of a measure with affected parties before proposing retirement. We agree that high levels of unvarying performance across hospitals should be among the

factors considered in measure retirement. Such measures do not afford opportunities for improvements in care, nor do they allow consumers to discern meaningful differences in performance among hospitals.

We currently do not have mechanisms available to conduct continued surveillance of retired measures, but will explore options for monitoring whether the performance on retired measures deteriorates following their retirement. We also agree that quality measures should relate to high quality care processes, should be related to better patient outcomes, should align with current clinical guidelines when possible, and should not be overly burdensome to collect. We will consider these factors when evaluating current RHQDAPU program measures for retirement. We agree that outcome measures are useful indicators of quality, and in recent years have added outcome measures for mortality, readmission, and patient safety indicators to the RHQDAPU program. However, we do not believe that outcome measures necessarily render process measures incompatible or redundant.

Also, we agree that measures should be evaluated for negative unintended consequences, and that this should be a consideration for measure retirement. We strive to stay informed about measure support in current scientific literature, the continuing ability of measures to assess quality of care, and evolving unintended consequences. Some negative unintended consequences (such as patient harm) may warrant immediate action while other consequences (such as increased burden on the hospital) may need to be weighed against the utility of continuing to collect and publicly post the measure.

Comment: One commenter indicated that there are no further measures that needed to be retired because there are no other “topped out” measures.

Response: We have observed and other commenters have pointed out that there may be a number of RHQDAPU program measures that have high levels of unvarying performance. However, as we stated in the response to a previous comment, we also believe that there are other criteria that we must additionally consider before we propose to retire a measure from the RHQDAPU program.

3. Quality Measures for the FY 2011 Payment Determination and Subsequent Years

a. Considerations in Expanding and Updating Quality Measures Under the RHQDAPU Program

In the FY 2009 IPPS proposed rule, we solicited public comment on several considerations related to expanding and updating quality measures, including how to reduce the burden on the hospitals participating in the RHQDAPU program and which approaches to measurement and collection would be most useful while minimizing burden (73 FR 23653 through 23654).

In the FY 2009 IPPS final rule, we responded to the public comments we received on these issues (73 FR 48613 through 48616). We also stated that in future expansions and updates to the RHQDAPU program measure set, we would be taking into consideration several important goals. These goals include: (a) 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; (b) expanding the scope of hospital services to which the measures apply; (c) considering the burden on hospitals in collecting chart-abstracted data; (d) harmonizing the measures used in the RHQDAPU program with other CMS quality programs to align incentives and promote coordinated efforts to improve quality; (e) 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 data bases; and (f) weighing the relevance and utility of the measures compared to the burden on hospitals in submitting data under the RHQDAPU program. Specifically, 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. We have used and continue to use these criteria to guide our decisions regarding what measures to add to the RHQDAPU program measure set.

Although RHQDAPU program payment decisions were initially based solely on a hospital's submission of chart-abstracted quality measure data, in recent years we have adopted measures,

including structural and claims-based quality measures that do not require a hospital to submit chart-abstracted clinical data. This supports our stated goal to expand the measures for the RHQDAPU program while minimizing the burden on hospitals and, in particular, without significantly increasing the chart abstraction burden.

In addition to claims-based measures, we are considering registries¹⁰ and electronic health records (EHRs) as alternative ways to collect data from hospitals. Many hospitals submit data to and participate in existing registries. In addition, registries often capture outcome information and provide ongoing quality improvement feedback to registry participants. Instead of requiring hospitals to submit the same data to CMS that they are already submitting to registries, we believe that we could collect the data directly from the registries, thereby enabling us to expand the RHQDAPU program measure set without increasing the burden of data collection for those hospitals participating in the registries. Examples of registries actively used by hospitals include the Society of Thoracic Surgeons (STS) Cardiac Surgery Registry (with approximately 90 percent participation by cardiac surgery programs), the AHA Stroke Registry (with approximately 1200 hospitals participating), and the American Nursing Association (ANA) Nursing Sensitive Measures Registry (with approximately 1400 hospitals participating). In the FY 2009 IPPS final rule (73 FR 48608 through 48609), we adopted the first RHQDAPU program measure related to registries: Participation in a Systematic Database for Cardiac Surgery. We continue to evaluate whether it is feasible to adopt measures that rely on one or more registries as a source for data collection.

We also stated our intention to explore mechanisms for data submission using EHRs (73 FR 48614). Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and the adoption of standards for the capturing, formatting, and transmission of data elements that make up the measures. However, once these activities are accomplished, the adoption of measures that rely on data obtained directly from EHRs will enable us to expand the RHQDAPU program measure set with less cost and burden to hospitals.

¹⁰ A registry is a collection of clinical data for purposes of assessing clinical performance, quality of care, and opportunities for quality improvement.

In the FY 2009 IPPS final rule, we adopted nine AHRQ measures for the RHQDAPU program. Although we stated that we would initially calculate the measures using Medicare claims data (73 FR 48608), we also stated that we remained interested in using all-payer claims data to calculate them and that we might propose to collect such data in the future. In the FY 2010 IPPS/R Y 2010 LTCH PPS proposed rule (74 FR 24169), we invited input and suggestions on how all-payer claims data can be collected and used by CMS to calculate these measures, as well as on additional AHRQ measures that we should consider adopting for future RHQDAPU program payment determinations.

We noted that we continue to use these criteria to guide our decisions on what measures to propose for the RHQDAPU program measure set. Therefore, we invited comments on the new quality measures we have proposed to include in future payment years and on the criteria we should use to retire measures.

Comment: Several commenters supported the concept of EHR-based data collection. One commenter expressed concern that the process to implement electronic data collection may delay the adoption of measures, in particular the stroke measures, for the RHQDAPU program. Another commenter applauded CMS for considering EHRs as an alternative way to collect data, but suggested that no new quality measures be introduced for 2 years while the industry implements EHRs, and that some consideration be given to small rural hospitals that may not be able to adopt EHRs as soon as larger urban hospitals. One commenter believed that infrastructure development for establishing interoperability will be challenging and asked that CMS consider a phase-in period of 5 years, with reasonable benchmarks for every 6 months to 1 year.

Response: We appreciate these supportive comments regarding EHR-based data collection as an alternative data source for quality measures. We encourage adoption of EHRs, and we also acknowledge the challenges that must be met both by hospitals and CMS to establish the infrastructure and interoperability necessary to collect data on quality measures via EHRs. In determining whether to adopt new quality measures for the RHQDAPU program, we weigh the potential benefit of improvement that would result from reporting a given measure against the potential resource burden associated with reporting a measure. For purposes

of the RHQDAPU program, EHR-based data submission may provide an alternative means of submitting quality data that would benefit hospitals by reducing their chart abstraction burden. However, because of the challenges noted above, we do not plan to make EHR-based data submission the only means by which hospitals can submit quality data for the RHQDAPU program in the near future.

Comment: Several commenters opposed the direct collection of data from EHRs for quality measures, stating that quality data produced in this manner is unlikely to be useful or valid either for quality measurement or for research, and that programming software is incapable of interpreting and deciding between discrepant documentation in a single medical record.

Response: We disagree with the comment that quality data produced from EHRs is not likely to be useful for quality measurement and research. The data collected from the EHR would essentially be the same data that hospitals would otherwise have to manually abstract from a medical chart. These data are what we currently use for quality measure reporting and for research. We acknowledge that additional programming work may need to be completed to enable current EHR systems to collect and submit quality measure data. We are currently working with the Healthcare Information Technology Standards Panel (HITSP), a public-private partnership working to establish Health IT interoperability standards under contract to the DHHS Office of the National Coordinator on Health IT, to standardize the specifications of data elements used in stroke, VTE, and emergency department measures so that they may be collected and reported via EHRs. Standardization of the specifications allows software to convert clinical data of different types into a form that can be analyzed for quality measurement. We encourage collaboration between standards setting organizations and measure developers on the creation of standards for electronic collection of data elements for other quality measures as well, particularly those used in our quality data reporting programs.

Comment: A number of commenters supported the use of registries as an alternative source of hospital-specific data on quality measures and as a means to reduce hospital burden. Several commenters indicated that the use of registries to collect hospital-level data would reduce administrative burden and ensure appropriate risk-adjustment for quality improvement and public

reporting purposes, as well as other benefits, including the identification of opportunities for quality improvement, improvements in patient safety practices and coordination of care, and improved patient outcomes.

However, several commenters expressed concern regarding the possibility that they may be required to participate in proprietary registries in the future, and requested clarity regarding alternatives for data submission should some hospitals (for example, small hospitals, rural hospitals) not have the resources to participate in registry-based data collection initiatives. These commenters saw registry-based data collection as costly and labor intensive because many registries require chart abstraction. Other commenters saw registries as useful for monitoring quality, but indicated that many data fields collected by registries are not related to quality measures, and preferred that if such a mechanism were to be used for data collection, CMS only receive data relevant to the quality measures of interest, and that the data be limited to the Medicare population only.

Response: We are interested in reducing the burden associated with quality measurement. If hospitals are participating in registries and submit the same data to those registries that they would otherwise have to submit for measures that are part of the RHQDAPU program, we believe that the registry data would be an efficient alternative source from which to collect the data, and that this would prevent the hospital from having to report the same data twice. Many hospitals are currently participating in a number of registries that collect data on quality measures that are topics of interest to us. However, we acknowledge the commenters' concern regarding the cost associated with participation in certain registries which may make this alternative mechanism for data submission less feasible for some hospitals. We anticipate that registry-based data collection may be one means, but not an exclusive means, of submitting data for quality measures. We will take these considerations into account when selecting measures and potential data submission mechanisms for those measures for the RHQDAPU program in the future.

Comment: A number of commenters indicated that it would not be feasible for hospitals to implement all-payer claims reporting for the AHRQ measures while trying to adopt a standardized EHR at the same time. Another commenter indicated that, for all-payer data to be transmitted to the QIO

Clinical Warehouse, data vendors that currently collect and submit most of the clinical data for the RHQDAPU program would need to develop the capability to process and submit all-payer administrative data to the QIO Clinical Warehouse, and that the current CMS Abstraction & Reporting Tool (CART) would need to be modified to collect these additional data. One commenter urged CMS to develop a national all-payer claims database.

Response: We thank the commenters for these comments. While we are interested in collecting all-payer claims data from hospitals in the future, we currently do not have a data collection mechanism in place to receive these claims. We will continue to explore the feasibility of collecting all-payer claims data in the future.

Comment: Several commenters encouraged CMS to look to the National Priorities Partnership goals as a framework for the types of measures that should be included in the RHQDAPU program. Some commenters believe that some of the measures proposed are not NQF-endorsed. Some commenters suggested that CMS consider adopting the criteria for measure selection developed by The Joint Commission.

Response: The National Priorities Partnership is a 28 member organization convened by the NQF for the purpose of identifying improvement goals and action steps for the U.S. healthcare system. We are a member of the National Priorities Partnership and participate in its framework-setting activity. Our measure selection activity for the RHQDAPU program is informed by this framework. The SCIP—Infection-9 and -10 measures and the two measures of registry participation included in the proposed rule address the National Priorities Partnership goals of increasing patient safety and population health. The proposed SCIP—Infection-9 and -10 measures are NQF-endorsed, and the two structural measures regarding registry participation are inpatient applications of an NQF-endorsed measure of registry participation (NQF #0493). We regularly communicate with The Joint Commission regarding the aligned measures and participate in measure maintenance workgroups with The Joint Commission.

Comment: Several commenters stated that measures selected for the RHQDAPU program should be both endorsed by the NQF and adopted by the HQA. Some commenters suggested that these steps were required by the DRA. One commenter stated that the standard for consensus for selection of

quality measures should be consistent with the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) (NTTAA) standards.

Response: Section 1886(b)(3)(B)(viii)(V) of the Act requires, effective for payments beginning with FY 2008, that the Secretary add quality 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. This provision does not require that the measures we adopt for the RHQDAPU program be endorsed by any particular entity, and we believe that consensus among affected parties can be reflected by means other than endorsement by a voluntary consensus organization, including consensus achieved during the measure development process, consensus shown through broad acceptance and use of measures, and consensus through public comment (74 FR 24165 through 24166). Nevertheless, we have stated on numerous occasions that we prefer to adopt quality measures that have been endorsed by the NQF. The NQF uses a formal consensus development process. As the NQF notes on its Web site at: http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx, it has been recognized as a voluntary consensus standards-setting organization as defined by the NTTAA and Office of Management and Budget Circular A–119.

In contrast, the HQA has a limited membership and its current policy is to limit measures that it selects for adoption to a subset of NQF-endorsed measures. In selecting measures for the RHQDAPU program we consider a variety of factors that we have discussed both in this final rule and in previous final rules and take into consideration input received from the public including but not limited to members of the HQA.

Comment: One commenter supported the measure selection criteria that CMS stated in the proposed rule and suggested that emphasis in measure selection be placed upon the following: results of cost-benefit analyses; opportunities to leverage data reported to State health agencies and State hospital associations; alignment of measures and incentives across providers and settings through the application of care coordination measures and measures of quality across episodes of care that increase providers' clinical and financial accountability; and measurement of ambulatory care sensitive and preventable hospital admissions and readmissions for

beneficiaries with chronic conditions. The commenter also suggested that CMS avoid selecting measures that allow hospitals to be rewarded for providing marginally effective care or care that is already routinely furnished.

Response: We thank the commenter for these suggestions. In general, we agree with these suggested considerations for measure selection. We adopt measures of high relevance to the Medicare population for which the benefit of public reporting and improvement justifies the collection burden, and intend to reduce the collection burden by utilizing data sources such as administrative data, registries, and EHRs. We strive to align measures across settings whenever possible and will continue to do so. The current and proposed RHQDAPU program measure set contains measures of readmission for beneficiaries with certain acute and chronic conditions, and we intend to expand measurement in this area. We also intend to adopt measures of care coordination suitable for inclusion in the RHQDAPU program when such measures are developed. We also agree with the commenter that quality measures should emphasize effective care for which there is evidence of wide variability despite the presence of established guidelines. With regard to measurement of quality across episodes of care, the current RHQDAPU program process measures focus on topics of acute care quality. However, we believe that the 30-day mortality and 30-day readmission measures adopted for the RHQDAPU program also touch on the issue of quality across the continuum of care because other providers in the larger community share responsibility with the hospital for mortality and readmission during the 30-day period measured, as the quality of ambulatory follow up care or postacute care after discharge affects the likelihood of these events occurring.

Comment: Two commenters supported the RHQDAPU program in general. One of these commenters attributed great improvements in performance and benefits to patients to the reporting of quality data and indicated that the reporting program allows hospitals to see comparative information that they otherwise might not see.

Response: We agree with and appreciate these supportive comments.

Comment: One commenter opposed quality data reporting and stated that decreasing payments via incentive programs leads to decreases in quality and safety of care for patients.

Response: We disagree with this statement. The IOM, in its 2005 volume

titled *Performance Measurement: Accelerating Improvement* (part of the IOM series on “Pathways to Quality Health Care”) credits performance measurement as the cornerstone of quality improvement in healthcare. Analyses of *Hospital Compare* data over time indicates improvement trends in most of the measures since reporting began in 2004.

In summary, we will continue to pursue goals regarding the expansion and updating of quality measures under the RHQDAPU program while minimizing burden. We will take into account the public comments we received on the possible uses of EHRs, registries, and all-payer claims data in the RHQDAPU program. We also will consider the measure selection criteria suggested by various commenters in prioritizing and selecting quality measures for the future.

b. RHQDAPU Program Quality Measures for the FY 2011 Payment Determination

(1) Retention of Existing RHQDAPU Program Quality Measures

For the FY 2011 payment determination, in the FY 2010 IPPS/RV 2010 LTCH PPS proposed rule (74 FR 24169), we proposed to retain 41 RHQDAPU program quality measures that we are using for the FY 2010 payment determination. We refer readers to the table in the proposed rule (74 FR 24169 through 24170) for a complete list of the measures we proposed to retain.

As we discussed in section V.A.1.c.(1) of this final rule, we retired the AMI–6 Beta blocker at arrival measure from the RHQDAPU program measure set for the FY 2010 payment determination and subsequent years.

We discussed above the public comments we received regarding the retirement of measures that are proposed for the FY 2011 payment determination. We did not receive any other public comments regarding our proposal to retain for the FY 2011 payment determination the 41 measures that we are using for the FY 2010 payment determination. Therefore, we are adopting as final, without change, our proposal to retain the 41 quality measures used for the FY 2010 payment update.

(2) NQF Harmonization of Two Existing RHQDAPU Program Measures

In May 2008, the NQF reviewed the specifications for two of the RHQDAPU program measures that we adopted for the FY 2010 payment determination: PSI 04—Death among surgical patients with treatable serious complications;

and Nursing Sensitive—Failure to rescue (Medicare claims only). This was part of an NQF project titled “National Voluntary Consensus Standards for Hospital Care 2007: Performance Measures.” As a result of this project by the NQF, these two measures now have the same name: “Death among surgical inpatients with serious, treatable complications” and share a single set of measure specifications.

In order to maintain consistency with national voluntary consensus standards with respect to referencing the measure, in the FY 2010 IPPS/R Y 2010 LTCH PPS proposed rule (74 FR 24170), we proposed to combine PSI 04—Death among surgical patients with treatable serious complications; and Nursing Sensitive—Failure to rescue (Medicare claims only) into a single measure, Death among surgical inpatients with serious, treatable complications, and to list the measure under proposed topic name—AHRQ PSI and Nursing Sensitive Care. This measure, as well as its specifications, would replace, for purposes of hospital reporting, the two RHQDAPU program measures that we adopted for the FY 2010 payment determination: PSI 04: Death among surgical patients with treatable serious complications; and Nursing Sensitive—Failure to rescue (Medicare claims only). However, we indicated that we may continue to publicly report the measure in two different topics areas on the *Hospital Compare* Web site—Nursing Sensitive Care and AHRQ PSIs, IQIs and Composite Measures. We invited public comment on this proposal.

Comment: Several commenters supported harmonization of the Failure to Rescue measure and PSI 04: Death among surgical inpatients with serious, treatable complication in accordance with consensus standards. However, a number of commenters questioned the possible display of the harmonized measure in more than one topic area on the *Hospital Compare* Web site, stating this may be unnecessary, redundant, and result in confusion. One commenter indicated that continuing to report the measure under the two separate topic areas is beneficial.

