compared to their own previous performance.

Comment: One commenter argued that because urban safety net hospitals typically serve a diverse patient population, these hospitals are likely to score poorly on the communication dimensions of the HCAHPS survey, and that for this reason, the use of HCAHPS in the Hospital VBP Program would be detrimental to them. Several commenters stated that CMS should distinguish safety net and urban safety net hospitals from other hospitals because of the distinct challenges faced by such hospitals and because such hospitals are disadvantaged by the Hospital VBP Program, particularly the HCAHPS domain.

Response: We thank the commenters for their input. As we discussed in the Hospital Inpatient VBP Program final rule (76 FR 26502), we recognize that urban hospitals, particularly large ones, have historically not performed as well on HCAHPS as rural hospitals. However, our internal studies of HCAHPS results show that hospitals in some urban areas scored in the top 25 percent of hospitals overall. We believe that those results suggest that urban hospitals can achieve high scores under the HCAHPS domain.

''Safety net'' hospital is not an official CMS term or category. However, we are aware of several differing definitions of this term. Employing a definition of ''Safety Net hospital'' created by the AHRQ, we looked into the ability of safety net hospitals to score well on HCAHPS in the Hospital VBP Program. We found 30 hospitals that meet all three of AHRQ's criteria for Safety Net hospital: (1) high Medicaid percentage; (2) high percentage of uncompensated care; and (3) located in a high poverty county. Of these 30 hospitals, 3 hospitals (10 percent) fall in the top 10 percent of all hospitals in terms of projected earned total HCAHPS points for the Hospital VBP Program. This suggests that safety net hospitals can achieve the highest HCAHPS Hospital VBP Program scores and at a similar rate to non-safety net hospitals.

Comment: One commenter requested that CMS publicly report the patient mix characteristics of each hospital, and publicly report the non-patient-mix adjusted HCAHPS scores to allow hospitals to determine the impact of patient-mix adjustment in Hospital VBP Program payments.

Response: We thank the commenter for the suggestion. We currently provide patient-mix adjustment coefficients for HCAHPS measures on our HCAHPS On-Line Web site, *http://www.hcahpsonline.org,* along with

instructions on how hospitals can derive the adjustments that apply to their scores. We will consider the benefits of publicly reporting the patient mix characteristics and the pre- and post-patient-mix adjusted HCAHPS scores of participating hospitals.

C. Hospital Readmissions Reduction Program

1. Background

a. Overview

CMS is committed to promoting high quality health care and improving patient health outcomes. Readmission to a hospital may be an adverse event for patients and many times imposes a financial burden on the health care system. Successful efforts to reduce preventable readmission rates will improve quality of care while simultaneously decreasing costs. Hospitals can work with their communities to lower readmission rates and improve patient care in a number of ways, such as ensuring patients are clinically ready to be discharged, reducing infection risk, reconciling medications, improving communication with community providers responsible for post-discharge patient care, improving care transitions, and ensuring that patients understand their care plans upon discharge.

Many studies have demonstrated the effectiveness of these types of in-hospital and post-discharge interventions in reducing the risk of readmission, confirming that hospitals and their partners have the ability to lower readmission rates.[37][38][39] These types of efforts taken during and after a hospitalization have been shown to be effective in reducing readmission rates in geriatric populations generally,[40][41] as well as for multiple specific conditions. Moreover, such interventions can be cost saving. For example, in the case of

---

[37] Gwadry-Sridhar FH, Flintoft V, Lee DS, Lee H, Guyatt GH: A systematic review and meta-analysis of studies comparing readmission rates and mortality rates in patients with heart failure. Arch Intern Med. 2004;164(21):2315–2320.

[38] McAlister FA, Lawson FM, Teo KK, Armstrong PW.: A systematic review of randomized trials of disease management programs in heart failure. AmJMed. 2001;110(5):378–384.

[39] Krumholz HM, Amatruda J, Smith GL, et al.: Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. J Am Coll Cardiol. 2002;39(1):83–89.