Response: We thank the commenters for their support of our use of the single harmonized measure and measure specification for the RHQDAPU program. The harmonized measure addresses two areas of topical significance, patient safety and nursing sensitive care. Therefore, we believe that publicly displaying the measure results in more than one topic area on the *Hospital Compare* Web site will give end-users a richer picture of a hospital's

performance in both of these topic areas. We will conduct consumer testing to ensure that display of the measure on the *Hospital Compare* Web site does not appear redundant or confusing to consumers.

After consideration of the public comments we received, we have decided to adopt as final our proposal to harmonize these two measures for the FY 2011 payment determination.

(3) New Chart-Abstracted Measures

For the FY 2011 payment determination, in the FY 2010 IPPS/R Y 2010 LTCH PPS proposed rule (74 FR 24170), we proposed to add two new chart-abstracted measures. These proposed new measures, SCIP—Infection-9 Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2 and SCIP—Infection-10: Perioperative Temperature Management, are additions to the existing SCIP measure set. The SCIP Infection measures are designed to assess practices that reduce the risk of infections that surgical patients could acquire in the hospital. They have high relevance to the Medicare population, and address the growing concern regarding hospital-acquired infections.¹¹

Although these two measures require that hospitals abstract data from medical records, they add to the scope of the existing SCIP measure set. Hospitals currently collect and report data elements for eight SCIP measures. Additional data elements required for these two proposed new SCIP measures are minimal, and would be abstracted from the same records hospitals use to abstract data for the other SCIP measures. Therefore, we expect the additional burden on hospitals to be minimal. The two measures are NQF-endorsed. We invited public comment on our proposal to include SCIP—Infection-9 and SCIP—Infection-10 as RHQDAPU program measures to be used for the FY 2011 payment determination.

Comment: Several commenters supported CMS' recognition of the burden associated with collection of chart-abstracted measures and limiting the number of chart-abstracted measures proposed this year.

Response: We appreciate these comments and will continue to carefully consider the potential burden associated with the collection of chart-abstracted measures for the RHQDAPU program

relative to potential benefit of public reporting and quality improvement.

Comment: Several commenters supported the two proposed new chart-abstracted measures. The commenters indicated that these measures have the potential to reduce hospital-acquired infections while minimizing burden, as the data elements would come from the same records hospitals are using to abstract data for the other SCIP measures.

Response: We appreciate these supportive comments. We believe that these measures address areas of topical importance to the Medicare program because they measure quality of surgical care and practices associated with reduction of hospital-acquired infections, and thus, ensure better patient outcomes.

Comment: A few commenters opposed the inclusion of both SCIP—Infection-9 and SCIP—Infection-10 in the RHQDAPU program solely because they are not HQA adopted.

Response: As we discussed more fully in our response to a prior comment, we do not believe that HQA endorsement is a required prerequisite for quality measure selection under the RHQDAPU program.

Comment: One commenter expected a moderate increase in the administrative burden related to abstraction. Another commenter asked CMS to consider whether it should adopt SCIP—Infection-9 if it is considering implementing the Nursing Sensitive/HAI measure, Catheter Associated Urinary Tract Infection (CA UTI), in FY 2012. The commenter stated that the two measures work toward the same goal of reduced UTIs, and ultimately, a broader outcome measure should supplant the related process measure that is more likely to become outdated as science evolves.

Response: Both SCIP—Infection-9 and SCIP—Infection-10 impose minimal additional abstraction burden as they build upon an existing measurement set for a population for which charts are already being pulled for abstraction. We acknowledge that the process measured by SCIP—Infection-9 is related to the outcome measured by the CA UTI measure being considered among measures for future adoption in FY 2012 and beyond. Though CA UTI is being considered for the future, SCIP—Infection-9 was proposed for the FY 2011 payment determination because there is widespread variation in practice for the processes measured, and the practices associated with the measure improve patient outcomes. The processes measured in SCIP—Infection-9 may be related to the CA UTI measure, but the process measure is not

¹¹ U.S. Government Accountability Office. Health-Care Associated Infections in Hospitals: An Overview of State Reporting Programs and Individual Hospital Initiatives to Reduce Certain Infections. September 2008.

supplanted by the outcome measure. The processes SCIP–Infection-9 is intended to measure are of clinical relevance to the Medicare population and have the potential to improve patient care outcomes.

After consideration of the public comments we received, we have decided to finalize our proposal, without change, to adopt SCIP–Infection-9: Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2 and SCIP–Infection-10: Perioperative Temperature Management as quality measures under the RHQDAPU program for the FY 2011 payment determination. As we stated in the proposed rule, the collection of the new chart-abstracted measures for the FY 2011 payment determination will begin with 1st calendar quarter 2010 discharges, for which the submission deadline will be August 15, 2010.

(4) New Structural Measures

In the FY 2010 IPPS/R Y 2010 LTCH PPS proposed rule (74 FR 24170), we also proposed to adopt two additional structural measures for the FY 2011 payment determination. Structural measures assess the characteristics and capacity of the provider to deliver quality health care. We proposed to add two additional registry participation measures. The two structural measures are: (1) Participation in a Systematic Clinical Database Registry for Stroke Care; and (2) Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care. These measures are specific applications for the inpatient setting of a structural measure entitled “Participation by a physician or other clinician in a systematic clinical database registry that includes consensus endorsed measures,” which received NQF endorsement under a project titled “National Voluntary Consensus Standards for Health IT: Structural Measures 2008.” The proposed measures are appropriate applications of the NQF-endorsed measure because the NQF has endorsed measures for Stroke Care and Nursing Sensitive Care which are currently being collected by widely used stroke and nursing sensitive care registries. Therefore, we believe that the proposed Stroke Registry Participation structural measure and Nursing Sensitive Care Registry Participation structural measure meet the consensus requirement in section 1886(b)(3)(B)(viii)(V) of the Act.

As we have previously stated, we also believe that participation in registries reflects a commitment to assessing the quality of care provided and identifying opportunities for improvement. Many

registries also collect outcome data and provide feedback to hospitals about their performance. Moreover, registries offer a potential future data source from which we can collect quality data.

The Participation in a Systematic Clinical Database Registry for Stroke structural measure would require each hospital that participates in the RHQDAPU program to indicate whether it is participating in a systematic qualified clinical database registry for inpatient stroke care and, if so, to identify the registry.

The Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care structural measure would similarly require each hospital participating in the RHQDAPU program to indicate whether it is participating in a systematic qualified clinical database registry measuring nursing sensitive care quality for inpatient care and, if so, to identify the registry.

We solicited public comment on these registry structural measures. Specifically, we invited public comment on whether “systematic qualified clinical database registry” is adequately defined and, if not, how it should be defined. In defining “systematic qualified clinical database registry,” should registries that do not collect outcome measures and/or do not provide feedback to hospitals about their performance be excluded? Are there other registries that we should consider in future rulemakings, beyond stroke and nursing sensitive registries, particularly for conditions where there is high mortality/morbidity in the Medicare population, high cost to the health care system, and widespread treatment variations despite established clinical guidelines? Finally, we welcomed more precise data on what percentage of hospitals already participate in a stroke registry or a nursing sensitive registry.¹² Because we also retire measures when performance has reached a sufficiently high level, we invited public comment on whether reporting on stroke registry and nursing sensitive care registry structural measures has sufficient relevance and utility to justify the reporting burden, if a substantial proportion of hospitals already participate in these registries.

Both proposed structural measures can be submitted using a Web-based

¹² Examples of registries that we are aware of that are being actively used by hospitals include the Society of Thoracic Surgeons (STS) Cardiac Surgery Registry (with approximately 90 percent participation by cardiac surgery programs), the AHA Stroke Registry (with approximately 1200 hospitals participating), and the American Nursing Association (ANA) Nursing Sensitive Measures Registry (with approximately 1400 hospitals participating).

collection tool that we will make available on the QualityNet Web site. We invited public comment on our proposal to adopt these two structural measures for the FY 2011 payment determination.

Comment: Several commenters indicated that the two structural measures of clinical registry participation should not be included in the RHQDAPU program. They indicated that the measures had not been endorsed by the NQF or adopted by the HQA and there appears to be no established connection between whether a hospital answers “yes” or “no” to the registry participation measures and the quality of the care that hospital provides. Some commenters expressed concern that these measures contain an implicit encouragement by the Medicare program for hospitals to participate in clinical data registries designed and operated by external organizations, which can be costly. Others commenters applauded the use of registries to promote quality improvement.

Response: The proposed structural measures are specific applications for the inpatient setting of NQF-endorsed measure “participation by a physician or other clinician in a systematic clinical database registry that includes consensus endorsed measures.” Therefore, we believe that they meet the requirement for consensus in section 1886(b)(3)(B)(viii)(V) of the Act. The measure as endorsed by the NQF is an indicator of quality, because it measures adoption of technology that has the capacity to improve quality of care. We believe that registries can play an important role in providing hospitals with information and services for internal quality improvement by providing performance benchmarking information, continuous feedback, and opportunities to learn best practices. Our intent with these structural measures is to assess the degree of current participation in registries collecting NQF-endorsed measures on the topics of stroke and nursing sensitive quality measures among hospitals participating in the RHQDAPU program. We note that hospitals are not required to actually participate in the registries in order to meet the RHQDAPU program requirements. We also note that in the public comments we received, many hospitals indicated that registry participation afforded them with valuable insights for improving quality and patient outcomes.

Comment: Several commenters supported the structural measure “Participation in a systematic clinical database registry for stroke.” The

commenters agreed that stroke measurement should be a priority for the RHQDAPU program because strokes cause significant mortality and morbidity in the Medicare population, and are treated with wide variation despite established guidelines. The commenters also stated that participation in such registries has resulted in improvements in the quality of care delivered to stroke patients. Commenters recommended that the Massachusetts Department of Public Health's acute stroke registry, the American Stroke Association (ASA) Get With the Guidelines-Stroke registry, and the CDC Paul Coverdell stroke registry should be recognized as qualifying registries for the Systematic Clinical Database Registry for Stroke measures. A few commenters indicated that quarterly submission of registry participation, while not overly burdensome, is unnecessary because hospitals tend to participate for an entire year, and not on an intermittent basis.

Response: We agree that strokes cause high morbidity and mortality in the Medicare population, and we believe that stroke registries can play an important role in providing hospitals with information and services for internal quality improvement by providing performance benchmarking information, continuous feedback, and opportunities to learn best practices. We understand that hospitals that participate in registries tend to participate continuously for an entire year, rather than intermittently. Based on the feedback, we are modifying our proposal to require that hospitals only report whether they participate in a stroke and/or nursing sensitive care registry once annually. We also are modifying our submission requirement with respect to the cardiac surgery registry participation measure to be consistent with the annual submission requirement for the stroke and nursing sensitive care registry participation measures.

Comment: A number of commenters indicated that participation in stroke registries should not be mandated due to perceived burden, and that hospitals should be allowed to report the measures to CMS without a vendor. One commenter asked whether and how CMS would determine volume thresholds for participation in a stroke registry, and specifically whether there would be an expectation that hospitals having a low volume of stroke cases participate in a registry.

Response: We acknowledge that registry participation may be burdensome for some hospitals, and we

note that the proposed structural measures do not mandate that hospitals actually participate in either a stroke or nursing sensitive care registry. We also note that there is no requirement under the RHQDAPU program that hospitals use a vendor to report measures to the QIO Clinical Warehouse, the structural measures can be reported directly by hospitals using a Web-based tool.

Comment: Commenters suggested criteria for a qualified systematic clinical database registry for stroke care. One commenter suggested a data collection system that supports real-time data collection concurrent with patient care, that collects at a minimum all data required to support the NQF-endorsed stroke measures, and that uses the data to guide improvement in stroke care within an organized program of quality improvement. Another commenter suggested that registries should be required to include the following services and information: (1) A feedback component; (2) the intended use (that is, plan of action/care) of the information; (3) potential intervention actions; (4) evaluation; and (5) the outcome measure intended to impact (this could be either a process-outcome link supported by literature, intermediate outcome, or long-term outcome). Commenters also suggested that the risk adjustment methodologies employed must be explained if a hospital is collecting outcome data, and the feedback provided should be "systematic," which requires coordination of the feedback and dissemination of that feedback to the defined stroke team (not just the statement feedback to hospital).

Response: We appreciate these suggestions and will consider these for future measure refinement. We note that the current NQF-endorsed measure #0493, upon which the stroke and nursing sensitive registry participation structural measures are based, contains the following definition for systematic clinical database registry:

"c. Registry measures shall include at least two (2) representative NQF consensus endorsed measures for registry's clinical topic(s) and report on all patients eligible for the selected measures.

"d. Registry provides calculated measures results, benchmarking, and quality improvement information to individual physicians and clinicians.

"e. Registry must receive data from more than 5 separate practices and may not be located (warehoused) at an individual group's practice. Participation in a national or state-wide registry is encouraged for this measure.

"f. Registry may provide feedback directly to the provider's local registry if one exists."

This definition of systematic clinical database registry is part of the specification for measure #0493 shown in NQF's 2008 Consensus Report regarding National Voluntary Consensus Standards for Health Information Technology. We will modify this definition to apply to inpatient hospitals, and to the specific topics of stroke and nursing sensitive care registries.

Comment: Some commenters supported the structural measure for "Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care." One commenter suggested that the Patients First nursing sensitive measure project be recognized as a qualifying registry under the measure. Another commenter suggested that the National Database of Nursing Quality Indicators (NDNQI) be considered a qualifying registry.

Response: We appreciate these supportive comments. Participation in a particular registry is not required in order for a hospital to properly report the Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care measure, or any of the other structural measures we have, to date, adopted for the RHQDAPU program. A hospital can successfully report this structural measure simply by indicating whether they participate in a systematic clinical database registry for nursing sensitive care and, if so, which registry.

Comment: A number of commenters indicated that participation in a nursing sensitive care registry, though currently widespread, may not be feasible for smaller hospitals due to the cost and the need for additional staff for data abstraction and reporting.

Response: We understand the cost implications of participating in such registries. However, as we have stated above, actual participation in a nursing sensitive care registry is not required under the RHQDAPU program.

Comment: Commenters suggested that CMS consider three additional registry topics for measuring hospital participation:

- Sepsis Survival
- Surgical Quality Improvement
- Healthcare Safety and Healthcare Acquired Infections

Response: We thank the commenters for these suggestions and will consider these registry topics in the future.

After consideration of the public comments we received, we are adopting as final the two proposed structural measures: Participation in a Systematic

Clinical Database Registry for Stroke Care; and Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care under the RHQDAPU program for the FY 2011 payment determination. Based on public comments, we will collect these structural measures once annually rather than quarterly as originally proposed. Annual data submission for these structural measures via a Web-based collection tool will begin in July 2010 with respect to the time period January 1, 2010, through June 30, 2010. In summary, after consideration of the public comments we received, for the

FY 2011 payment determination, we are adopting as final our proposals to retain 41 of the measures we adopted for the FY 2010 payment determination. In addition, we are adopting as final our proposal to harmonize an AHRQ measure and a Nursing Sensitive measure by combining these measures into a single measure entitled Death among surgical inpatients with serious, treatable complications for the RHQDAPU program measure set for FY 2011 payment determination. Finally, we are adopting as final our proposal to add an additional four measures to the

RHQDAPU program measure set for the FY 2011 payment determination: SCIP–Infection-9: Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2; SCIP–Infection-10: Perioperative Temperature Management; Participation in a Systematic Clinical Database Registry for Stroke Care; and Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care. Set out below are the 46 RHQDAPU program quality measures we are adopting for the FY 2011 payment determination:

Topic	RHQDAPU Program quality measures for the FY 2011 payment determination
Acute Myocardial Infarction (AMI)	<ul style="list-style-type: none"> • AMI–1 Aspirin at arrival. • AMI–2 Aspirin prescribed at discharge. • AMI–3 Angiotensin Converting Enzyme Inhibitor (ACE–I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction. • AMI–4 Adult smoking cessation advice/counseling. • AMI–5 Beta blocker prescribed at discharge. • AMI–7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival. • AMI–8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI).
Heart Failure (HF)	<ul style="list-style-type: none"> • HF–1 Discharge instructions. • HF–2 Left ventricular function assessment. • HF–3 Angiotensin Converting Enzyme Inhibitor (ACE–I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction. • HF–4 Adult smoking cessation advice/counseling.
Pneumonia (PN)	<ul style="list-style-type: none"> • PN–2 Pneumococcal vaccination status. • PN–3b Blood culture performed before first antibiotic received in hospital. • PN–4 Adult smoking cessation advice/counseling. • PN–5c Timing of receipt of initial antibiotic following hospital arrival. • PN–6 Appropriate initial antibiotic selection. • PN–7 Influenza vaccination status.
Surgical Care Improvement Project (SCIP)	<ul style="list-style-type: none"> • SCIP–1 Prophylactic antibiotic received within 1 hour prior to surgical incision. • SCIP–3 Prophylactic antibiotics discontinued within 24 hours after surgery end time. • SCIP–VTE–1: Venous thromboembolism (VTE) prophylaxis ordered for surgery patients. • SCIP–VTE–2: VTE prophylaxis within 24 hours pre/post surgery. • SCIP–Infection-2: Prophylactic antibiotic selection for surgical patients. • SCIP–Infection-4: Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose. • SCIP–Infection-6: Surgery Patients with Appropriate Hair Removal. • SCIP–Infection-9: Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2*. • SCIP–Infection-10: Perioperative Temperature Management*. • SCIP–Cardiovascular-2: Surgery Patients on a Beta Blocker Prior to Arrival Who Received a Beta Blocker During the Perioperative Period.
Mortality Measures (Medicare Patients)	<ul style="list-style-type: none"> • MORT–30–AMI: Acute Myocardial Infarction 30-day mortality –Medicare patients. • MORT–30–HF: Heart Failure 30-day mortality Medicare patients. • MORT–30–PN: Pneumonia 30-day mortality –Medicare patients.
Patients' Experience of Care	<ul style="list-style-type: none"> • HCAHPS survey.
Readmission Measure (Medicare Patients)	<ul style="list-style-type: none"> • READ–30–HF: Heart Failure 30-Day Risk Standardized Readmission Measure (Medicare patients). • READ–30–AMI: Acute Myocardial Infarction 30-Day Risk Standardized Readmission Measure (Medicare patients). • READ–30–PN: Pneumonia 30-Day Risk Standardized Readmission Measure (Medicare patients).
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures.	<ul style="list-style-type: none"> • PSI 06: Iatrogenic pneumothorax, adult.

Topic	RHQDAPU Program quality measures for the FY 2011 payment determination
AHRQ PSI and Nursing Sensitive Care ** Cardiac Surgery Stroke Care Nursing Sensitive Care	<ul style="list-style-type: none"> • PSI 14: Postoperative wound dehiscence. • PSI 15: Accidental puncture or laceration. • IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume). • IQI 19: Hip fracture mortality rate. • Mortality for selected surgical procedures (composite). • Complication/patient safety for selected indicators (composite). • Mortality for selected medical conditions (composite). • Death among surgical inpatients with serious, treatable complications. • Participation in a Systematic Database for Cardiac Surgery. • Participation in a Systematic Clinical Database Registry for Stroke Care*. • Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care*.

* New measure for FY 2011 payment determination.

** Harmonized measure. This measure may be publicly reported under two topics—the AHRQ PSIs and the Nursing Sensitive Care topic.

4. Possible New Quality Measures for the FY 2012 Payment Determination and Subsequent Years

In the FY 2010 IPPS/R Y 2010 LTCH PPS proposed rule (74 FR 24172), we

invited public comment on the following quality measures and topics that we might consider adopting beginning with the FY 2012 payment determination. We also sought

suggestions and rationales to support the adoption of measures and topics for the RHQDAPU program that are not included in this list.

Measure topic	Measure description
AMI	Statin at discharge.
ED—Throughput	Median time from admit decision time to time of departure from the emergency department for emergency department patients admitted to inpatient status.
ED—Throughput	Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department.
Complications	Lower Extremity Bypass Complications.
Complications	Comorbidity Adjusted Complication Index.
PCI	PCI mortality rate for patients without ST segment elevation myocardial infarction (STEMI) and without cardiogenic shock.
Stroke	Patients with an ischemic stroke or a hemorrhagic stroke and who are non-ambulatory should start receiving DVT prophylaxis by end of hospital day two.
Stroke	Patients with an ischemic stroke prescribed antithrombotic therapy at discharge.
Stroke	Patients with an ischemic stroke with atrial fibrillation discharged on anticoagulation therapy.
Stroke	Acute ischemic stroke patients who arrive at the hospital within 120 minutes (2 hours) of time last known well and for whom IV t-PA was initiated at this hospital within 180 minutes (3 hours) of time last known well.
Stroke	Patients with ischemic stroke who receive antithrombotic therapy by the end of hospital day two.
Stroke	Ischemic stroke patients with LDL \geq 100 mg/dL, or LDL not measured, or, who were on cholesterol reducing therapy prior to hospitalization are discharged on a statin medication.
Stroke	Patients with ischemic or hemorrhagic stroke or their caregivers who were given education or educational materials during the hospital stay addressing all of the following: personal risk factors for stroke, warning signs for stroke, activation of emergency.
Stroke	Patients with an ischemic stroke or hemorrhagic stroke who were assessed for rehabilitation services.
VTE	This measure assesses the number of patients that receive VTE prophylaxis or have documentation why no VTE prophylaxis was given within 24 hours after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end time.
VTE	Patients who received parenteral and warfarin therapy (overlap therapy): (1) For at least 5 days, with an INR greater than or equal to 2 prior to discontinuation of parenteral therapy OR (2) For more than 5 days, with an INR less than 2, but were discharged on overlap therapy OR (3) Who were discharged in less than five days on overlap therapy.

Measure topic	Measure description
VTE	This measure assesses the number of patients receiving intravenous (IV) UFH therapy with documentation that the dosages and platelet counts are monitored by protocol (or nomogram).
VTE	This measure assesses the number of VTE patients that are discharged home, home care, or home hospice on warfarin with written discharge instructions that addresses all four criteria: Follow-up Monitoring; Compliance Issues; Dietary Restrictions; and, Potential for Adverse Drug Reactions/Interactions.
VTE	This measure assesses the number of patients that were diagnosed with VTE during hospitalization (not present at admission) that did not receive VTE prophylaxis.
Cardiac Surgery	Post-operative Renal Failure.
Cardiac Surgery	Surgical Re-exploration.
Cardiac Surgery	Anti-Platelet Medication at Discharge.
Cardiac Surgery	Beta Blockade at Discharge.
Cardiac Surgery	Anti-Lipid Treatment Discharge.
Cardiac Surgery	Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft CABG.
Cardiac Surgery	Risk-Adjusted Operative Mortality for Aortic Valve Replacement (AVR).
Cardiac Surgery	Risk-Adjusted Operative Mortality for Mitral Valve Replacement/Repair (MVR).
Cardiac Surgery	Risk-Adjusted Operative Mortality MVR+CABG Surgery.
Cardiac Surgery	Risk-Adjusted Operative Mortality for AVR+CABG.
Cardiac Surgery	Pre-Operative Beta Blockade.
Cardiac Surgery	Duration of Prophylaxis for Cardiac Surgery Patients.
Cardiac Surgery	Prolonged Intubation (ventilation).
Cardiac Surgery	Deep Sternal Wound Infection Rate.
Cardiac Surgery	Stroke/Cerebrovascular Accident.
Nursing Sensitive	Patient Falls: All documented falls with or without injury, experienced by patients on an eligible unit in a calendar month.
Nursing Sensitive	Falls with Injury: All documented patient falls with an injury level of minor or greater.
Nursing Sensitive/HAI	Catheter Associated Urinary Tract Infection.
Nursing Sensitive/HAI	Central Line Associated Blood Stream Infection in the ICU and high risk neonatal intensive care unit.
Nursing Sensitive/HAI	Ventilator Associated Pneumonia in the ICU.
Nursing Sensitive	Pressure Ulcer Prevalence.
Nursing Sensitive	Restraint Prevalence (vest and limb).
Nursing Sensitive	Skill Mix: Percentage of hours worked by: RN, LPN/LVN, UAP, Contract/Agency.
Nursing Sensitive	Hours per patient day worked by RN, LPN, and UAP.
Nursing Sensitive	Practice Environment Scale-Nursing Work Index.
Nursing Sensitive	Voluntary turnover for RN, APN, LPN, UAP.
Outcomes	PSI 03: Decubitus Ulcer.
Outcomes	PSI 07: Infection Due to Medical Care.
Outcomes	PSI 08: Post Operative Hip Fracture.
Outcomes	PSI 09: Post Operative Hemorrhage or Hematoma*.
Outcomes	PSI 10: Post Operative Physiologic Metabolic Derangement*.
Outcomes	PSI 11: Post Operative Respiratory Failure.
Outcomes	PSI 12: Post Operative PE or DVT.
Outcomes	PSI 13: Post Operative Sepsis.
Outcomes	IQI 08: In-hospital Mortality for Esophageal Resection.
Outcomes	IQI 09: In-hospital Mortality for Pancreatic Resection.
Outcomes	IQI 12: In-hospital Mortality for Coronary Artery Bypass Graft CABG.
Outcomes	IQI 13: In-hospital Mortality for Craniotomy*.
Outcomes	IQI 14: In-hospital Mortality for Hip Replacement.
Outcomes	IQI 15: In-hospital Mortality for AMI.
Outcomes	IQI 16: In-hospital Mortality for CHF.
Outcomes	IQI 17: In-hospital Mortality for Stroke.
Outcomes	IQI 18: In-hospital Mortality for GI Hemorrhage*.
Outcomes	IQI 20: In-hospital Mortality for Pneumonia.
SCIP	Short Half-Life prophylactic administered preoperatively redosed within 4 hours after preoperative dose.
PCI Readmission	Hospital-specific 30-day risk-standardized readmission rate following Percutaneous Coronary Intervention (PCI) among patients aged 18 years or older.
PCI Mortality	PCI Mortality for STEMI/shock patients: Hospital-specific 30-day all-cause risk-standardized mortality rate following Percutaneous Coronary Intervention (PCI) among patients aged 18 years or older with ST segment elevation myocardial infarction (STEMI) or cardiogenic shock at the time of procedure.

Measure topic	Measure description
ICD Complications	PCI Mortality for non-STEMI/non-shock patients: Hospital-specific 30-day all-cause risk-standardized mortality rate following Percutaneous Coronary Intervention (PCI) among patients aged 18 years or older without ST segment elevation myocardial infarction (STEMI) and without cardiogenic shock at the time of procedure.
Hospital Acquired Infections	Hospital-specific risk-standardized complication rate following implantable cardioverter defibrillator (ICD) implantation among patients aged 18 years or older.
Hospital Acquired Infections	Methicillin-Resistant <i>Staphylococcus Aureus</i> (MRSA). Clostridium Difficile Associated Diseases (CDAD).

* AHRQ is currently working with to improve and refine these measures, after which they will be updated to reflect the most current evidence learned as a result of validation efforts and empirical analyses.

We invited public comment on these measures for potential future use in the RHQDAPU program, as well as suggestions and supporting rationales for additional measures to consider using in the program at a future time.

• General Comments

Comment: Several commenters expressed concern over the number of measures listed as being under consideration for FY 2012 and subsequent years in the proposed rule. Commenters believed that a large increase in measures in future years would compete with other critical initiatives that would be occurring (such as HIT adoption for incentive payments and transitioning to ICD-10-CM and ICD-10-PCS implementation). The commenters recommended that CMS give consideration to the number and burden associated with the measures particularly as many are not EHR-based or registry-based measures. The commenters also suggested that CMS prioritize the measures, avoid redundancy by adopting measures that add information not captured in other measures, and consider measures that are closest in relation to desired outcomes for patients. One commenter also suggested that CMS assess the feasibility of constructing measures from data contained in the typical hospital electronic health record.

Response: We listed an array of measures that we are considering for the future. We will carefully weigh the burden associated with the adoption of measures against the benefit of publicly reporting that data. We anticipate limited adoption of chart-abstracted measures in the future because we wish to minimize the burden associated with quality measurement during a time when hospitals will be implementing new technologies and systems. We also will continue to assess the feasibility of alternative data sources for measures, such as registries and EHRs.

Comment: Commenters recommended that CMS provide clarity on the status of the proposed measures regarding

NQF endorsement, information about the data abstraction burden, and a central location for specifications for measures under consideration. Another commenter also suggested that for measures under consideration, CMS provide information on benchmarking, potential use, affect on patient care, and development.

Response: We understand the commenters' desire to have more information about the measures being considered for the future. We provide some additional information in our responses to comments below, and we will endeavor to provide more detailed information about measures under consideration in the future.

• Comment on Measure Topic: AMI

Comment: One commenter indicated that the Statin at Discharge measure for AMI would be better suited as a physician measure rather than a hospital measure.

Response: We will take this into consideration in determining whether to adopt this measure for the RHQDAPU program in the future. However discharge medications, such as aspirin at discharge, form the basis for other measures which we have implemented in the RHQDAPU program.

• Comments on Measure Topic: ED-Throughput

Comment: Several commenters supported the concept of the ED-Throughput measures. Some commenters made suggestions for refinements to the specifications for "Median time from admit decision time to time of departure from the emergency room for patients admitted to the facility from the ED" measure. They suggested using the time when an admit order is written, and the time of departure from the emergency department to calculate the median times for this measure. Other commenters suggested stratification by population type.

Response: We appreciate the supportive comments. These suggestions are in keeping with the

current measure specifications as endorsed by NQF. These ED-Throughput measure specifications are available in the Specifications Manual on <http://www.QualityNet.org>.

Comment: One commenter opposed the ED-Throughput measures because the commenter believed that they measured utilization.

Response: The ED-Throughput measures are NQF-endorsed quality measures. The ED-Throughput measures reflect not only the processes of care that occur while the patient is in the emergency department, but also reflect the coordination of care, communication, and efficiency of service provision beyond the walls of the emergency department. They address ED overcrowding, which has been identified as a major quality issue by the IOM.

• Comment on Measure Topic: Complications

Comment: One commenter stated that global measures such the Comorbidity Adjusted Complication Index are useful to hospitals in quality improvement efforts.

Response: We agree that global measures can provide useful quality improvement information to hospitals. We also believe that the topic of complications is an important one for consumers. This measure is currently undergoing evaluation as part of the NQF consensus development project entitled Hospital Care: Outcomes and Efficiency Measures Phase II. We will take this comment into consideration in determining whether to adopt such measures in the future.

• Comments on Measure Topic: Stroke

Comment: Numerous commenters encouraged CMS to adopt the stroke measures, which they see as evidence-based measures that accurately measure evidence-based care of the stroke patient to minimize secondary strokes and other complications, have been thoroughly researched, and are widely recognized. Several commenters cited firsthand

experience with dramatic quality improvements resulting from the collection and reporting of these measures to a registry.

Response: We appreciate and agree with these supportive statements. Stroke is a topic of great relevance to the Medicare population due to its impact on morbidity and mortality, and an area of great potential improvement for hospitals.

Comment: Two commenters supported the stroke measures under consideration but recommended limiting the measures in scope to "Certified Stroke Centers" in order to minimize the possibility that patients will suffer from unintended consequences due to a provider's lack of expertise with stroke. One commenter supported all but the STK-10 Assessed for Rehabilitation stroke measure and recommended that CMS establish eligibility criteria for the Assessment of Rehabilitation measure instead of including the entire stroke population as currently defined in the Specifications Manual.

Response: We will consider these comments in deciding whether to adopt these measures in the future. We note that we adopt measures for the RHQDAPU program that are broadly applicable to all participating hospitals, and that acute care for stroke is not given only by hospitals that have attained specific certifications. Regarding the measure on stroke assessment, the scope of the NQF-endorsed measure includes the entire stroke population. However, the measure allows for variation in the extent/degree of the assessment based on clinical indications. Specifications for the stroke measures are available in the Specifications Manual at <https://www.QualityNet.org>.

Comment: Several commenters generally opposed the future adoption of one or more of the stroke measures into the RHQDAPU program. One commenter stated that the abstraction rules for stroke are in need of greater refinement as they currently allow too much room for subjective interpretation. One commenter had concerns regarding inclusion of the anticoagulation measure because falls in the elderly population can be a significant problem with the risk of intracranial bleeding surpassing the benefit of anticoagulation therapy for atrial fibrillation. A few commenters opposed "Thrombolysis therapy" for stroke, stating that this therapy is not yet the standard of care for community or rural hospitals and that administering thrombolytic therapy to stroke patients has a high risk of complications.

Response: We appreciate these comments and will take them into consideration. Most of the comments we received overwhelmingly supported the adoption of these measures for the RHQDAPU program in the future. We believe that the stroke topic is of great clinical relevance to the Medicare population because of its impact on morbidity and mortality, as well as a stroke's debilitating effect on the quality of life among Medicare beneficiaries. All of the measures in the stroke set under consideration are important to the overall outcome of the patient. The stroke measures are based on current AHA and ASA guidelines. We believe that current guidelines for stroke care apply across hospital types. The measure "Patients with an ischemic stroke with atrial fibrillation discharged on anticoagulation therapy" currently excludes patients for whom risks associated with treatment with an anticoagulant would outweigh potential benefits. Providing timely thrombolytic therapy has shown to greatly reduce complications, mortality and morbidity related to stroke. The measures are intended for public reporting, and are not intended to encourage a particular treatment when it is not warranted.

- Comments on Measure Topic: VTE

Comment: Two commenters supported CMS adding measures VTE-1, -2 and -3 as shown in the inpatient measure specification manual in FY 2012, but did not support measures VTE-4, -5, and -6. The commenters stated that the measures shown in the table do not seem to align with the VTE measures included in the Specifications Manual effective with October 1, 2009 discharges. The commenters also recommended that the measure "VTE-1: prophylaxis in medical and non-SCIP-VTE surgical patients", which we proposed in the FY 2009 IPPS proposed rule (73 FR 23648) but did not adopt, be considered for future adoption into the RHQDAPU program.

Response: The VTE measures we listed in the FY 2010 IPPS/RV 2010 LTCH PPS proposed rule are the same as the VTE measures in the aligned Specifications Manual. VTE-1 appears in the aligned Specifications Manual, and we will include VTE-1 on the list of measures to be considered for FY 2012 and beyond.

Comment: One commenter supported all but VTE-3 and -4 as shown in the inpatient measure specification manual, and suggested that the measure descriptions be clarified.

Response: The formal specifications can be found in the aligned Specifications Manual on the

QualityNet Web site: <https://www.QualityNet.org>.

- Comments on Measure Topic: Cardiac Surgery

Comment: One commenter supported adopting the Cardiac Surgery measures for the RHQDAPU program because these measures are appropriate and useful for quality improvement and public reporting purposes. Another commenter indicated that the data element specifications for the Cardiac Surgery topic need more rigor and standardization.

Response: Cardiac surgery is a topic of high relevance to the Medicare program because of its high volume among Medicare beneficiaries. We note that the cardiac surgery measures that are under consideration for adoption in future years, as well as their specifications, are NQF-endorsed and are available at <http://www.qualityforum.org/>.

- Comments on Measure Topics: Nursing Sensitive and Nursing Sensitive/HAI

Comment: Several commenters supported the Central Line [catheter] Associated Blood Stream Infection in the ICU and high risk neonatal intensive care unit measure, and the CA UTI infection measure. Several commenters urged CMS to consider adopting a Center for Disease Control measure of Surgical Site Infection that is not listed in the table of measures under consideration for future years (Table—above) but which was listed in the future measure table in the 2009 IPPS rule at 73 FR 48611. The commenters stated that the Central Line Associated Blood Stream Infection, Catheter Associated Urinary Tract Infection, and Surgical Site Infection measures are thoroughly specified, are currently used in other reporting initiatives, are relevant to consumers, and reveal important information that hospitals can use for their quality improvement programs. One commenter supported adoption of these measures if hospitals do not have to join a registry to report the information.

Response: We thank the commenters for these suggestions and will add Surgical Site Infection to the list of measures being considered for FY 2012 and beyond because it addresses the high priority topical area of hospital-acquired infections. The Central Line [catheter] Associated Blood Stream Infection in the ICU and high risk neonatal intensive care unit measure and the Catheter Associated UTI measure are currently being collected by the CDC's National Healthcare Safety Network (NHSN) database as

surveillance measures. We are supportive of these measures as they address hospital-acquired infections. We are exploring the possibility of receiving data, with permission from participating hospitals, from the CDC to avoid duplicative reporting of information by hospitals that participate in NHSN. Furthermore, we are exploring the development of electronic specifications for the collection of these measures from EHRs.