[40] Coleman EA, Parry C, Chalmers S, Min SJ.: The care transitions intervention: Results of a randomized controlled trial. Arch Intern Med. 2006;166:1822–8.

[41] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, Schwartz JS.: Comprehensive discharge planning and home follow-up of hospitalized elders: A randomized clinical trial. JAMA. 1999;281:613–20.

heart failure, improved hospital [42] and post-discharge care,[43][44] including pre-discharge planning,[45][46] home-based follow-up, and patient education,[47][48] have been shown to lower heart failure readmission rates, suggesting that heart failure readmission rates might be reduced if proven interventions were more widely adopted. Financial incentives to reduce readmissions will in turn promote improvement in care transitions and care coordination, as these are important means of reducing preventable readmissions.[49]

In its 2007 ''Report to Congress: Promoting Better Efficiency in Medicare,'' [50] MedPAC noted the potential benefit to patients of lowering readmissions and suggested payment strategies that would incentivize hospitals to reduce these rates. MedPAC identified 7 conditions and procedures that accounted for almost 30 percent of potentially preventable readmissions: Heart failure; chronic obstructive pulmonary disease; pneumonia; acute myocardial infarction; coronary artery bypass graft surgery; percutaneous transluminal coronary angioplasty; and other vascular procedures.

To promote quality of care, CMS developed hospital quality of care

---

[42] Gwadry-Sridhar FH, Flintoft V, Lee DS, Lee H, Guyatt GH.: A systematic review and meta-analysis of studies comparing readmission rates and mortality rates in patients with heart failure. Arch Intern Med. 2004;164(21):2315–2320.

[43] Lappe JM, Muhlestein JB, Lappe´ DL, et al.: Improvements in 1-year cardiovascular clinical outcomes associated with a hospital-based discharge medication program. Ann Intern Med. 2004;141(6):446–453.

[44] Phillips CO, Wright SM, Kern DE, Singa RM, Shepperd S, Rubin HR.: Comprehensive discharge planning with postdischarge support for older patients with congestive heart failure: A metaanalysis [published correction appears in JAMA. 2004;292(9):1022]. JAMA. 2004;291(11): 1358–1367.

[45] Rich MW, Beckham V, Wittenberg C, Leven CL, Freedland KE, Carney RM.: A multi disciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. N Engl J Med. 1995;333(18):1190–1195.

[46] Schneider JK, Hornberger S, Booker J, Davis A, Kralicek R.: A medication discharge planning program: Measuring the effect on readmissions. Clin Nurs Res. 1993;2(1):41–53.

[47] Koelling TM, Johnson ML, Cody RJ, Aaronson KD.: Discharge education improves clinical outcomes in patients with chronic heart failure. Circulation. 2005;111(2):179–185.

[48] Krumholz HM, Amatruda J, Smith GL, *et al.:* Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. J Am Coll Cardiol. 2002;39(1):83–89.

[49] Coleman EA.: 2005. Background Paper on Transitional Care Performance Measurement. Appendix I. In: Institute of Medicine, Performance Measurement: Accelerating Improvement. Washington, DC: National Academy Press.

[50] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare; 2007. Available at *http://www.medpac.gov/documents/Jun07_EntireReport.pdf.* Accessed January 10, 2011.

measures that compare patient outcomes across different hospitals. These measures, including hospital risk-standardized readmission measures for Acute Myocardial Infarction (AMI), Heart Failure (HF) and Pneumonia (PN), were originally developed for public reporting as a part of the Hospital IQR Program. We adopted the HF readmission measure for the Hospital IQR Program in the FY 2009 IPPS final rule for the FY 2010 payment determination (73 FR 48606) and the AMI and PN readmission measures in the CY 2009 OPPS/ASC final rule with comment period for the FY 2010 payment determination (73 FR 68781). Details about the methodology used for these measures may be found on the Web site at: *http://www.qualitynet.org/ dcs/ContentServer?c=Page&pagename= QnetPublic%2FPage%2FQnetTier4& cid=1219069855841.*

As described above, readmission rates are important markers of quality of care, particularly of the care of a patient in transition from an acute care setting to a non-acute care setting, and improving readmissions can positively influence patient outcomes and the cost of care. The above hospital risk-standardized readmission measures are endorsed by the National Quality Forum (NQF) and have been publicly reported on *Hospital Compare* Web site since 2009 (*http:// www.hospitalcompare.hhs.gov*) to encourage quality improvement and lower readmission rates. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25928 through 25937), we proposed that the readmission measures for these three conditions be used for the Hospital Readmissions Reduction Program under section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act. Below is a discussion of the proposals we included regarding these measures, the public comments we received regarding these proposals, our response to these public comments, and our final policy decisions.

b. Statutory Basis for the Hospital Readmissions Reduction Program

Section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act, added a new subsection (q) to section 1886 of the Act. Section 1886(q) of the Act establishes the "Hospital Readmissions Reduction Program" effective for discharges from an "applicable hospital" beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions.

In this year's IPPS rulemaking, we address: (i) Those aspects of the Hospital Readmissions Reduction Program that relate to the conditions and readmissions to which the Hospital Readmissions Reduction Program will apply for the first program year beginning October 1, 2012; (ii) the readmission measures and related methodology used for those measures, as well as the calculation of the readmission rates; and (iii) public reporting of the readmission data. Specific information regarding the payment adjustment required under section 1886(q) of the Act will be proposed in next year's IPPS/LTCH PPS proposed rule. Although we did not propose specific policies regarding the payment adjustment under the Hospital Readmissions Reduction Program in the FY 2012 IPPS/LTCH PPS proposed rule, we believe that it is still important to set forth the general framework of the Hospital Readmissions Reduction Program, including the payment adjustment provisions, in order for the public to understand how the measures discussed and finalized in this rulemaking will affect certain hospital payments beginning in FY 2013.

Section 1886(q)(1) of the Act sets forth the methodology by which payments to "applicable hospitals" will be adjusted to account for excess readmissions. Pursuant to section 1886(q)(1) of the Act, payments for discharges from an "applicable hospital" will be an amount equal to the product of the "base operating DRG payment amount" and the adjustment factor for the hospital for the fiscal year. That is, the "base operating DRG payments" are reduced by an adjustment factor that accounts for excess readmissions. Section 1886(q)(1) of the Act requires the Secretary to make payments for a discharge in an amount equal to the product of "the base operating DRG payment amount" and "the adjustment factor" for the hospital in a given fiscal year. Section 1886(q)(2) of the Act defines the base operating DRG payment amount as "the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o) [the Hospital VBP Program]) for a discharge if this subsection did not apply; reduced by * * * any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d)." Paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection(d) refer to outlier payments, IME payments, DSH payments, and payments for low volume hospitals, respectively.

Furthermore, section 1886(q)(2)(B) of the Act specifies special rules for defining "the payment amount that would otherwise be made under subsection (d)" for certain hospitals. Specifically, section 1886(q)(2)(B) of the Act states that "[i]n the case of a Medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal years 2012 and 2013) or a sole community hospital * * * the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5)." We intend to propose regulations to implement the statutory provisions related to the definition of "base operating DRG payment amount" in the FY 2013 IPPS/LTCH PPS proposed rule.