Comment: Several commenters indicated that more specificity, information, and clear expectations are needed for the following Nursing Sensitive measures: Patient Falls: All documented falls with or without injury, experienced by patients on an eligible unit in a calendar month; Falls with Injury: All documented patient falls with an injury level of minor or greater; CA UTI; Pressure Ulcer Prevalence; and Restraint Prevalence (vest and limb). In particular, the commenters believe that definitions for falls and CA UTI are needed. Two commenters indicated that the Pressure Ulcer Prevalence measure needs more specificity regarding the stage of the ulcer and whether the pressure ulcer was present on admission or hospital-acquired. One commenter indicated that, at times, pressure ulcers may not be preventable (for example, cases where patients experience multisystem organ failure, malnutrition, when vasopressors or fluid resuscitation have been employed, or when the patient cannot be turned due to traumas requiring surgery to be performed).

Response: The Nursing Sensitive measures are currently the subject of an NQF reevaluation project. We anticipate that considerations such as these will be brought forth and addressed as necessary during the reevaluation process prior to the time we would propose to adopt the measures.

Comment: A few commenters indicated that they would not be able to calculate the voluntary turnover measure unless this was manually tracked, making the collection of data necessary for this measure resource intensive. Another commenter indicated that the measures in the Nursing Sensitive measure set that rely on administrative data (such as voluntary turnover and skill mix) are of questionable validity for quality improvement.

Response: We appreciate these comments and will take them into consideration in deciding whether to adopt these measures in the future. Our understanding is that most hospitals are currently collecting the data elements for the voluntary turnover and skill mix

measures. Registries of Nursing Sensitive Care quality measures currently feature these administrative-based measures in hospital feedback reports for quality improvement purposes.

Comment: Two commenters criticized the Ventilator Associated Pneumonia [VAP] in the ICU measure. One commenter noted that a recent HHS National Action Plan to Prevent Healthcare-Associated Infections indicated that “no valid outcome or process metric had been identified for VAP.” Another commenter indicated that, while VAP in the ICU is frequently tracked for State reporting purposes, it is a poor measure for quality improvement or for external comparison because of the challenges with diagnosis and definitions.

Response: Healthcare-associated infections are a high priority area for us because they increase complications and treatment costs, and we are looking to this as an area for future measurement. We agree that the definition of VAP should undergo further standardization. Therefore, we will not consider adopting this measure for the RHQDAPU program until such a definition has been determined.

- **Comments on Measure Topic: Outcomes**

Comment: Several commenters supported adoption of the AHRQ patient safety indicators and inpatient quality indicators, but many commenters suggested limiting adoption to two or three AHRQ measures annually because collection of more than three may present a burden to hospitals. A few commenters suggested reporting one or more of the AHRQ indicators separately from the composite measures.

Response: We agree that these are important patient safety and outcome measures for the inpatient setting. These would be claims-based measures. Therefore, because we currently calculate claims-based measures using only Medicare claims, there would be no additional reporting burden associated with these measures. To the extent that the measures focus on quality of care issues, we believe that hospitals will benefit from the information these measures reveal. We will consider the suggestion for separate public reporting of selected indicators. However, if any of these individual measures are adopted, we will engage in consumer testing regarding how best to display the measures on the *Hospital Compare* Web site. The measure specifications for the AHRQ inpatient quality indicators and patient safety

indicators are available at <http://www.qualityindicators.ahrq.gov/>.

Comment: One commenter stated that, while AHRQ patient safety measures may have value to hospitals for internal quality improvement purposes, they currently lack the sensitivity and specificity required for use as comparative, publicly reported measures, especially the research-oriented PSI measures. Because they are derived from administrative data, one commenter suggested that they are less sensitive than measures derived from clinical chart abstraction at identifying relevant patients and excluding other patients. One commenter indicated that some of the AHRQ indicators have very high false positive rates and that extensive field testing and respecification would be needed. One commenter suggested that the risk adjustment seems unfairly advantageous to larger volume hospitals.

Response: We appreciate these comments and will take them into consideration in determining which measures to adopt for the RHQDAPU program in the future. We are aware of and encourage current validation projects involving positive predictive value and sensitivity being performed on these measures as they will lead to improvements in the measure specifications.

Comment: One commenter expressed concern that traditional risk adjustment would not be appropriate for IQI 17: In-hospital Mortality for Stroke. The commenter suggested that a proper risk adjustment model for in-hospital stroke mortality should account for stroke severity on presentation and stroke type (hemorrhagic versus ischemic stroke). The commenter suggested stratification of stroke mortality by type and suggested use of a well-established stroke severity scale in risk adjustment models for stroke mortality.

Response: We appreciate this suggestion. However, we note that the current risk adjustment model for the in-hospital stroke mortality measure has been endorsed by the NQF as appropriate for this measure, and we also believe the model is appropriate because it underwent a rigorous consensus development process.

- **Comments on Measure Topics: PCI Readmission and PCI Mortality**

Comment: Two commenters supported the PCI 30-day mortality and 30-day readmission rates and requested that CMS consider adopting the PCI measure set for FY 2011 payment determination. One commenter also stated that it is imperative that the outcome findings are drilled down far

enough that hospital-specific results can be obtained and patients can view hospital results based upon the condition or procedure they are undergoing. One commenter recommended that the PCI Readmission and PCI Mortality measure related to STEMI/Shock be defined to include the base population as defined in the AMI Core Measure in order to reduce additional abstraction burden in identifying and defining shock.

Response: We thank the commenters for their support for the PCI mortality and readmission measures and will consider adopting these measures for the RHQDAPU program. Before we add them to the RHQDAPU program measure set, however, we will propose to adopt them as part of the rulemaking process. The current outcomes and readmissions measures are all calculated at the hospital level for various conditions, allowing patients to view hospital level results. Future outcomes and readmission measures, including the PCI 30-day mortality and 30-day readmission rates, if adopted for the RHQDAPU program, would be calculated in this manner as well. These measures are specified as claims-based measures for which there is no chart abstraction. These measures are currently undergoing evaluation as part of an NQF consensus development project entitled Hospital Care: Outcomes and Efficiency Measures Phase II.

- Comment on Measure Topic: ICD Complications

Comment: One commenter recommended that CMS follow definitions established by the ICD Registry to assure standardization of the ICD Complications measure.

Response: We intend to use standardized measure specifications for measures that are adopted into the RHQDAPU program and seek to adopt measures that have been endorsed by the NQF. Therefore, when available, we adopt NQF-endorsed measures for a particular topic and utilize the measure specifications that were endorsed by the NQF.

- Comment on Measure Topic: Hospital-Acquired Infections

Comment: One commenter indicated that, because of increased screening, there is a need to distinguish between healthcare-acquired MRSA infections and community-associated infections, and that all multi-drug resistant infections should be reported in order to focus efforts on reducing these infections, rather than one in particular.

Response: We agree that the distinction between the sources of

MRSA infections is important. The MRSA measure under consideration for the RHQDAPU program focuses only on hospital-acquired infections. As for the reporting of other multi-drug resistant infections, we will take this comment into account as we develop future measures.

- Comments on Measure Topic: Topics and Measures Suggested by Commenters

Comment: Commenters suggested seven additional topics and measures to consider for future adoption into the RHQDAPU program:

- Surgical site infection rate
- Dysphagia screening for stroke
- Pediatric Quality Indicators
- Chronic Obstructive Pulmonary Disease (COPD)
- Inpatient Resource Use and Efficiency
- Global smoking cessation measure
- Inpatient Psychiatric Measures

Commenters noted that two of these topics (Surgical Site Infection and Chronic Obstructive Pulmonary Disease (COPD) were discussed in the future measure section of the FY 2009 IPPS proposed rule but not in the current proposed rule for FY 2010.

Response: We will consider these suggestions when selecting measures for the RHQDAPU program in the future. We agree that surgical site infection, dysphagia screening for stroke, and COPD are appropriate areas for the RHQDAPU program because they address conditions that are of high prevalence and cost to the Medicare program.

CMS currently includes several indicators of Pediatric Quality on the *Hospital Compare* Web site based on the submission of the data as part of other voluntary quality reporting initiatives. While we publicly report these measures, we are not currently considering requiring these indicators or other Pediatric Quality indicators for the RHQDAPU program because pediatric conditions affect a very small number of Medicare beneficiaries.

In summary, we appreciate the public comments we received and will consider them as we develop proposals for new quality measures for the FY 2012 payment determination and subsequent years.

5. Form, Manner, and Timing of Quality Data Submission

Section 1886(b)(3)(B)(viii)(I) of the Act requires that subsection (d) hospitals submit data on measures selected under that clause with respect to the applicable fiscal year. In addition, section 1886(b)(3)(B)(viii)(II) of the Act requires that each subsection (d)

hospital submit data on measures selected under that clause to the Secretary in a form and manner, and at a time, specified by the Secretary. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet Web site at: <https://www.QualityNet.org>. CMS requires that hospitals submit data in accordance with the specifications for the appropriate discharge periods.

Hospitals submit quality data through the secure portion of the QualityNet Web site (formerly known as QualityNet Exchange) (<https://www.QualityNet.org>). This Web site meets or exceeds all current Health Insurance Portability and Accountability Act requirements for security of protected health information.

a. RHQDAPU Program Procedures for the FY 2011 Payment Determination

For the FY 2011 payment determination, in the FY 2010 IPPS/R Y 2010 LTCH PPS proposed rule (74 FR 24174), we proposed that the following procedures would apply to hospitals participating in the RHQDAPU program. These procedures are, for the most part, the same as the procedures that apply to the FY 2010 payment determination. We identify below where we proposed to modify a procedure.

- Register with QualityNet, before participating hospitals initially begin reporting data, regardless of the method used for submitting data.

- Identify a QualityNet Administrator who follows the registration process located on the QualityNet Web site (<https://www.QualityNet.org>).

- Notice of Participation. New subsection (d) hospitals and existing hospitals that wish to participate in the RHQDAPU program for the first time must complete a revised "Reporting Hospital Quality Data for Annual Payment Update Notice of Participation" form (Notice of Participation form) that includes the name and address of each hospital campus that shares the same CMS Certification Number (CCN).

We proposed that any hospital that receives a new CCN on or after October 15, 2009 (including new subsection (d) hospitals and hospitals that have merged) that wishes to participate in the RHQDAPU program and has not otherwise submitted a Notice of Participation form using that CCN must submit a completed Notice of Participation form no later than 180 days from the date identified as the open date (that is, the Medicare acceptance date) on the approved CMS Online System Certification and Reporting (OSCAR) system. We believe that this deadline will give these

hospitals a sufficient amount of time to get their operations up and running while simultaneously providing CMS with clarity regarding whether they intend to participate in the RHQDAPU program for FY 2011.

We also proposed that hospitals having an open date (or Medicare acceptance date) (as noted on the approved CMS OSCAR system) before October 15, 2009, that did not participate in the RHQDAPU program in FY 2010 but that wish to participate in the RHQDAPU program for the FY 2011 payment determination must submit completed Notice of Participation forms to CMS on or before December 31, 2009. These hospitals, unlike hospitals that receive a new CCN, do not need to get their operations up and running. Therefore, we believe this is a reasonable deadline that will enable these hospitals to decide whether they want to participate in the RHQDAPU program while also enabling CMS to collect enough data from them to make an accurate FY 2011 payment determination.

We note that under our current requirements, hospitals must begin submitting RHQDAPU program data starting with the first day of the quarter following the date when the hospital registers to participate in the program. For purposes of meeting this requirement, we interpret the registration date to be the date that the hospital submits a completed Notice of Participation form. As proposed previously in this section, hospitals must also register with QualityNet and identify a QualityNet Administrator who follows the QualityNet registration process before submitting RHQDAPU program data.

- Collect and report data for each of the quality measures under the topic areas that require chart abstraction. For the FY 2011 payment determination, these topic areas are AMI, HF, PN, and SCIP. Hospitals must report these data by each quarterly deadline. Hospitals must submit the data to the QIO Clinical Warehouse using the CART, The Joint Commission ORYX® Core Measures Performance Measurement System, or another third-party vendor tool that meets the measurement specification requirements for data transmission to QualityNet. All submissions will be

executed through My QualityNet, the secure part of the QualityNet Web site. Because the information in the QIO Clinical Warehouse is considered QIO information, it is subject to the stringent QIO confidentiality regulations in 42 CFR part 480. The QIO Clinical Warehouse will submit the data to CMS on behalf of the hospitals.

- Submit complete data for each quality measure that requires chart abstraction in accordance with the joint CMS/The Joint Commission sampling requirements located on the QualityNet Web site. These requirements specify that hospitals must submit a random sample or complete population of cases for each of the topics covered by the quality measures. Hospitals must meet the sampling requirements for these quality measures for discharges in each quarter.

- Submit to CMS on a quarterly basis aggregate population and sample size counts for Medicare and non-Medicare discharges for the topic areas for which chart-abstracted data must be submitted (currently AMI, HF, PN, and SCIP). However, in order to reduce the burden on hospitals that treat a low number of patients in a RHQDAPU program topic area, a hospital that has five or fewer discharges (Medicare and non-Medicare combined) in a topic area during a quarter in which data must be submitted is not required to submit patient-level data for that topic area for the quarter. The hospital must still submit its aggregate population and sample size counts for Medicare and non-Medicare discharges for the four topic areas each quarter. We also note that hospitals meeting the five or fewer patient discharge exception may voluntarily submit these data.

- Continuously collect and submit HCAHPS data in accordance with the HCAHPS *Quality Assurance Guidelines, V4.0* (the most current version of the guidelines), located at the Web site <http://www.hcahponline.org>. The QIO Clinical Warehouse will accept zero HCAHPS-eligible discharges. However, in order to reduce the burden on hospitals that treat a low number of patients that would be otherwise covered by the HCAHPS submission requirements, a hospital that has five or fewer HCAHPS-eligible discharges during a month is not required to

submit HCAHPS surveys for that month. However, hospitals that meet this exception may voluntarily submit this data. The hospital must still submit its total number of HCAHPS-eligible cases for that month as part of its quarterly HCAHPS data submission.

- The quarterly data submission deadline for hospitals to submit patient level data for the proposed measures that require chart abstraction is 4 months following the last discharge date in the calendar quarter. CMS will post the quarterly submission deadline schedule on the QualityNet Web site (<https://www.QualityNet.org>). The collection of new chart-abstracted measures for the FY 2011 payment determination would begin with 1st calendar quarter 2010 discharges, for which the submission deadline would be August 15, 2010.

- The data submission deadline for hospitals to submit aggregate population and sample size count data for the measures requiring chart abstraction is four months following the last discharge date in the calendar quarter. This requirement allows CMS to advise hospitals regarding their submission status in enough time for them to make appropriate revisions before the data submission deadline. We will post the aggregate population and sample size count data submission deadlines on the QualityNet Web site (<https://www.QualityNet.org>).

- CMS strongly recommends that hospitals review the QIO Clinical Warehouse Feedback Reports and the RHQDAPU Program Provider Participation Reports that are available after patient level data are submitted to the QIO Clinical Warehouse. CMS generally updates these reports on a daily basis to provide accurate information to hospitals about their submissions. These reports enable hospitals to ensure that their data were submitted on time and accepted into the QIO Clinical Warehouse.

Hospitals are encouraged to regularly check the QualityNet Web site, <https://www.QualityNet.org>, for program updates and information.

- We also proposed that the following RHQDAPU program claims-based measures would be calculated using Medicare claims:

Topic	FY 2011 payment determination: proposed claims-based quality measures (no hospital data submission required)
Mortality Measures (Medicare Patients)	
<ul style="list-style-type: none"> • MORT-30-AMI Acute Myocardial Infarction 30-day mortality—Medicare patients. • MORT-30-HF Heart Failure 30-day mortality—Medicare patients. 	

Topic	FY 2011 payment determination: proposed claims-based quality measures (no hospital data submission required)
	<ul style="list-style-type: none"> • MORT–30–PN Pneumonia 30-day mortality—Medicare patients.
Readmission Measures (Medicare Patients)	
	<ul style="list-style-type: none"> • READ–30–HF Heart Failure (HF) 30-Day Risk Standardized Readmission Measure (Medicare patients). • READ–30–AMI Acute Myocardial Infarction (AMI) 30-Day Risk Standardized Readmission Measure (Medicare patients). • READ–30–PN Pneumonia (PN) 30-Day Risk Standardized Readmission Measure (Medicare patients).
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures	
	<ul style="list-style-type: none"> • PSI 06: Iatrogenic pneumothorax, adult. • PSI 14: Postoperative wound dehiscence. • PSI 15: Accidental puncture or laceration. • IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume). • IQI 19: Hip fracture mortality rate. • Mortality for selected surgical procedures (composite). • Complication/patient safety for selected indicators (composite). • Mortality for selected medical conditions (composite).
AHRQ Patient Safety Indicator (PSI) and Nursing Sensitive Care	
	<ul style="list-style-type: none"> • Death among surgical inpatients with serious, treatable complications.

For the claims-based RHQDAPU program measures listed in the table above, hospitals are not required to submit the data to the QIO Clinical Warehouse. CMS uses the existing Medicare fee-for-service claims to calculate the measures. For the FY 2011 payment determination, CMS will use 3 years of discharges from July 1, 2006, through June 30, 2009, for the 30-day mortality and 30-day readmission measures. For the AHRQ PSI, IQI and Composite measures (including the AHRQ PSI and Nursing Sensitive Care measure, Death among surgical inpatients with serious, treatable complications), we will use 1 year of claims from July 1, 2008, through June 30, 2009, to calculate these measures.

- We proposed that hospitals report the information needed to calculate the

three proposed structural measures directly onto the QualityNet Web site on a quarterly basis starting with 1st calendar quarter 2010. The quarterly submission deadline for reporting these measures will be 4½ months following the last date in the quarter covered by the data report. For example, the reporting deadline for these structural measures covering 1st calendar quarter 2010 is August 15, 2010. The 4½ month lag between the end of the quarter and the reporting deadline is intended to provide hospitals with sufficient time to collect the information needed to accurately report the proposed structural measures, and aligns with the quarterly submission deadlines for the measures for which chart-abstraction is required. As noted above in section

V.A.3.b.(4). of this final rule, after consideration and review of public comments, we are modifying our proposal that the two new structural measures be reported quarterly and instead, we are finalizing a requirement that hospitals report these data annually. We also are requiring annual reporting for the existing cardiac surgery structural requirement for the FY 2011 payment determination. Annual data submission for the structural measures via a Web-based collection tool will begin in July 2010 with respect to the time period of January 1, 2010 through June 30, 2010.

Below is the list of three structural measures we are adopting for the FY 2011 payment determination:

Topic	FY 2011 payment determination: structural measures
Cardiac Surgery	
	<ul style="list-style-type: none"> • Participation in a Systematic Database for Cardiac Surgery.
Stroke Care	
	<ul style="list-style-type: none"> • Participation in a Systematic Clinical Database Registry for Stroke Care.
Nursing Sensitive Care	
	<ul style="list-style-type: none"> • Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care.