Section 1886(q)(3)(A) of the Act defines the "adjustment factor" for an applicable hospital for a fiscal year as equal to the greater of "(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C)." Section 1886(q)(3)(B) of the Act in turn describes the ratio used to calculate the adjustment factor. It states that the ratio is "equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions * * *; and (ii) the aggregate payments for all discharges * * *." Section 1886(q)(3)(C) of the Act describes the floor adjustment factor, which is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

Section 1886(q)(4) of the Act sets forth the definitions of "aggregate payments for excess readmissions" and "aggregate payments for all discharges" for an applicable hospital for the applicable period. The term "aggregate payments for excess readmissions" is defined in section 1886(q)(4)(A) of the Act as "the sum, for applicable conditions * * * of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the "Excess Readmission Ratio * * * for such hospital for such applicable period minus 1." The "Excess Readmission Ratio" is a hospital-specific ratio based on each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the Excess Readmission Ratio as the ratio of "risk-adjusted readmissions based on actual readmissions" for an applicable hospital

for each applicable condition, to the ''risk-adjusted expected readmissions'' for the applicable hospital for the applicable condition.

Section 1886(q)(5) of the Act provides definitions of ''applicable condition,'' ''expansion of applicable conditions,'' ''applicable hospital,'' ''applicable period,'' and ''readmission.'' The term ''applicable condition,'' which we addressed in detail below in section IV.C.3.a. of this preamble, is defined as a ''condition or procedure selected by the Secretary among conditions and procedures for which: (i) Readmissions * * * represent conditions or procedures that are high volume or high expenditures * * * and (ii) measures of such readmissions * * * have been endorsed by the entity with a contract under section 1890(a) * * * and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).'' The term ''expansion of the applicable condition'' refers to the Secretary's authority, beginning with FY 2015, ''to the extent practicable, [to] expand the applicable conditions beyond the 3 conditions for which measures have been endorsed * * * to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary.''

Section 1886(q)(5)(C) of the Act defines ''applicable hospital,'' that is, a hospital subject to the Hospital Readmissions Reduction Program, as a ''subsection (d) hospital or a hospital that is paid under section 1814(b)(3) [of the Act], as the case may be.'' The term ''applicable period,'' as defined by section 1886(q)(5)(D) of the Act, ''means, with respect to a fiscal year, such period as the Secretary shall specify.'' As explained in the FY 2012 IPPS/LTCH PPS proposed rule and in this final rule, the ''applicable period'' is the period from which data are collected in order to calculate various ratios and adjustments under the Hospital Readmissions Reduction Program.

Section 1886(q)(6) of the Act sets forth the reporting requirements for hospital-specific readmission rates. Section 1886(q)(7) of the Act limits administrative and judicial review of certain determinations made pursuant to section 1886(q) of the Act. Finally, section 1886(q)(8) of the Act requires the Secretary to collect data on readmission rates for all hospital inpatients for ''specified hospitals'' in order to calculate the hospital-specific readmission rates for all hospital inpatients and to publicly report these readmission rates.

2. Implementation of the Hospital Readmissions Reduction Program

a. Overview

We intend to implement the requirements of the Hospital Readmissions Reduction Program in the FY 2012, FY 2013, and future IPPS/LTCH PPS rulemaking cycles.

Comment: A few commenters supported CMS' implementation of the Hospital Readmissions Reduction Program and CMS's implementation approach. One commenter specifically appreciated the phased-in approach for implementation.

Response: We appreciate the commenters' support for the Hospital Readmissions Reduction Program and the phased-in approach we have taken.

Comment: Some commenters urged that, prior to next year's rulemaking in which CMS will discuss and implement the provisions related to the payment adjustment and other outstanding issues, CMS hold a series of stakeholder calls to solicit input in the development of the Hospital Readmissions Reduction Program.

Response: We appreciate the comments on our implementation process of the Hospital Readmissions Reduction Program. We intend to solicit formal public input on our proposal related to the readmissions reduction through rulemaking. In addition, the public can provide input on proposals related to the Hospital Readmissions Reduction Program through the Hospital Open Door Forums calls that we hold periodically to provide hospitals with information on various issues and to listen to questions and concerns from hospitals. The public can find out more information about the Hospital Open Door Forums, including when they will be held, on the CMS Web site: *http://www.cms.gov/OpenDoorForums/18_ODF_Hospitals.asp#TopOfPage.*

Comment: One commenter expressed concern that the Hospital Readmissions Reduction Program's payment adjustments are likely to have a disproportionate impact on rural hospitals.

Response: We appreciate the comment on the impact of the Hospital Readmissions Reduction Program on rural hospitals. We note that we did not propose policies related to the Hospital Readmissions Reduction Program payment adjustment in the proposed rule. Therefore, this comment is outside the scope of the issues addressed in the proposed rule. As discussed in more detail below, we plan to propose policies related to the implementation of the payment adjustment set forth in section 1886(q) of the Act in the FY 2013 IPPS/LTCH PPS proposed rule. We will consider this comment when formulating these policies.

Comment: One commenter stated that the simultaneous implementation of the readmissions reduction measures for AMI, HF, and PN in the Hospital Readmissions Reduction Program and the Hospital IQR Program would cause ''double jeopardy,'' that is, the hospital would be penalized twice for care provided to the same patients.

Response: While the readmissions measures that we proposed for the Hospital Readmissions Reduction Program are also part of the Hospital IQR Program, hospitals are not assessed under the Hospital IQR Program based on their performance on the measures. Rather, under the Hospital IQR Program, hospitals are only required to participate in the program and to report the measure in order to avoid a payment reduction, regardless of their performance on the reported measures. Moreover, the readmission measures included in the Hospital IQR Program are not eligible to be included in the Hospital VBP Program. In the case of the three proposed NQF-endorsed 30-day risk standardized readmissions measures for AMI, HF, and PN, no additional information is required of hospitals because we use information that is already submitted on Medicare Part A and Part B claims for payment purposes. The Hospital Readmissions Reduction Program includes a payment adjustment based on the hospital's performance with regard to the claims-based readmissions measures. Therefore, in this situation, we do not believe hospitals will be penalized twice based on the same readmissions measures. However, we intend to monitor any potential interactions that the Hospital Readmissions Reduction Program may have with other programs. We anticipate implementing the readmissions payment adjustment through future rulemaking.

Comment: One commenter expressed concern about a number of potential unintended consequences that could result from the Hospital Readmissions Reduction Program, including premature discharge of patients, providers avoiding certain types of patients who are more ill or complicated and therefore likely to be readmitted. Another commenter suggested that the Hospital Readmissions Reduction Program resulted in increased pressure on emergency physicians not to readmit

patients within the 30-day window. This commenter also expressed concerns that physicians in emergency departments do not have access to the patient's record if they have had a recent inpatient stay at another hospital.

Response: We appreciate the commenters pointing out these potential unintended consequences of the Hospital Readmissions Reduction Program. As part of our implementation of the Hospital Readmissions Reduction Program, we will monitor trends to determine if there are unintended consequences of the policy, such as systematic shifting, diversion, and delays in care, in order to assess and take appropriate action to minimize any such unintended consequences.

Comment: One commenter stated that it is important to ensure that transplant centers are not unduly penalized by the Hospital Readmissions Reduction Program, when transplant patients are readmitted for infections caused by the transplantation of organs from marginal donors.

Response: The three applicable conditions for readmission measures only apply to patients discharged with a primary diagnosis code for AMI, HF, and PN, and do not apply to transplant patients who have contracted infections from the transplantation of infected organs. Therefore, patient admissions for transplants and corresponding discharges with those primary codes are not included in the index hospitalizations counted for these measures. However, if a transplant recipient is subsequently admitted with AMI, HF or PN and is readmitted within 30 days, the readmission would be included in the readmissions methodology. Therefore, we do not believe that transplant centers would be disproportionately penalized by the Hospital Readmissions Reduction Program.

Comment: One commenter stated that it is important for hospitals to be able to track patients who are subsequently admitted to other hospitals and requested that CMS develop patient identifiers that would allow for this tracking. Two commenters stated that hospitals need a mechanism to track and understand patient readmissions in real time.