We indicated that we would add a link on the QualityNet Web site to the Web page(s) that hospitals can use to report the structural measures after we issued this final rule.

Comment: Several commenters supported our proposal to allow hospitals with five or fewer heart

failure, pneumonia, or surgical care patients in a calendar quarter to not submit quality measure data for that quarter. However, the commenters suggested that should a hospital wish to voluntarily report such data, it should be permitted to do so. This will reduce

the burden on small hospitals with a very small number of cases.

Response: We currently allow hospitals treating five or fewer patients in a calendar quarter in a topic area that do not otherwise have to submit data for that topic area to voluntarily report data for that topic. We believe that this

allowance is consistent with the intent of the RHQDAPU program to promote public reporting and hospital quality improvement through measuring quality of care. Currently, many hospitals to which the RHQDAPU program does not apply (including CAHs and hospitals located in Maryland and Puerto Rico) report these data on a voluntary basis as part of their quality improvement efforts.

We note that we will publicly report the measure rates for all data submitted by RHQDAPU program participating hospitals, including data voluntarily reported by RHQDAPU program participating hospitals treating five or fewer cases in a topic in a calendar quarter, because we expect that a portion of these hospitals will have variable quarterly caseloads and will submit data on a sufficient number of cases (that is, more than 25) across all four posted quarters to make their overall measure rates generally reliable. However, we also will continue to include a footnote on the *Hospital Compare* Web site in the event that some of these hospitals do not have data for at least 25 cases combined over the four quarters. That footnote states that "The number of cases is too small (<25) to reliably tell how well a hospital is performing." We believe that this footnote adequately addresses hospital concerns about data reliability.

Comment: One commenter stated that the proposed rule does not address the issue of data resubmission when a hospital or its vendor becomes aware of an error in the data that was sent for posting on the *Hospital Compare* Web site. The commenter urged immediate adoption of an effective mechanism that allows hospitals and their vendors to resubmit quality measure data if they discover an error. The commenter stated that the point of public reporting is to put accurate and useful information into the hands of the public, and this is facilitated by allowing known mistakes to be corrected.

Response: Although we understand the commenter's concern, the quarterly validation sample selection is reliant on a locked final data file of hospital submitted cases. Allowing resubmission after the quarterly deadline would delay the final lockdown date of the quarterly data file, and CMS would have to delay the validation process or simply not validate resubmitted data. We believe that both of these options would adversely impact data quality.

We remind the commenter that hospitals can correct information and resubmit cases until the quarterly submission deadline, which generally occurs 4½ months following the last

discharge date in a calendar quarter. We also encourage hospitals to submit data early in the submission schedule, so that they can identify errors and resubmit data before the quarterly submission deadline. Generally, hospitals can submit cases from the first discharge date in a quarter until the quarterly submission deadline.

After consideration of the public comments we received, we are adopting as final our proposals regarding RHQDAPU program procedures for the FY 2011 payment determination.

b. RHQDAPU Program Disaster Extensions and Waivers

In the FY 2010 IPPS/RV 2010 LTCH PPS proposed rule (74 FR 24176), we solicited public comment about rules we could adopt that would enable hospitals to request either an extension or a waiver of various RHQDAPU program requirements in the event of a disaster (such as a hurricane that damages or destroys the hospital).

Specifically, we welcomed public comment on the following issues:

- Recommendations for rules that we could follow when considering whether to grant an extension or waiver of RHQDAPU program requirements in the event of a disaster, including suggested criteria that we should take into account (for example, specific hospital infrastructure damage, hospital closure time period, degree of destruction of medical records, impact on data vendors, and long-term evacuation of discharged patients impacting HCAHPS survey participation).

- The role that QIOs and QIO support contractors should play in the event of a disaster, including communicating with affected hospitals, communicating with State hospital associations, and collecting information directly from hospitals.

- How CMS extension or waiver decisions should be communicated to affected hospitals.

- Any other issues commenters deem relevant to a hospital's request for an extension or waiver of RHQDAPU program requirements in the event of a disaster.

Comment: One commenter appreciated CMS recognizing that hospitals facing certain disasters, such as a hurricane, should be granted an extension or waiver of the RHQDAPU program requirements. Commenters suggested that, although the decision to grant an extension or waiver is best made on a case-by-case basis depending on each hospital's unique situation, CMS develop some general criteria for when such extensions or waivers would be granted. Commenters reminded CMS

that when a hospital is damaged or destroyed, CMS' usual means of communicating to the hospital, such as by QualityNet or the mail, may be impossible. Commenters urged CMS to develop a creative and flexible approach to communicating with hospitals in these situations to ensure that such hospitals are aware that they may receive waivers during difficult times.

Response: We will consider these comments as we develop program procedures for disaster extensions or waivers. We are mindful that many hospitals operating in these adverse situations cannot access the Internet or mail service. We note that we currently use a variety of means to communicate with hospitals in these circumstances, including utilizing our State QIOs and national/state hospital associations, and we will continue to do so.

Comment: One commenter supported CMS and QIOs contacting both hospitals in affected areas and their data vendors in the event of disaster. The commenter also supported using e-mail first to communicate this information, followed by a phone call (if phone service is available) from a QIO, then a follow-up letter to the hospital administrator and hospital QualityNet Administrator. The commenter believed that the reasons for providing a waiver as outlined in the proposed rule were fair, but suggested that when a hospital response is requested by State or local government for any reason, then a waiver or extension should also be considered. The commenter recommended that, if a vendor is impacted, that should be should also be grounds for a hospital extension or waiver.

Response: We will consider these recommendations when considering disaster extension/waiver communications and reasons for granting extensions or waivers. We interpret the comment about "when a hospital response is requested by a State or local government" to mean that the governmental entity has asked the hospital to continue or cease certain operations. Since hospital resources might be redirected from activities related to hospital quality data reporting to providing critical services in disaster situations, we will also consider State and local government requirements for hospitals providing critical services to the public while continuing to operate in disaster situations. We believe that if a hospital is required to provide critical public health services during a disaster or pandemic, this should be a factor that we consider when deciding whether to grant a waiver or extension. We will also consider the impact a disaster

might have had on a vendor when developing our policy on this issue.

Comment: One commenter supported granting extensions and waivers of RHQDAPU program requirements in the event of a disaster and agreed with some of the criteria we requested comment on in the proposed rule. The commenter also supported CMS' interest in the role that QIOs would play in the event of a disaster and believes that they should be as proactive as possible in providing support to hospitals.

Response: We thank the commenter for the feedback as we further develop our policy for disaster extensions/waivers. We also acknowledge the important service that QIOs provide to hospitals in their support of inpatient quality data reporting and will incorporate this comment into our future plans for operating the RHQDAPU program.

c. HCAHPS Requirements for the FY 2011 Payment Determination

In the FY 2010 IPPS/R/2010 LTCH PPS proposed rule (74 FR 24176), we proposed that, for the FY 2011 payment determination, the RHQDAPU program HCAHPS requirements we adopted for FY 2010 would continue to apply. Under these requirements, a hospital must continuously collect and submit HCAHPS data in accordance with the current HCAHPS *Quality Assurance Guidelines* and the quarterly data submission deadlines, both of which are posted at <http://www.hcahpsonline.org>. In order for a hospital to participate in the collection of HCAHPS data, a hospital must either: (1) Contract with an approved HCAHPS survey vendor that will conduct the survey and submit data on the hospital's behalf to the QIO Clinical Warehouse; or (2) self-administer the survey without using a survey vendor provided that the hospital attends HCAHPS training and meets Minimum Survey Requirements as specified on the Web site at: <https://www.hcahpsonline.org>. A current list of approved HCAHPS survey vendors can be found on the HCAHPS Web site at: <https://www.hcahpsonline.org>.

Every hospital choosing to contract with a survey vendor should provide the sample frame of HCAHPS-eligible discharges to its survey vendor with sufficient time to allow the survey vendor to begin contacting each sampled patient within 6 weeks of discharge from the hospital. (We refer readers to the *Quality Assurance Guidelines* located at <https://www.hcahpsonline.org> for details about HCAHPS eligibility and sample frame creation.) In addition, the hospital must authorize the survey vendor to submit

data via My QualityNet, the secure part of the QualityNet Web site, on the hospital's behalf.

After the survey vendor submits the data to the QIO Clinical Warehouse, we strongly recommend that hospitals employing a survey vendor promptly review the two HCAHPS Feedback Reports (the Provider Survey Status Summary Report and the Data Submission Detail Report) that are available. These reports enable a hospital to ensure that its survey vendor has submitted the data on time and the data has been accepted into the QIO Clinical Warehouse.

As we stated above, any hospital that has five or fewer HCAHPS-eligible discharges in any month is no longer required to submit HCAHPS surveys for that month, although the hospital may voluntarily choose to submit these data. However, the hospital must still submit its total number of HCAHPS-eligible cases for that month as part of its quarterly HCAHPS data submission.

In order to ensure compliance with HCAHPS survey and administration protocols, hospitals and survey vendors must participate in all oversight activities. As part of the oversight process, during the onsite visits or conference calls, the HCAHPS Project Team will review the hospital's or survey vendor's survey systems and assess protocols based upon the most recent HCAHPS *Quality Assurance Guidelines*. All materials relevant to survey administration will be subject to review. The systems and program review includes, but is not limited to: (a) Survey management and data systems; (b) printing and mailing materials and facilities; (c) telephone and IVR materials and facilities; (d) data receipt, entry and storage facilities; and (e) written documentation of survey processes. Organizations will be given a defined time period in which to correct any problems and provide follow-up documentation of corrections for review. As needed, hospitals and survey vendors will be subject to follow-up site visits or conference calls. If CMS determines that a hospital is not compliant with HCAHPS program requirements, CMS may determine that the hospital is not submitting HCAHPS data that meet the requirements of the RHQDAPU program.

We continue to strongly recommend that each new hospital participate in an HCAHPS dry run, if feasible, prior to beginning to collect HCAHPS data on an ongoing basis to meet RHQDAPU program requirements. New hospitals can conduct a dry run in the last month of a calendar quarter. We refer readers to the Web site at [https://](https://www.hcahpsonline.org)

www.hcahpsonline.org for a schedule of upcoming dry runs. The dry run will give newly participating hospitals the opportunity to gain first-hand experience collecting and transmitting HCAHPS data without the public reporting of results. Using the official survey instrument and the approved modes of administration and data collection protocols, hospitals/survey vendors will collect HCAHPS data and submit the data to My QualityNet, the secure portion of QualityNet.

For FY 2011, we are again encouraging hospitals to regularly check the HCAHPS Web site at <https://www.hcahpsonline.org> for program updates and information.

We did not receive any public comments regarding our HCAHPS proposals. Therefore, we are adopting as final our proposals regarding HCAHPS requirements for the FY 2011 payment determination.

6. Chart Validation Requirements

a. Chart Validation Requirements and Methods for the FY 2011 Payment Determination

For the FY 2011 payment determination, in the FY 2010 IPPS/R/2010 LTCH PPS proposed rule (74 FR 24177), we proposed to generally continue using the following existing requirements implemented in previous years. We note below where we proposed to modify a requirement. These requirements, as well as additional information on these requirements, will be posted on the QualityNet Web site after we issue this FY 2010 IPPS final rule.

- The Clinical Data Abstraction Center (CDAC) contractor will, each quarter, ask every participating hospital to submit five randomly selected medical charts from which the hospital previously abstracted and submitted data to the QIO Clinical Warehouse.

We proposed the following timeline with respect to CDAC contractor requests for paper medical records for the purpose of validating RHQDAPU program data. Beginning with CDAC contractor requests for second calendar quarter 2009 paper medical records, the CDAC contractor will request paper copies of the randomly selected medical charts from each hospital via certified mail, and the hospital will have 45 days from the date of the request (as documented on the request letter) to submit the requested records to the CDAC contractor. If the hospital does not comply within 30 days, the CDAC contractor will send a second certified letter to the hospital, reminding the hospital that it must return paper copies

of the requested medical records within 45 calendar days following the date of the initial CDAC contractor medical record request. If the hospital still does not comply, then the CDAC contractor will assign a “zero” score to each data element in each missing record.

We proposed this timeline to provide hospitals with transparent and documented correspondence about RHQDAPU program validation paper medical record requests. Hospitals have submitted numerous questions to CMS about this process, and we believe this timeline will provide hospitals with adequate notice and time to submit paper copies of requested medical records to the CDAC contractor. We also believe that this timeline does not unduly burden hospitals. We remind

hospitals that CMS reimburses up to 12 cents per copied page to copy the requested medical records, and CMS also pays United States Postal Service fees for hospitals to mail back a paper copy of the requested medical records.

- Once the CDAC contractor receives the charts, it will re-abstract the same data submitted by the hospitals and calculate the percentage of matching RHQDAPU program data element values for all of that data.

- The hospital must pass our validation requirement of a minimum of 80 percent reliability. We use appropriate confidence intervals to determine if a hospital has achieved 80 percent reliability. The use of confidence intervals allows us to establish an appropriate range below the

80 percent reliability threshold that demonstrates a sufficient level of reliability to allow the data to still be considered validated. We estimate the percent reliability based upon a review of the sampled charts, and then calculate the upper 95 percent confidence limit for that estimate. If this upper limit is above the required 80 percent reliability, the hospital data are considered validated.

- We will pool the quarterly validation estimates for the four most recently validated quarters (except for the SCIP–Cardiovascular-2 measure discussed below). For the FY 2011 payment update, we proposed to validate 4th quarter CY 2008 through 3rd quarter 2009 discharge data for the following measures:

Topic	Quality measures validated using data from 4th quarter CY 2008 through 3rd quarter CY 2009 discharges	Measure ID No.
AMI (Acute Myocardial Infarction)	Aspirin at Arrival Aspirin Prescribed at Discharge ACEI or ARB for LVSD Adult Smoking Cessation Advice/Counseling Beta-Blocker Prescribed at Discharge Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival Primary PCI Received Within 90 Minutes of Hospital Arrival	AMI–1. AMI–2. AMI–3. AMI–4. AMI–5. AMI–7a. AMI–8a.
HF (Heart Failure)	Discharge Instructions Evaluation of LVS Function ACEI or ARB for LVSD Adult Smoking Cessation Advice/Counseling	HF–1. HF–2. HF–3. HF–4.
PN (Pneumonia)	Pneumococcal Vaccination Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital. Adult Smoking Cessation Advice/Counseling	PN–2. PN–3b. PN–4. PN–5c. PN–6.
SCIP (Surgical Care Improvement Project)—named SIP for discharges prior to July 2006 (3Q06).	Influenza Vaccination Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision Prophylactic Antibiotic Selection for Surgical Patients Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time Cardiac Surgery Patients With Controlled 6 A.M. Postoperative Blood Glucose Surgery Patients with Appropriate Hair Removal Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered. Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.	PN–7. SCIP–Inf-1. SCIP–Inf-2. SCIP–Inf-3. SCIP–Inf-4. SCIP–Inf-6. SCIP–VTE–1. SCIP–VTE–2.

- SCIP–Cardiovascular-2 will be validated using data from 2nd and 3rd calendar quarter 2009 discharges. CMS adopted this measure in the FY 2009 IPPS final rule and hospitals began submitting data for this measure starting with 1st calendar quarter 2009 discharges (73 FR 48605). However, because we generally strive to provide hospitals with ample notice before we add a new measure to the list of measures for which we will validate data, we believe that 2nd quarter discharge data is an appropriate validation starting point for this

measure (these data are not due to the QIO Clinical Warehouse until November 15, 2009).

- We will continue using the design-specific estimate of the variance for the confidence interval calculation, which, in this case, is a stratified single stage cluster sample, with unequal cluster sizes. (For reference, see Cochran, William G.: Sampling Techniques, John Wiley & Sons, New York, chapter 3, section 3.12 (1977); and Kish, Leslie: Survey Sampling, John Wiley & Sons, New York, chapter 3, section 3.3 (1964).) Each quarter is treated as a

stratum for variance estimation purposes.

Comment: Several commenters supported CMS’ proposal to document the validation contact process. Specifically, the commenters supported CMS’ plans to send two certified letter requests for medical records for data validation in case the hospital does not receive the first letter. The commenters suggested that CMS contractors also place phone calls to any hospital that does not respond to the first letter to ensure that every effort is made to

communicate the request to the appropriate staff in the hospital.

Response: We thank the commenters and agree that certified letters provide hospitals with multiple written documented notification and reminder attempts. We did not propose supplementing this notification with telephone calls because the CDAC contractor already attempts to call hospitals as current practice at least three times about 30 calendar days after it sends the initial medical record request. As a practice, we intend to continue attempting to call hospitals at least three times around the 30th calendar day following the initial request, in addition to sending written certified letters. We believe that these attempted calls at different time periods around the 30th calendar day following the initial request demonstrate our commitment to notify hospitals using multiple communication modes.

Comment: Two commenters indicated that under the current process, the validation does not incorporate skip logic, despite The Joint Commission and CMS measure specifications and algorithms that clearly call for skip logic. The commenters stated that as a result, charts that are appropriately abstracted do not pass validation with the contractor. The commenters noted that this can be a challenge for some hospitals because the CDAC contractor's decision could affect the cumulative annual results and cause a hospital to fail the validation requirement for the year.

Response: The Specifications Manual contains instructions regarding the use of skip logic by hospitals. Starting with discharges on or after April 1, 2008, and continuing to the most current update of the Specifications Manual, CMS and The Joint Commission have included the following text in the Missing and Invalid Data appendix of the Specifications Manual (currently under the heading "Abstraction Software Skip Logic and Missing Data"):

"Skip logic allows hospitals and vendors to minimize abstraction burden by using vendor software edit logic to bypass abstraction of data elements not utilized in the measure algorithm. However, these bypassed elements also negatively impact data quality and the hospital's CMS chart audit validation results when elements are incorrectly abstracted and subsequent data elements are bypassed and left blank."

"The use of skip logic by hospitals and ORYX vendors is optional and not required by CMS and The Joint Commission. Hospitals should be aware of the potential impact of skip logic on data quality, abstraction burden, and

CMS chart audit validation scores. Vendors and hospitals utilizing skip logic should closely monitor the accuracy rate of abstracted data elements, particularly data elements placed higher in the algorithm flow (for example, Comfort Measures data element)."