Response: We recognize the value in being able to track patients' readmissions to other hospitals real time both for a hospital's internal quality improvement purpose, and for validating our readmission measure criteria. We thank the commenters for their suggestions, and we will consider whether it is operationally possible to provide these data to hospitals and

whether sharing these data would be consistent with patient privacy considerations.

Comment: One commenter recommended that CMS provide hospitals with their expected readmission ratio and actual readmission counts on a quarterly basis, as well as claims data for the prior 12 months for any readmission attributed to them.

Response: To provide the measures quarterly, including the expected readmission rates and the actual counts of readmissions, is resource intensive. We thank the commenters for their suggestions and will consider them if resources allow us to do so in the future. The readmission measures are calculated using the data from the claims that hospitals submitted to CMS for payment. Therefore, hospitals should have access to at least their own facility's patient claims data for the prior 12 months for any readmission attributed to them.

We thank the commenters for these suggestions. We will consider whether it is operationally possible to provide hospitals with these measures quarterly and the patient data for any readmission attributed to the hospitals. In addition we will look into whether sharing these patient data would be consistent with patient privacy considerations.

Comment: Two commenters requested that data be made available to advocacy and watchdog organizations so that the proposed measures can be replicated and validated independently prior to the end of the comment period. One commenter recommended that CMS' calculations, including its methodology for all risk adjustments and how it calculates hospital-specific observed and expected rates be made available to the public so that CMS' work can be replicated and verified.

Response: We have made the methodology reports for risk-adjusting the proposed measures and the software (in SAS format) to calculate the measures publicly available through *https://www.Qualitynet.org.* However, because of the comparative nature inherent to the calculating the measures, we note that the statistical models used to calculate the measures require data from all applicable hospitals, and cannot be replicated using only a single hospital's data. With regard to providing data to advocacy and watchdog groups for independent validation, we have provided the downloadable files on the *Hospital Compare* Web site. The downloadable files contain the aggregate-level data that we publicly reported. As we noted above, we will consider whether it is operationally

possible to provide additional data to third parties and whether sharing these data would be consistent with patient privacy considerations.

b. Provisions in the FY 2012 IPPS/LTCH PPS Final Rule

As explained above, the adjustment factor set forth in section 1886(q) of the Act does not apply to discharges until FY 2013. Therefore, we are able to implement the Hospital Readmissions Reduction Program over two years. We are first addressing issues such as the selection of readmission measures and the calculation of the Excess Readmission Ratio, which will then be used, in part, to calculate the readmission payment adjustment factor. Specifically, in the FY 2012 IPPS/LTCH PPS proposed rule and in this final rule, we addressed portions of section 1886(q) of the Act related to the following provisions:

• Selection of applicable conditions;
• Definition of "readmission;"
• Measures for the applicable conditions chosen for readmission;
• Methodology for calculating the Excess Readmission Ratio;
• Public reporting of the readmission data; and
• Definition of "applicable period."

With respect to the topics of "measures for readmission" for the applicable conditions, and "methodology for calculating the Excess Readmission Ratio," we are specifically addressing the following:

• Index hospitalizations;
• Risk Adjustment;
• Risk Standardized Readmission Rate;
• Data sources; and
• Exclusion of Certain Readmissions.

c. Provisions To Be Included in the FY 2013 IPPS/LTCH PPS Proposed Rule

In the FY 2013 IPPS/LTCH PPS rulemaking, we will address the provisions in section 1886(q) of the Act that are related to the payment adjustment, as well as the rest of the provisions in section 1886(q) of the Act that are not addressed in the FY 2012 IPPS/LTCH PPS rulemaking. Specifically, in the FY 2013 IPPS/LTCH PPS proposed rule, we plan to address section 1886(q) of the Act related to the following provisions:

• Base operating DRG payment amount, including policies for SCHs and MDHs;
• Adjustment factor (both the ratio and floor adjustment factor);
• Aggregate payments for excess readmissions;
• Applicable hospital.

We believe it is appropriate to first address the readmission measures and

the calculation of the Excess Readmission Ratio that will be used, in part, to calculate the readmission payment adjustment factor and the application of the readmission payment adjustment factor to inpatient hospital payments. We believe the 2-year rulemaking schedule provides adequate time and opportunities for careful consideration of the various aspects of the Hospital Readmissions Reduction Program by both CMS and stakeholders prior to implementation of the Hospital Readmissions Reduction Program in FY 2013.

Comment: One commenter asked that cancer hospitals payment based on limits set by the Tax Equity and Fiscal Responsibility Act of 1982 be exempt from the Hospital Readmissions Reduction Program.

Response: We appreciate the comment, but we note that this comment is not within the scope of the proposals in the FY 2012 IPPS/LTCH PPS proposed rule regarding the Hospital Readmissions Reduction Program. In the proposed rule, we noted that we plan to address the provisions of section 1886(q)(5)(C) of the Act related to the definition of ''applicable hospital'' in the FY 2013 IPPS/LTCH PPS proposed rule.

Comment: Several comments addressed the payment adjustment under section 1886(q) of the Act. One commenter expressed appreciation that the readmission payment adjustment factor would not be applied to Medicare DSH, IME, or outlier payments. Some commenters believed that the readmission payment adjustment factor should only be applied to discharges following readmissions and not all discharges. Other commenters believed that the formula set forth in the statute to calculate the aggregate payments due to excess readmissions would result in a payment penalty that is too severe. Commenters also stated that the formula to calculate the aggregate payments due to excess readmissions should be the product of the Excess Readmission Ratio, the average base DRG operating payment, and the expected number of readmissions, rather than the current statutory language that defines aggregate payments for excess readmissions as the product of the total number of admissions for the condition, the average base DRG payment for the condition, and the Excess Readmission Ratio.

Commenters also stated that the statutory formula is inconsistent and combines quantities that are not comparable because the Excess Readmission Ratio is based on the ratio of risk-adjusted actual readmissions to risk-adjusted expected readmissions and that ratio, which is based on readmissions, is applied to the total number of admissions. Commenters believed that the statutory formula is contrary to Congressional intent, because the monetary savings if the formula were implemented consistent with the statute is far greater than the CBO score of the provision. Commenters suggested that CMS adopt a less literal and rigid interpretation of the statute or seek a technical amendment to the law.

Response: We appreciate the comments on the readmission payment adjustment factor, but we again note that we did not propose policies related to the Hospital Readmissions Reduction Program payment adjustment in the proposed rule. Therefore, these comments are not within the scope of issues discussed in the FY 2012 IPPS/LTCH PPS proposed rule. We will consider these comments when formulating policies related to the Hospital Readmissions Reduction Program payment adjustment in next year's IPPS/LTCH PPS rulemaking.

d. Expansion of the Applicable Conditions To Be Included in the Future Rulemaking

Pursuant to section 1886(q)(5)(B) of the Act, beginning in FY 2015, the Secretary ''shall, to the extent practicable,'' expand the list of applicable conditions for the Hospital Readmissions Reduction Program beyond the three conditions described in section 1886(q)(5)(A) of the Act to include additional conditions that have been identified by MedPAC as high cost or high volume in its 2007 Report to Congress, as well as other conditions as determined appropriate by the Secretary. We plan to implement this provision of the Hospital Readmissions Reduction Program in future rulemaking.

Comment: A few commenters expressed support for the future expansion of applicable conditions for the Hospital Readmissions Reduction Program. One commenter requested that CMS consider some often undertreated clinical conditions that commonly afflict hospital patients (such as disorders associated with abnormal sodium level). Some commenters urged CMS to provide details about expansion of the applicable conditions soon so that they can begin interventions to improve readmissions for these conditions.