"Historically, CMS chart audit validation results have been used in previous payment years as one of many requirements in the Reporting Hospital Quality for Annual Payment Update (RHQDAPU) program. We refer readers to the **Federal Register** and the QualityNet Web site for the current payment year's proposed and final requirements for acute care IPPS hospitals."

The CDAC contractor abstracts all data elements necessary to calculate a sampled case's measure status. The CDAC contractor uses skip logic only when it abstracts a data element value resulting in no additional data necessary to calculate a measure status. When it re-abstracts the data elements, the CDAC contractor also uses the CART tool provided by CMS free of charge to hospitals. Under the current validation process, hospitals are at risk when utilizing skip logic, if they incorrectly abstract data elements and do not abstract subsequent data elements for the measure.

We do recognize that the use of skip logic has been an issue for some hospitals, and we believe that our proposal for FY 2012 to change the methodology for calculating the validation score from data element counts to a measure match basis will reduce the likelihood that the use of skip logic will create validation problems for hospitals.

After consideration of the public comments we received, we have decided to adopt as final, without change, our proposals regarding chart validation requirements and methods for the FY 2011 payment determination.

b. Chart Validation Requirements and Methods for the FY 2012 Payment Determination and Subsequent Years
RHQDAPU program data are currently validated by re-abstracting on a quarterly basis a random sample of five medical records for each hospital. This quarterly sample generally results in an annual combined sample of 20 patient records across four calendar quarters per hospital, but because each sample is random, it might not include medical records from each of the measure topics (for example, AMI, SCIP, etc.). As a result, data submitted by a hospital for one or more measure topics might not be validated for a given quarter or, in some cases, for an entire year or longer.

In the FY 2009 IPPS proposed rule (73 FR 23658), we solicited public comments on the impact of adding measures to the validation process, as well as on modifications to the current validation process that could improve the reliability and validity of the methodology. We specifically requested input concerning the following:

- Which of the measures or measure sets should be included in the chart validation process for subsequent years?
- What validation challenges are posed by the RHQDAPU program measures and measure sets? What improvements could be made to validation or reporting that might offset or otherwise address those challenges?
- Should CMS switch from its current quarterly validation sample of five charts per hospital to randomly selecting a sample of hospitals, and selecting more charts on an annual basis to improve the reliability of hospital level validation estimates?
- Should CMS select the validation sample by clinical topic to ensure that all publicly reported measures are covered by the validation sample?

In the FY 2009 IPPS final rule, we summarized and responded to commenters' views on these issues and stated that we will consider the issues raised by these commenters if we decide to make changes to the RHQDAPU program chart validation methodology.

Our objective is to validate the accuracy of RHQDAPU program data collected by hospitals using medical record abstraction. Accurate data provide consumers with objective publicly reported information about hospital quality for more informed decision making. Consistent with the public comments we received in response to the FY 2009 IPPS proposed rule (73 FR 23658–9) and discussed in the FY 2009 IPPS final rule (73 FR 48623), we believe that the methodology recommended in the CMS Hospital Value-Based Purchasing Report to Congress is a promising approach worth consideration in the RHQDAPU program. This approach is designed to validate the accuracy of hospital reported quality measure data, and is also directly applicable to validating RHQDAPU program chart-abstracted quality data.

We recognize that hospitals need ample notification regarding proposed changes to the current RHQDAPU program validation process. We believe that the FY 2012 RHQDAPU program annual payment determination is the earliest opportunity to make significant modifications to our validation process.

Therefore, in the FY 2010 IPPS/RV 2010 LTCH PPS proposed rule (74 FR

24178), we proposed modifications to the RHQDAPU program validation methodology beginning with the FY 2012 payment determination. Specifically, we proposed to do the following:

- Randomly select on an annual basis 800 participating hospitals that submitted chart-abstracted data for at least 100 discharges combined in the measure topics to be validated. To determine whether a hospital meets this “100-case threshold,” we will look to the discharge data submitted by the hospital during the *calendar* year three years prior to the *fiscal* year of the relevant payment determination. For example, if the 100-case threshold applied for the FY 2011 payment determination (which it will not), the applicable measure topics would be AMI, HF, PN, and SCIP, and we would choose 800 hospitals that submitted discharge data for at least 100 cases combined in these topics during calendar year 2008. If a hospital did not submit discharge data for at least 100 cases in these topics during CY 2008, we would not select the hospital for validation. We will announce the topic areas that apply for the FY 2012 payment determination at a later date, and we plan to select the first 800 hospitals in July 2010. We will select hospitals for the FY 2012 validation if they meet the 100-case threshold during CY 2009. We have proposed this 100-case threshold because we believe that it strikes the appropriate balance between ensuring that the selected hospitals have a large enough patient population to be able to submit sufficient data to allow us to complete an accurate validation, while not requiring validation for hospitals with a low number of submitted quarterly cases and relatively unreliable measure estimates. Based on previously submitted data, we estimate that 98 percent of participating RHQDAPU program hospitals will meet this threshold and, thus, be eligible for validation. As noted below, we solicited comments and suggestions on how we might be able to target the remaining 2 percent of hospitals for validation.

- We validate for each of the 800 hospitals a randomly selected stratified sample for each quarter of the validation period. Each quarterly sample will include 12 cases, with at least one but no more than three cases per topic for which chart-abstracted data was submitted by the hospital. However, we recognize that some selected hospitals might not have enough cases in all of the applicable topics to submit data (for example, if they have 5 or fewer discharges in a topic area in a quarter).

For those hospitals, we would validate measures in only those topic areas for which they have submitted data. For the FY 2012 payment determination, we will validate 1st calendar quarter 2010 through 3rd calendar quarter 2010 discharge data. We proposed to validate 3 quarters of data for FY 2012 in order to provide hospitals with enough time to assess their medical record documentation and abstraction practices, and to take necessary corrective actions to improve these practices, before documenting their 1st calendar quarter 2010 discharges into medical records that may be sampled as part of this proposed validation process.

Beginning with the FY 2013 payment determination, we proposed to validate data submitted by hospitals during the four quarters that make up the fiscal year that occurs two years prior to the year that applies to the payment determination. For example, for FY 2013, we would validate 4th calendar quarter 2010 through 3rd quarter 2011 discharge data. This lag between the time a hospital submits data and the time we can validate that data is necessary because data is not due to the QIO Clinical Warehouse until 4½ months after the end of each quarter, and we need additional time to select hospitals and complete the validation process.

- We proposed that the CDAC contractor will, each quarter that applies to the validation, ask each of the 800 selected hospitals to submit 12 randomly selected medical charts from which data was abstracted and submitted by the hospital to the QIO Clinical Warehouse. We note that, under our current requirements, hospitals must begin submitting RHQDAPU program data starting with the first day of the quarter following the date when the hospital registers to participate in the program. For purposes of meeting this requirement, we interpret the registration date to be the date that the hospital submits a completed Notice of Participation form. As proposed previously in this section, hospitals must also register with QualityNet and identify a QualityNet Administrator who follows the QualityNet registration process before submitting RHQDAPU program data.

In addition, we proposed to continue the following timeline with respect to CDAC contractor requests for paper medical records for the purpose of validating RHQDAPU program data. Beginning with CDAC contractor requests for second calendar quarter 2009 paper medical records, the CDAC contractor will request paper copies of the randomly selected medical charts from each hospital via certified mail,

and the hospital will have 45 days from the date of the request (as documented on the request letter) to submit the requested records to the CDAC contractor. If the hospital does not comply within 30 days, the CDAC contractor will send a second certified letter to the hospital, reminding the hospital that it must return paper copies of the requested medical records within 45 calendar days following the date of the initial CDAC contractor medical record request. If the hospital still does not comply, then the CDAC contractor will assign a “zero” score to each measure in each missing record.

- Once the CDAC contractor receives the charts, it will re-abstract the same data submitted by the hospitals and calculate the percentage of matching RHQDAPU program measure numerators and denominators for each measure within each chart submitted by the hospital. Specifically, we will estimate the accuracy by calculating a match rate percent agreement for all of the variables submitted in all of the charts. For any selected record, a measure’s numerator and denominator can have two possible states, included or excluded, depending on whether the hospital accurately included the cases in the measure numerator(s) and denominator(s). We will count each measure in a selected record as a match if the hospital-submitted measure numerator and denominator sets match the measure numerator and denominator states independently abstracted by our contractor. For example, one heart failure case from which data has been abstracted for four RHQDAPU program chart-abstracted measures (that is, HF-1, HF-2, HF-3, and HF-4) would receive a 75 percent match if three out of four of the hospital-reported heart failure measure numerator and denominator states matched the re-abstracted numerator and denominator states. This proposed scoring approach is the same as recommended in the CMS Hospital Value-Based Purchasing Report to Congress, and is illustrated in further detail using an example in pages 83–84 of the report which can be found on our Web site at: <http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/HospitalVBPPIanRTCFINALSUBMITTED2007.pdf>. We believe that this approach is appropriate, and was supported by many commenters when we requested comment in the FY 2009 IPPS final rule for input about the RHQDAPU program validation process (73 FR 48622 and 48623).

- Use, as we currently do, each selected case as a cluster comprising

one or multiple measures utilized in a validation score estimate. Each selected case will have multiple measures included in the validation score (for example, for the FY 2011 payment determination, a heart failure record will include 4 heart failure measures). Specifically, we propose to continue using the design-specific estimate of the variance for the confidence interval calculation, which, in this case, is a stratified single-stage cluster sample, with unequal cluster sizes. (For reference, see Cochran, William G.: *Sampling Techniques*, John Wiley & Sons, New York, chapter 3, section 3.12 (1977); and Kish, Leslie: *Survey Sampling*, John Wiley & Sons, New York, chapter 3, section 3.3 (1964).) Each quarter and clinical topic is treated as a stratum for variance estimation purposes.

In the proposed rule, we indicated that we believe that the proposed clustering approach is a statistically appropriate technique for calculating the annual validation confidence interval. Because CMS will not be validating all hospital records, we need to calculate a confidence interval that incorporates a potential sampling error. Our clustering approach incorporates the degree of correlation at the individual data record level, because our previous validation experience indicates that hospital data mismatch errors tend to be clustered in individual data records. We have used this clustering since the inception of the RHQDAPU program validation requirement to calculate variability estimates needed for calculating confidence intervals (70 FR 47423).

- Use the upper bound of a one-tailed 95 percent confidence interval to estimate the validation score; and
- Require all RHQDAPU program participating hospitals selected for validation to attain at least a 75 percent validation score per quarter to pass the validation requirement.

We believe that this proposal incorporates many of the principles supported by the vast majority of commenters in response to our solicitation for public comments in the FY 2009 IPPS proposed rule (73 FR 23658 through 23659). Specifically, we believe that the increased annual sample size per hospital will provide more reliable estimates of validation accuracy. The proposed sample size of 12 records per quarter would provide a total of 36 records across the three sampled quarters for the FY 2012 payment determination, and 48 records in subsequent years. This estimate would improve the reliability of our validation estimate, as compared to the

current RHQDAPU program annual validation sample of 20 cases per year. We also believe that modifying the validation score to reflect measure numerator and denominator accuracy will ensure that accurate data are posted on the *Hospital Compare* Web site.

In addition, we believe that stratified quarterly samples by topic will improve the feedback provided to hospitals. CMS would provide validation feedback to hospitals about all sampled topics submitted by the hospitals each quarter. Because all relevant data elements submitted by the hospital must match the independently re-abstracted data elements to count as a match, we have proposed to reduce the passing threshold from 80 percent to 75 percent. We proposed to use an one-tail confidence interval to calculate the validation score because we strongly believe that a one-tail test most appropriately reflects the pass or fail dichotomous nature of the statistical test regarding whether the confidence interval includes or is completely above the 75 percent passing validation score.

We also proposed to continue to allow hospitals that fail to meet the passing threshold for the quarterly validation an opportunity to appeal the validation results to their State QIO. QIOs are currently tasked by CMS to provide education and technical assistance about RHQDAPU program data abstraction and measures to hospitals, and the quarterly validation appeals process will provide hospitals with an opportunity to both appeal their quarterly results and receive education free of charge from their State QIO. This State QIO quarterly validation appeals process is independent of the proposed RHQDAPU program reconsideration procedures for hospital reconsideration requests involving validation for the FY 2010 payment update proposed below in section V.A.9. of this final rule.

Comment: Several commenters supported setting a slightly lower validation threshold for the beginning years of the new validation process as hospitals and CMS gain experience with the new system. These commenters were generally pleased with CMS' proposal for the changes to the data validation process and urged CMS to continue to refine the plan put forward in the proposed rule.

Response: We agree with the commenters that the proposed 75 percent threshold provides a reasonable passing threshold for the proposed validation process. We will evaluate the new validation process after initial implementation through data analysis of validation results. Based on the results of this data analysis, we may consider

proposing modifications in future years to further refine the validation process.

Comment: Several commenters stated that the burden to hospitals will be reduced if they do not have to submit records for validation every year. However, because hospitals will be selected at random each year and there is no guarantee that a hospital selected in one year will not be selected in the following year as well, some commenters urged CMS to refine the validation selection process so that hospitals selected for validation in one year are not eligible for selection again until 2 years later. Alternatively, the commenters suggested that CMS could ensure that no hospital is selected more than two times within a 5-year period, arguing that this would help guarantee that a particular hospital is not disproportionately burdened by the selection process. In addition, the commenters suggested that CMS should consider allowing hospitals that pass validation with a very high score to receive a "pass" from the validation process for several years. The commenters believed that such a policy would encourage hospitals to ensure their data are as accurate as possible and reward those hospitals with high accuracy rates.

Response: We appreciate these comments and understand the concern about being selected multiple times during a short timeframe. We also appreciate the recommendation that hospitals receiving a high validation score be exempt from validation for two years. We must weigh this burden relative to the policy objective to ensure that we receive accurate data, and believe that using a truly random selection process strikes the appropriate balance. We considered options such as providing hospitals achieving high validation scores with a "free pass" for a certain period, and using a 4 to 5 year rotating panel of hospitals to lessen burden. However, we believe that using a truly random sample on an annual basis is fair to all hospitals included in the sample and will encourage all hospitals to take steps to ensure that their data are consistently accurate. We believe that providing hospitals with automatic exemptions from our validation requirement could detract from this policy objective, because hospitals receiving these exemptions would know in advance of data abstraction that CMS would not be validating their data.

Comment: Commenters agreed that it is appropriate to focus on the hospital's measure rate, as opposed to individual data elements, because the measure rate captures the information that is

important to patient care. Commenters noted that for data validation in the current program, there have been several instances in which a mismatch between single data elements unrelated to the quality of care provided by a hospital, such as the patient's birth date, has caused hospitals to fail validation. Comments believe that validating the hospital's measure rate should eliminate these unfortunate incidents.

Response: The proposed validation process focuses on validating whether hospital abstracted data results in accurate measure rates and denominator inclusion. We wish to clarify that the proposed validation process would measure the accuracy of each measure rate and measure denominator count posted on the *Hospital Compare* Web site. We will continue to use the data elements used in the current validation process to calculate the validation scores. We also note that all data used as part of the validation process (both the current process and the process proposed for FY 2012 and beyond) is protected under the Business Associate provisions of HIPAA and the QIO regulations.

Comment: Commenters stated that CMS' proposed process for validating hospitals' quality data beginning in FY 2012 holds promise as a reasonable approach to ensure the accuracy of the quality data and improve upon the deficiencies in the current validation process.

Response: We agree with the commenters that the proposed new validation process is an improved approach for the validation process. We will evaluate the new validation process after initial implementation and may consider proposing modifications in future years to further refine it.

Comment: Several commenters stated that the current CMS validation sample of five charts per quarter does not provide a reliable estimate and advocated increasing the sample size.

Response: We agree that the proposed requirement to increase the quarterly sample size from 5 records to 12 records will provide a more reliable annual validation estimate.

Comment: One commenter objected to the proposal to randomly sample hospitals in the proposed validation process, as all hospitals would not be held equally accountable via a valid sample across all measures.

Response: We believe that the proposed approach is equitable because all hospitals meeting the 100-case threshold will have an equal probability of being selected in the random sample. As we stated in the proposed rule (74 FR 24180), we are considering ways to

include hospitals that do not meet the 100 case threshold in the validation process, such as by developing targeting criteria that would focus on these hospitals.

Comment: One commenter asked for clarity on how CMS plans to address validation for hospitals with low numbers. While the commenter agreed that it is appropriate to ease the burden on hospitals with a very small number of cases, the commenter also believed that hospitals should always be able to voluntarily report on quality measures if they wish and should be held equally accountable for their participation and reported data.

Response: As we stated in the proposed rule (74 FR 24180), we are considering ways to include hospitals that do not meet the 100-case threshold in the validation process, such as by developing targeting criteria that would focus on these hospitals. One possible approach would be to randomly sample these hospitals as part of the targeted sample, thereby ensuring that data from some of these hospitals also would be validated.

Comment: One commenter urged that State QIOs be supportive not only during the validation appeals process but also proactively during data collection and reporting.

Response: We agree with the commenter. CMS currently requires QIOs under their contract to improve or maintain consistently high levels of RHQDAPU program participation to meet all RHQDAPU program requirements, not solely validation appeals.

Comment: Several commenters asked CMS to consider sending formal notification to hospitals not selected as part of the random sample. The commenters believe that this notification will aid hospitals with recordkeeping and internal operating procedures. The commenters were concerned that the lack of a consistent validation could cause internal processes within the hospitals to break down in the event that a hospital is not selected as part of the data validation sample for multiple years.

Response: We will consider this comment and will consider using our QIOs to provide outreach to both selected and non-selected hospitals. We understand that hospitals must receive ample and clear communication about the requirements, and we recognize that the absence of quarterly medical record requests for all hospitals under the proposed validation process could affect the hospital's knowledge and ability to efficiently comply with the validation requirement.

Comment: One commenter supported keeping validation standardized to a quarterly process that includes all hospitals. The commenter objected to excluding hospitals submitting fewer than 100 records.

Response: We appreciate the comment but believe that the improved reliability of the validation estimate under the proposed new validation process will outweigh the benefit of validating a smaller number of records for all hospitals. As hospitals have improved their abstraction methods over time, we believe that the benefit of every hospital receiving quarterly feedback on their hospital's data has lessened over time. Regardless of whether a hospital was included in our annual validation sample, we plan to continue providing validation feedback on highly mismatching data elements and measures to all hospitals by providing aggregate validation information to all hospitals that submit quality data.

Comment: Commenters stated that the lack of timely quarterly validation feedback is a huge problem. Some commenters did not believe that the 2,500 hospitals not selected for annual validation under the proposed new validation process would incorporate feedback provided to other selected hospitals, and data errors would increase over time due to the lack of hospital-specific feedback.

Response: We interpret the comment to mean that hospitals that are not selected under the proposed, new validation process would not incorporate aggregate feedback information because they would not believe that the aggregate information would be relevant to them; and that their failure to incorporate supplied feedback would cause these hospitals' data errors to increase over time.

However, we believe that the improved reliability of the validation estimate under the proposed new validation process will outweigh the benefit of validating a smaller number of records for all hospitals. As hospitals have improved their abstraction over time, we believe that the benefit of every hospital receiving quarterly feedback has lessened over time. As we noted in an earlier response, we plan to continue providing aggregate validation feedback at a State and national level on highly mismatching data elements and measures to all hospitals regardless of whether they were included in the annual validation sample.

Comment: One commenter requested that CMS clarify that, under the proposed validation process, only those hospitals that are selected for validation

would have their payment at risk, and that the remaining hospitals would not be affected in any way by the validation results of the selected hospitals for that given year.

Response: Only hospitals randomly selected for the proposed new annual validation process would have to meet the validation requirement for the applicable payment year. We note, however, that hospitals that are not selected for validation in a given year may nonetheless not receive the full annual payment update if they fail to meet other RHQDAPU program requirements, or if they withdraw from the program.

Comment: One commenter supported a randomized selection of 200 hospitals per quarter for validation with a minimum number of 20 charts reviewed. The commenter believes that hospitals should not be selected for validation any more frequently than one time per year. The commenter expressed concern that if validation occurred more than one time per year, hospitals may become complacent in their validation processes and this may lead to issues with data integrity. The commenter urged CMS to reduce the current administrative burden of quarterly validation and supported random selection of hospitals one per quarter per year with more charts reviewed.

Response: We appreciate the commenter's concern and the suggestion to reduce the burden on the hospitals through validating one quarter of data per year. However, we believe that our proposed approach will enable hospitals to incorporate feedback learned earlier in the year and make improvements if necessary. The increased annual sample size from the current 20 records per year to 48 records per year also provides a more reliable validation estimate for sampled hospitals.

Comment: One commenter urged continued attention to the data element level in order to increase the denominator and minimize the impact of a small number of errors.

Response: We understand this comment and remind hospitals that they must continue to monitor their data element level validation processes because we use individual data elements as a combined set to calculate quality measures. The proposed validation score serves as a composite score of all data elements used to calculate quality measures, so it is critical that hospitals continue to ensure that data elements are abstracted accurately because inaccurately abstracted data elements can result in inaccurate measure rates and denominators.

Comment: One commenter urged CMS to extend the turnaround time for chart selection to 60 days. The commenter suggested that CMS give hospitals the option to submit validation cases electronically rather than by mailing printed copies because such submissions would avoid shipping delays and allow faster turn around time.

Response: We understand the commenter's concern about the deadline for hospitals to return requested medical records but note that under the current quarterly validation process, it takes 5 to 6 months from the initial medical record request until the CDAC contractor completes the validation process each quarter and the QIO completes its review of an appeal (if so requested by the hospital). We are concerned that adding time to this process would adversely impact hospitals' ability to incorporate validation feedback into future abstraction work.

We will consider accepting electronic submission of validation cases using compact disc and electronic health record submission in future years. We must consider both the cost to accept and review these submissions, and the added benefit to the hospitals using electronic methods to store medical record information.

Comment: Several commenters recommended that any changes to the validation process be tested before CMS imposes a payment penalty against the hospitals. These commenters also recommended that no hospital be penalized in terms of its annual payment update if it fails the validation requirement for only a single quarter.

Response: We believe that the proposed changes represent a small relative change to the overall validation process. We have assessed the impact by calculating revised scores using the proposed new validation method. Preliminary results indicate that our proposal would not adversely impact the number of hospitals failing to meet our annual validation requirement. We will continue to assess the impact of this change in the near future, and consider changes in future years.

Comment: One commenter recommended allowing all hospitals passing quarterly validation to appeal individual mismatches and adjust the score on a quarterly basis based upon a successful appeal.

Response: Our proposal, which we discuss below, to require all hospitals failing our annual validation requirement to submit all mismatched data elements partially addresses this concern because hospitals failing our annual validation requirement would be

able to appeal all data elements classified as mismatches by the CDAC contractor. We understand the desire of the commenter to correct mismatches on a quarterly basis; however, we do not currently have a mechanism in place to accommodate this need. We will investigate a possible solution to address mismatches on a quarterly basis for the future.

Comment: One commenter suggested that CMS and CMS contractors return case detail reports in Excel file format rather than using portable document format (pdf).

Response: We believe that this is an excellent suggestion, and we will consider the feasibility of implementing this suggestion for future years.

Comment: One commenter asked whether hospitals would be selected from each State.

Response: In order to maximize the overall sampling efficiency, the random sample would not be stratified by State. The intent of the random sample is to provide all participating hospitals that meet the 100-case threshold with an equal probability of selection.

Comment: Commenters asked whether hospitals not selected for validation would be considered for VBP. Commenters stated that hospitals use the validation process to learn and educate their staff about abstraction and documentation in the medical record.

Response: We interpret the comment "considered for VBP" to mean eligible to receive payment under a proposed VBP methodology, as outlined in the 2007 CMS Hospital Value-Based Purchasing Report to Congress. As of the date of this final rule, value-based purchasing for hospitals has not been legislatively authorized. The proposed validation requirements would apply only for purposes of the RHQDAPU program.

Comment: Commenters asked what would be the incentive for hospitals submitting fewer than 100 cases to continue abstracting and reporting data.

Response: We remind the commenter that all RHQDAPU program participating hospitals must continue to meet the data submission and other requirements. We also note that we are considering developing targeting criteria that would enable us to also validate data submitted by hospitals that do not meet the 100-case threshold.

Comment: Commenters noted that both hospitals and QIOs will have difficulty allocating resources for staffing when they do not know, from year to year, what hospitals will be selected for validation.

Response: We understand that hospitals selected for validation will

need to allocate staffing for this effort and that hospitals that are not selected will not need to do so. However, the additional, minimal burden would be to submit the documentation for the requested medical records; a maximum of 12 records 4 times spaced over a year. Therefore, we do not believe that there will be a need for a large allocation of resources to meet this validation requirement.

Comment: One commenter asked how CMS can compare all hospitals when different measure evaluations are being used, if some hospitals are using the new validation process and their measure score is based on this process.

Response: We interpret the comment to be asking how we would validate all publicly reported data through a random sample of hospitals. We believe that a random sample of 800 hospitals provides a reliable estimate of accuracy for both sampled hospitals and national measure rates, since the sample is random and of sufficient size. We proposed stratifying the validation sample to ensure that all hospital-submitted data are validated for selected hospitals. The validation sample for all sampled hospitals would be similar in sample size by clinical topic to ensure that the sample is representative of each hospital's population of submitted cases.

After consideration of the public comments we received, we have decided to adopt as final our proposal regarding chart validation requirements and methods for the FY 2012 payment determination and subsequent years.

c. Possible Supplements to the Chart Validation Process for the FY 2013 Payment Determination and Subsequent Years

In the FY 2010 IPPS/R Y 2010 LTCH PPS proposed rule (74 FR 24180), we also solicited public comment about criteria we could use to target hospitals for validation in the future. These targeting criteria could include abnormal data patterns identified by analyzing hospital-submitted measure rates and counts for RHQDAPU program measures. For example:

- A high number of years a hospital was not randomly selected for annual validation (for example, at least 5 years);
- Consistently high measure denominator exclusion rates resulting in unexpectedly low denominator counts;
- Consistently high measure rates, relative to national averages;
- Small annual submission in the number of cases in previous years resulting in hospital exclusion from RHQDAPU program validation sample.

Comment: One commenter recommended that CMS not implement

targeting criteria for the FY 2013 validation. The commenter indicated that it does not appear to be random, and CMS would not provide all hospitals with feedback on their abstraction accuracy. The commenter believed that because hospitals widely vary in their abstraction accuracy, feedback to all hospitals is more important than lessening burden through targeted validation.

Response: We recognize that providing feedback to hospitals is an important part of the validation process. We will continue to work with State QIOs to provide data element and measure-specific feedback to all participating hospitals, regardless of inclusion in the random sample. Additionally, our targeting criteria would not be random; they would be designed to select hospitals based on specific criteria. The increased annual sample size and stratification is designed to provide hospitals selected for validation with reliable information about all of their abstracted data.

Comment: With regard to the reconsideration process, several commenters supported CMS' proposal to require hospitals to submit their paper medical records for re-abstraction when they submit a request for reconsideration involving data validation. The commenters believe that this process will give hospitals that believe the results of their data validation testing were inaccurate an opportunity to have their data re-abstracted.

Response: We agree with the commenters that hospitals should be able to seek reconsideration of all validation mismatched data elements and measures throughout the year if the hospital fails to meet the annual validation requirement.

Comment: Some commenters recommended continuing with the process of random selection of five charts per quarter for hospitals having fewer than 100 discharges.

Response: We appreciate the recommendation that we continue validating hospital data for hospitals having fewer than 100 discharges. As we discussed above, we are considering developing targeting criteria that would focus on these hospitals.

We appreciate the public comments we received and will take them into consideration as we consider possible supplements to the chart validation process for the FY 2013 payment determination and subsequent years. Specifically, CMS plans to propose the following targeting criteria for FY 2013:

- Validating hospital data when the hospital failed the previous year's RHQDAPU program validation;
- Validating a sample of hospitals not included in the previous year's RHQDAPU program validation random sample for submitting fewer than 100 cases; and
- Validating hospital data when the hospital was not selected in 3 previous years' RHQDAPU program random validation samples.

We will also consider other targeting criteria for FY 2013 and future years.

7. Data Accuracy and Completeness Acknowledgement Requirements for the FY 2011 Payment Determination and Subsequent Years

For the FY 2011 payment determination and subsequent years, in the FY 2010 IPPS/R Y 2010 LTCH PPS proposed rule (74 FR 24180), we proposed to require hospitals to electronically acknowledge on an annual basis the completeness and accuracy of the data submitted for the RHQDAPU program payment determination. Hospitals will be able to submit this acknowledgement on the same Web page that they use to submit data necessary to calculate the structural measures, and we believe that this Web page will provide a secure vehicle for hospitals to directly acknowledge that their information is complete and accurate to the best of their knowledge. A single annual electronic acknowledgement will provide us with explicit documentation acknowledging that the hospital's data is accurate and complete, but will not unduly burden hospitals. We noted that commenters generally supported the idea of electronic attestation in the FY 2009 IPPS final rule (73 FR 48625) at the point of data submission to the QIO Clinical Warehouse.

In addition, the Government Accountability Office (GAO) recommended in a 2006 report (GAO-06-54) that hospitals self-report that their data are complete and accurate. Therefore, for the FY 2011 payment determination, we proposed to require hospitals to electronically acknowledge their data accuracy and completeness once between January 1, 2010, and August 15, 2010. Hospitals will acknowledge that all information that is, or will be, submitted as required by the RHQDAPU program for the FY 2011 payment determination is complete and accurate to the best of their knowledge.

Comment: Several commenters commended CMS for proposing to collect data accuracy and completeness acknowledgements using an electronic method.

Response: We thank the commenters, and believe that this proposed requirement imposes a minimal burden for hospitals.

Comment: A number of commenters questioned the benefit of the proposed electronic data accuracy and completeness acknowledgement, and believed that data quality would not be improved. The commenters believed that requiring hospitals to attest to the accuracy of their data will not increase the reliability of the data collected for the RHQDAPU program and noted that historically, almost all hospitals have passed the data validation requirements, meaning that their data are found to be accurate and complete.

Response: We believe that this proposed requirement will ensure that hospitals continue implementing procedures for ensuring data completeness and accuracy. This proposed requirement is intended to supplement our existing submission and validation requirements.

After consideration of the public comments we received, we are adopting as final, without modification, our proposal to require hospitals to electronically acknowledge on an annual basis the completeness and accuracy of the data submitted for the RHQDAPU program payment determination.

8. Public Display Requirements for the FY 2011 Payment Determination and Subsequent Years

For the FY 2011 payment determination, in the FY 2010 IPPS/R/2010 LTCH PPS proposed rule (74 FR 24180), we proposed to generally continue using the following existing requirements implemented in previous years. Our continued goal for the chart validation requirements is to validate the reliability of RHQDAPU program chart-abstracted data. Accurate data are needed to calculate accurate publicly reported quality measures that are posted on the *Hospital Compare* Web site. We added the validation requirement in the FY 2006 IPPS final rule (70 FR 47421 through 47422) to ensure that hospitals submit reliable data for RHQDAPU program chart-abstracted measures, based on our experience in FY 2005 that hospitals vastly differed in their data reliability. We modified the validation requirements in the FY 2008 IPPS final rule with comment period (72 FR 47366 and 47367) to update the RHQDAPU program list of validated measures for FY 2008, and pooled multiple quarterly validation estimates into a single annual estimate to improve reliability. We modified these requirements to reflect

the changing RHQDAPU program list of chart-abstracted measures and validate all available RHQDAPU program data.

We proposed to update the list of validated RHQDAPU program measures for the FY 2011 payment determination to incorporate changes to our list of required chart-abstracted RHQDAPU program measures for CY 2009 discharges. These requirements, as well as additional information on these requirements, will be posted on the QualityNet Web site after we issue this final rule.

Section 1886(b)(3)(B)(viii)(VII) of the Act provides that the Secretary shall establish procedures for making data submitted under the RHQDAPU program available to the public. The RHQDAPU program quality measures are posted on the *Hospital Compare* Web site (<https://www.hospitalcompare.hhs.gov>). We require that hospitals sign a Notice of Participation form when they first register to participate in the RHQDAPU program. Once a hospital has submitted a form, the hospital is considered to be an active RHQDAPU program participant until such time as the hospital submits a withdrawal form to CMS (72 FR 47360). Hospitals signing this form agree that they will allow CMS to publicly report the quality measures included in the RHQDAPU program.

We will continue to display quality information for public viewing as required by section 1886(b)(3)(B)(viii)(VII) of the Act. Before we display this information, hospitals will be permitted to review their information as recorded in the QIO Clinical Warehouse.

Currently, hospital campuses that share the same CCN must combine data collection and submission across their multiple campuses (for both clinical measures and HCAHPS). These measures are then publicly reported on the *Hospital Compare* Web site as if they apply to a single hospital. We estimate that approximately 5 to 10 percent of the hospitals reported on the *Hospital Compare* Web site share CCNs. To increase transparency in public reporting and improve the usefulness of the *Hospital Compare* Web site, we plan to note on the Web site instances where publicly reported measures combine results from two or more hospitals.

We did not receive any public comments on our proposals and are adopting them as final in this final rule.

9. Reconsideration and Appeal Procedures for the FY 2010 Payment Determination

The general deadline for submitting a request for reconsideration in

connection with the FY 2010 payment determination is November 1, 2009. As discussed more fully below, in the FY 2010 IPPS/R/2010 LTCH PPS proposed rule (74 FR 24181), we proposed that all hospitals submit a request for reconsideration and receive a decision on that request before they can file an appeal with the Provider Reimbursement Review Board (PRRB).

For the FY 2010 payment determination, in the FY 2010 IPPS/R/2010 LTCH PPS proposed rule (74 FR 24181), we proposed to continue utilizing most of the same procedures that we utilized in FY 2009. Under these proposed procedures, the hospital must—

- Submit to CMS, via QualityNet, a Reconsideration Request form (available on the *QualityNet* Web site) containing the following information:

- Hospital CMS Certification number (CCN).

- Hospital Name.

- CMS-identified reason for failure (as provided in the CMS notification of failure letter to the hospital).

- Hospital basis for requesting reconsideration. This must identify the hospital's specific reason(s) for believing it met the RHQDAPU program requirements and should receive the full FY 2010 IPPS annual payment update.

- CEO contact information, including name, e-mail address, telephone number, and mailing address (must include the physical address, not just the post office box). We proposed to no longer require that the hospital's CEO sign the RHQDAPU program reconsideration request. We have found that this requirement increases the burden for hospitals because it prevents them from electronically submitting the RHQDAPU program reconsideration request forms. In addition, to the extent that a hospital can submit a request for reconsideration on-line, the burden on our staff is reduced and, as a result, we can more quickly review the request.

- QualityNet System Administrator contact information, including name, e-mail address, telephone number, and mailing address (must include the physical address, not just the post office box).

- Paper medical record requirement for reconsideration requests involving validation. We proposed that if a hospital asks us to reconsider an adverse RHQDAPU program payment decision made because the hospital failed the validation requirement, the hospital must submit paper copies of all the medical records that it

submitted to the CDAC contractor each quarter for purposes of the validation. Hospitals must submit this documentation to a CMS contractor, which will redact all patient identifying information and forward the redacted copies to CMS. The contractor will be a QIO support contractor, which has authority to review patient level information under 42 CFR part 480. We will post the address where hospitals can ship the paper charts on the QualityNet Web site after we issue the FY 2010 IPPS/RV 2010 LTCH PPS final rule. Hospitals submitting a RHQDAPU program validation reconsideration request will have all mismatched data reviewed by CMS, and not their State QIO. (As discussed in section V.A.6.b. of this final rule, the State QIO is available to conduct a quarterly validation appeal if so requested by a hospital.)

For the FY 2010 payment determination, the RHQDAPU program data that will be validated is 4th calendar quarter 2007 through 3rd quarter calendar year 2008 discharge data, except for SCIP-Infection-4 and Infection-6, which will be validated using 2nd and 3rd calendar quarter 2008 discharges (73 FR 48621 through 48622). Hospitals must provide a written justification for each appealed data element classified during the validation process as a mismatch. We will review the data elements that were labeled as mismatched, as well as the written justifications provided by the hospitals, and make a decision on the reconsideration request. As we mentioned above, we proposed that all hospitals submit a reconsideration request to CMS and receive a decision on that request prior to submitting a PRRB appeal. We believe that the reconsideration process is less costly for both CMS and hospitals, and that this requirement will decrease the number of PRRB appeals by resolving issues earlier in the appeals process.

Following receipt of a request for reconsideration, we will—

- Provide an e-mail acknowledgement, using the contact information provided in the reconsideration request, to the CEO and the QualityNet Administrator that the request has been received.
- Provide written notification to the hospital CEO, using the contact information provided in the reconsideration request, regarding our decision. We expect the process to take approximately 60 to 90 days from the reconsideration request due date of November 1, 2009.

If a hospital is dissatisfied with the result of a RHQDAPU program reconsideration decision, the hospital may file a claim under 42 CFR part 405, Subpart R (a PRRB appeal). We solicited public comments on the extent to which these proposed procedures will be less costly for hospitals, and whether they will lead to fewer PRRB appeals.

Comment: One commenter agreed that CMS should no longer require the CEO to sign the RHQDAPU program reconsideration request so that the request does not get held up for a signature, and can be submitted electronically. The commenter believed that use of the PRRB is less cost efficient, and should be the last resort. The commenter requested that the reconsideration process provide both written notification to the hospital CEO and QualityNet notification to the QualityNet Administrator working at the hospital.

Response: We appreciate the comment and recognize the additional burden to hospitals associated with the requirement of a CEO signature.

Comment: Several commenters supported CMS' proposal to require hospitals to submit their paper medical records for re-abstraction when they submit an appeal involving data validation. The commenters indicated that this process will give hospitals that believe the results of the data validation were inaccurate an opportunity to have their data re-abstracted again as part of the reconsideration process.

Response: In the proposed rule, we proposed that hospitals must provide a written justification for each appealed data element classified during the validation process as a mismatch. We stated that we would review the data elements that were labeled as mismatched, as well as the written justifications provided by the hospitals, and make a decision on the reconsideration request. However, we wish to clarify that this would not be a re-abstraction, but a review of the hospital's justification and the medical record for each appealed mismatching data element. The intent of this proposal is for us to have all of the information necessary to review a request for reconsideration based on the hospital's validation results.

Comment: One commenter asked for clarification about two possible situations that could arise under CMS' proposal to review paper medical records as part of the reconsideration process (when the issue is validation):

1. *Hospital fails to return one or more medical records to the CDAC contractor for the quarterly validation request within the 45 calendar day timeframe.*

There are no CDAC contractor-abstracted data elements for the reconsideration contractor to review, except for medical records returned after the 45 calendar day deadline. Would the hospital be allowed to submit medical records during reconsideration to receive credit for information submitted to the CDAC contractor after the quarterly validation 45 day deadline? If not, would the reconsideration contractor's review be limited in scope to the CDAC contractor's original documentation that verifies contact with the hospital as outlined in this regulation, and documents that the CDAC contractor did not receive the requested medical records in the required timeframe (for example, reconsideration limited to data and hospital receipt of CDAC contractor's request for medical records, written reminder notes, and CDAC contractor's non-receipt of medical records).

2. *Hospital receives one or more "invalid record selection" zero scores for failing to provide the correct medical record for the requested episode of care.* Invalid record selections occur when the hospital submits medical record(s) that do not match the requested patient episode of care's admission date, discharge date, name or other hospital submitted identification information, and/or birthdate/birth year. Would the reconsideration contractor abstract medical records for these "invalid records," or would the reconsideration contractor and CMS simply review the electronic submitted data, relative to the hospital submitted data to the CDAC contractor in response to the original medical record request?

In both scenarios, the commenter argued that hospitals would attempt to circumvent the CDAC contractor validation process and submit medical records to the reconsideration process. The commenter recommended that CMS limit the scope of RHQDAPU program reconsideration review for validation to verification of CDAC contractor processing, and not circumventing the validation process to allow reconsideration contractor abstraction of these nonreturned and "invalid record selection" cases that receive zero validation scores. The commenter indicated that CMS should spend its dollars wisely and create processes that do not allow hospitals to bypass existing and expensive quarterly validation processes.

Response: We appreciate the comment. Our intent is to provide hospitals a process to request our reconsideration review of mismatched data elements abstracted by the CDAC

contractor affecting the hospitals' validation scores. Hospitals must submit a copy of the entire requested medical record to the CDAC contractor during the quarterly validation process for the requested case to be eligible for reconsideration of mismatched data elements. Our review of medical records that we classify as not matching what was requested by the CDAC contractor (called "invalid record selections") will initially be limited to ascertaining whether the copy of the record submitted to the CDAC contractor was actually an entire copy of the requested medical record. If we determine during reconsideration that the hospital did submit the entire copy of the requested medical record to the CDAC contractor, then we would abstract data elements from the medical record submitted by the hospital along with its reconsideration request.

We would also review the hospital's justification for medical records not returned in a timely manner to ascertain whether the CDAC contractor received the requested record within 45 calendar days, and whether the hospital received the initial medical record request and reminder notice as specified in this regulation. If we determine during reconsideration that the CDAC contractor did receive a paper copy of the requested medical record within 45 calendar days, then we would abstract data elements from the medical record submitted by the hospital along with its reconsideration request.

After reviewing the public comments we received, we are adopting as final the proposed RHQDAPU program reconsideration requirements for FY 2010. However, we wish to clarify the following regarding the scope of our review when a hospital requests reconsideration because it failed our validation requirements:

1. *Hospital requests reconsideration for CDAC contractor-abstracted data elements classified as mismatches affecting validation scores.* Hospitals must timely submit a copy of the entire requested medical record to the CDAC contractor during the quarterly validation process for the requested case to be eligible to request reconsideration of mismatched data elements.

2. *Hospital requests reconsideration for medical record copies submitted during the quarterly validation process and classified as invalid record selections.* Invalid record selections are defined as medical records submitted by hospitals during the quarterly validation process that do not match the patient's episode of care information as determined by the CDAC contractor (in other words, the contractor determines

that the hospital returned a medical record that is different from that which was requested). If the CDAC contractor determines that the hospital has submitted an invalid record selection case, it awards a zero validation score for the case because the hospital did not submit the entire copy of the medical record for that requested case. During the reconsideration process, our review of invalid record selections will initially be limited to determining whether the record submitted to the CDAC contractor was actually an entire copy of the requested medical record. If we determine during reconsideration that the hospital did submit the entire copy of the requested medical record, then we would abstract data elements from the medical record submitted by the hospital along with its reconsideration request.

3. *Hospital requests reconsideration for medical records not submitted to the CDAC contractor within the 45 calendar day deadline.* Our review will initially be limited to determining whether the CDAC contractor received the requested record within 45 calendar days, and whether the hospital received the initial medical record request and reminder notice as specified in this regulation. If we determine during reconsideration that the CDAC contractor did receive a paper copy of the requested medical record within 45 calendar days, then we would abstract data elements from the medical record submitted by the hospital along with its reconsideration request.

In sum, we are initially limiting the scope of our reconsideration reviews involving validation to information already submitted by the hospital during the quarterly validation process, and we will not abstract medical records that were not submitted to the CDAC contractor during the quarterly validation process. We will expand the scope of our review only if we find during the initial review that the hospital correctly and timely submitted the requested medical records. In that case, then we would abstract data elements from the medical record submitted by the hospital along with its reconsideration request.

After consideration of the public comments we received, we are adopting as final, with the clarifications outlined in this final rule, our proposals regarding reconsideration and appeals procedures for the FY 2010 payment determination.

10. RHQDAPU Program Withdrawal Deadlines

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24181), we

proposed to accept RHQDAPU program withdrawal forms for the FY 2011 payment determination from hospitals until August 15, 2010. We proposed this deadline so that we would have sufficient time to update the FY 2011 payment to hospitals starting on October 1, 2010. If a hospital withdraws from the program for the FY 2011 payment determination, it will receive a 2.0 percentage point reduction in its FY 2011 annual payment update. We noted that once a hospital has submitted a Notice of Participation form, it is considered to be an active RHQDAPU program participant until such time as the hospital submits a withdrawal form to CMS.

We did not receive any public comments about our proposal. Therefore, we are adopting as final our proposal to accept RHQDAPU program withdrawal forms for the FY 2011 payment determination from hospitals until August 15, 2010.

11. Electronic Health Records

a. Background

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of 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.

In the FY 2008 IPPS final rule with comment period (72 FR 47366), we responded to comments we received on EHRs and noted that CMS planned to continue participating in the American Health Information Community (which has now sunset and is replaced by the National eHealth Collaborative) and other entities to explore processes through which an EHR could speed the collection of data and minimize the resources necessary for quality reporting.

Recently, we initiated work directed toward enabling EHR submission of quality measures through EHR standards development and adoption. We are working under an inter-agency agreement between CMS and the Office

of the National Coordinator for Healthcare Information Technology (ONC) to identify and harmonize standards for the EHR-based submission of Emergency Department Throughput measures, Stroke measures, and Venous Thromboembolism measures. These measures have received NQF endorsement and are potential measures for future inclusion in the RHQDAPU program. Pursuant to this agreement, the Healthcare Information Technology Standards Panel (HITSP) has been tasked with harmonizing the EHR data element standards for the measure sets. The work for these three measure sets began in September 2008 and is due to be completed in a little more than 1 year. It is expected that interoperable standards will be developed and fully vetted by October 2009. When HITSP posts the standards, we anticipate that EHR vendors will be able to code their EHR systems with the new specifications and begin collecting this data electronically. We expect that these standards will be provided to its Certification Commission for Healthcare Information Technology (CCHIT) for inclusion in the criteria for certification of inpatient EHRs.

b. EHR Testing of Quality Measures Submission

As we have previously stated, we are interested in the reporting of quality measures using EHRs, and we continue to encourage hospitals to adopt and use EHRs that conform to industry standards. We believe that the testing of EHR submission is an important and necessary step to establish the ability of EHRs to report clinical quality measures and the capacity of CMS to receive such data.

Through CMS' interagency agreement with ONC previously described, the interoperable standards for EHR-based submission of the Emergency Department (ED) Throughput, Stroke, and Venous Thromboembolism (VTE) measures are scheduled to be finalized in late 2009 and will be available for review and testing. We anticipate testing the components required for the submission of clinical quality data extracted from EHRs for these measures, and are exploring different mechanisms and formats that will aid the submission process, as well as ensure that the summary measure results extracted from the EHRs are reliable. When the interoperable EHR-based submission standards become available, EHR vendors will be able to employ them in EHR systems and begin testing how they facilitate the electronic collection of these data. We intend to follow similar processes and procedures to those we

are using for the PQRI EHR testing being conducted as described in the CY 2009 Medicare Physician Fee Schedule final rule with comment period (73 FR 69828 through 69830).

We anticipate moving forward with testing CMS' technical ability to accept data from EHRs for the ED, Stroke, and VTE measures as early as July 1, 2010. Pursuant to the Paperwork Reduction Act, prior to the beginning of testing EHR-based data submission, we will publish a **Federal Register** notice seeking public comments on the process we intend to follow to select EHR vendors/hospitals and the methodology we plan to use for testing EHR-based data submissions.

The test measures described above are not currently required under the RHQDAPU program. As long as that remains the case, EHR test data that is received for these measures will not be used to make RHQDAPU program payment decisions. In addition, the posting of the electronic specifications for any particular measure should not be interpreted as a signal that we intend to select the measure for inclusion in the RHQDAPU program measure set.

We intend to select several EHR vendors/hospitals to develop and test EHR clinical quality data submission. EHR vendors/hospitals that wish to participate in the development and testing process will be able to self-nominate by sending a letter of interest to: "RHQDAPU Program IT Testing Nomination", Centers for Medicare and Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3-02-01, Baltimore, MD 21244-8532. The letter must be received by CMS by 6 p.m., E.S.T. on December 31, 2009. Vendors/hospitals will be selected based on the following criteria: (1) They are able to submit clinical EHR data using interoperability standards such as Cross Document Sharing (XDS), Cross Community Access (XCA), Clinical Data Architecture (CDA), and Health Level 7 Version 3 to a CMS-designated clinical data repository; and (2) they have established or have applied for a QualityNet account. More information regarding these capabilities will be made available on the Hospital Quality Initiative section of the CMS Web site at: <https://www.cms.hhs.gov/HospitalQualityInits/>. Preference may be given to EHR vendors/hospitals that utilize EHRs that are currently certified by the CCHIT, use the National Health Information Network (NHIN), and/or utilize Health Information Technology Standards Panel (HITSP)/Integrating the

Healthcare Environment (IHE) standards.

EHR vendors/hospitals that would like to test the submission of inpatient EHR data to the CMS-designated clinical data repository should update their EHR products or otherwise ensure that those products can capture and submit the necessary data elements identified for an EHR-based submission once the standardized format has been determined. We suggest that these entities begin submitting EHR data promptly after CMS announces that the clinical data repository is ready to accept such data so that problems that may complicate or preclude a successful quality measure data submission can be corrected.

In the FY 2010 IPPS/RV 2010 LTCH PPS proposed rule (74 FR 24182), we welcomed comments on this discussion of EHR-based data submission testing.

Comment: A number of commenters supported voluntary EHR testing, the creation of uniform data content standards, and the concept of reducing the burden to hospitals through automated data transmission via EHR products. The commenters applauded CMS for EHR testing and for working to expand quality data submission to include electronic formats. The commenters also commended CMS for working with ONC to establish electronic standards for ED, Stroke and VTE quality measures. The commenters urged CMS to ensure the scientific integrity of the electronic standards and resulting measures, and encouraged CMS to work closely with NQF's Health IT Expert Panel (HITEP) and to incorporate HITSP standards for measures. Some commenters urged CMS to conduct EHR testing for measures that have already been adopted into the RHQDAPU program as well. However, one commenter stated that the timelines suggested in the proposed rule do not take into account the realities faced by hospitals.

Response: We appreciate these supportive comments regarding voluntary EHR testing, and acknowledge the challenges faced by many hospitals in adopting EHRs at this time. We will continue to work with standard setting organizations toward standardization of data elements for quality measures in EHRs. A voluntary EHR-based data submission testing process would be initiated at such time as CMS systems are able to support it. Hospitals would not be required to participate in this testing process, but would do so voluntarily. We decided to begin EHR testing with non-implemented measures. However, we plan to create electronic formats for measures already

adopted for the RHQDAPU program as well.

We thank the commenters for their suggestions and will take these comments into consideration as we move forward with voluntary EHR testing. We will announce further details regarding this voluntary testing program in a separate **Federal Register** notice.

c. HITECH Act EHR Provisions

On February 17, 2009, the President signed into law the ARRA, Public Law 111–5. 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 the following three requirements: Meaningful use of certified EHR technology; electronic exchange of health information; and reporting on measures using certified EHR technology (provided the Secretary has the capacity to receive such information electronically). With respect to this requirement, under section 1886(n)(3)(A)(ii) 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 RHQDAPU 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. Any measures must be proposed for public comment prior to their selection, except in the case of measures previously selected for the RHQDAPU program under section 1886(b)(3)(B)(viii) of the Act.

Thus, the RHQDAPU program and the HITECH Act have important areas of overlap and synergy with respect to the reporting of quality measures using EHRs. We believe the financial incentives under the HITECH Act for the adoption and meaningful use of certified EHR technology by hospitals will encourage the adoption and use of certified EHRs for the reporting of clinical quality measures under the RHQDAPU program. Further, these efforts to test the submission of quality data through EHRs may provide a foundation for establishing the capacity of hospitals to send, and for CMS to

receive, quality measures via hospital EHRs for future RHQDAPU program measures. We again note that the provisions in this final rule do not implicate or implement any HITECH statutory provisions. Those provisions will be implemented in a future rulemaking.

B. Medicare-Dependent, Small Rural Hospitals (MDHs): Budget Neutrality Adjustment Factors for FY 2002-Based Hospital-Specific Rate (§ 412.79(i))

1. Background

Under the IPPS, special payment protections are provided to a sole community hospital (SCH). Section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary) is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations that set forth the criteria that a hospital must meet to be classified as an SCH are located at 42 CFR 412.92. Section 1886(d)(5)(D)(iii)(III) of the Act and the regulations at § 412.109 also provide that certain essential access community hospitals (EACHs) will be treated as an SCH for payment purposes under the IPPS.

Under the IPPS, separate special payment protections also are provided to a Medicare-dependent, small rural hospital (MDH). Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its 1987 cost reporting year or in two of its most recent three settled Medicare cost reporting years). The regulations that set forth the criteria that a hospital must meet to be classified as an MDH are located at 42 CFR 412.108.

Although SCHs and MDHs are paid under special payment methodologies, they are still paid under section 1886(d) of the Act. Like all IPPS hospitals paid under section 1886(d) of the Act, SCHs and MDHs are paid for their discharges based on the DRG weights calculated under section 1886(d)(4) of the Act.

For SCHs, effective with hospital cost reporting periods beginning prior to January 1, 2009, section 1886(d)(5)(D)(i) of the Act (as amended by section 6003(e) of Public Law 101–239 (OBRA 1989)) and section 1886(b)(3)(I) of the Act (as added by section 405 of Public Law 106–113 (BBRA 1999) and further

amended by section 213 of Public Law 106–554 (BIPA 2000) provide that SCHs are paid based on whichever of four statutorily specified rates (listed below) yields the greatest aggregate payment to the hospital for the cost reporting period. For cost reporting periods beginning on or after January 1, 2009, section 122 of Public Law 110–275 (MIPPA 2008) further amended the Act to specify that SCHs will be paid based on a FY 2006 hospital-specific rate (that is, based on their updated costs per discharge from their 12-month cost reporting period beginning during Federal fiscal year 2006), if this results in the greatest payment to the SCH. Therefore, currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment to the hospital for the cost reporting period:

- The Federal rate applicable to the hospital;
- The updated hospital-specific rate based on FY 1982 costs per discharge;
- The updated hospital-specific rate based on FY 1987 costs per discharge;
- The updated hospital-specific rate based on FY 1996 costs per discharge; or
- The updated hospital-specific rate based on FY 2006 costs per discharge.

For purposes of payment to SCHs for which the FY 1996 hospital-specific rate yields the greatest aggregate payment, payments for discharges during FYs 2001, 2002, and 2003 were based on a blend of the FY 1996 hospital-specific rate and the greater of the Federal rate or the updated FY 1982 or FY 1987 hospital-specific rate. For discharges during FY 2004 and subsequent fiscal years, payments based on the FY 1996 hospital-specific rate are based on 100 percent of the updated FY 1996 hospital-specific rate.

Through and including FY 2006, under section 1886(d)(5)(G) of the Act, MDHs are paid based on the Federal rate or, if higher, the Federal rate plus 50 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rates based on FY 1982 or FY 1987 costs per discharge, whichever of these hospital-specific rates is higher. Section 5003(b) of Public Law 109–171 (DRA 2005) amended section 1886(d)(5)(G) of the Act to provide that, for discharges occurring on or after October 1, 2006, MDHs are paid based on the Federal rate or, if higher, the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever of these hospital-specific rates is the highest. Unlike SCHs, MDHs