Response: We appreciate the commenters' support and their proactive approach to reduce hospital readmissions. We will take these suggestions into account as we continue to implement the Hospital Readmissions

Reduction Program in the future. We plan to consider the remaining four conditions that accounted for almost 12 percent of potentially preventable readmissions as identified by the MedPAC in its 2007 ''Report to Congress'' as well as other conditions as determined appropriate by the Secretary.[51]

Comment: One commenter stated that complying with the Hospital Readmissions Reduction Program measure requirements and concurrently undergoing the adoption of EHR technology is overwhelming. The commenter requested delaying the expansion of applicable conditions until after 2015, when the EHR transition is projected to be complete.

Response: We appreciate the commenter's concerns. The Secretary is authorized under section 1886(q)(5)(B) of the Act to expand the list of applicable conditions beginning in FY 2015. Therefore, we believe hospitals would have sufficient time to prepare to address both the HITECH EHR Incentive Program and the Hospital Readmissions Reduction Program. We will collaborate with stakeholders to assess the impact of expanding the list of applicable conditions as 2015 approaches.

Comment: Another commenter suggested that, if CMS were to adopt the Healthcare Associated Infection (HAI) measure of Clostridium *Difficile* infection proposed for the Hospital IQR Program, it should consider adopting a readmission measure for Clostridium *Difficile* infection for the Hospital Readmissions Reduction Program for FY 2013 or a subsequent year because doing so would help to achieve the goals of the HHS Action Plan to Prevent HAIs.

Response: We appreciate the commenter's suggestion. However, we want to clarify that there is currently no NQF-endorsed readmission measure that covers the condition of Clostridium *Difficile* infection that could have been considered as an applicable condition for FY 2013. For the FY 2013 payment determination for the Hospital Readmissions Reduction Program, we are required to adopt NQF-endorsed measures for the high cost/high expenditure conditions that are selected.

For the Hospital IQR Program, we proposed and are finalizing the clostridium *Difficile* infection measure that was listed among the targeted metrics in the HHS Action Plan to Prevent HAIs, and we believe that doing

[51] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare; 2007. Available at *http://www.medpac.gov/documents/Jun07_EntireReport.pdf*. Accessed January 10, 2011.

so will further the goals of the Action Plan. In the future, should this condition meet the statutory criteria and should a readmission measure for the condition be established that also meets the statutory criteria, we will consider it for future expansion of the Hospital Readmissions Reduction Program in accordance with the applicable condition requirements set forth in section 1886(q)(5) of the Act.

3. Provisions for the Hospital Readmissions Reduction Program

a. Applicable Conditions for the FY 2013 Hospital Readmissions Reduction Program

Section 1886(q) of the Act sets forth payment adjustments for applicable hospitals to account for excess readmissions, for applicable conditions, that are high volume or high expenditure, in the hospital. These payment adjustments are determined based on the occurrence of readmissions for ''applicable conditions.'' When selecting ''applicable conditions,'' the Secretary must select among conditions and procedures for which (1) readmissions are ''high volume or high expenditure''; and (2) ''measures of such readmissions'' have been endorsed by the entity with a contract under section 1890(a) of the Act'' (currently NQF) and (3) such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).'' Consistent with these requirements, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25931), we proposed to include AMI, HF, and PN as ''applicable conditions'' for the FY 2013 Hospital Readmissions Reduction Program. As set forth below, we believe these conditions meet the criteria for ''applicable conditions'' under section 1886(q)(5)(A) of the Act. We also note that in MedPAC's 2007 Report to Congress that we discussed in section IV.C.1.a. of this preamble, MedPAC listed three conditions (AMI, HF, and PN) as priorities for hospital-specific public reporting of readmission rates.

With regards to the first criterion, that readmissions of ''applicable conditions'' be ''high volume or high expenditure,'' MedPAC identified AMI, HF, and PN as being among the seven conditions and procedures associated with approximately 30 percent of potentially preventable readmissions, based on an 3M analysis conducted for MedPAC of 2005 MedPAR (Medicare FFS hospital claims). Of these seven conditions and procedures, HF and PN were the highest in terms of volume and expenditures.

In addition, in our analysis of the 235 diagnostic categories for hospitalization based on 2008 Medicare hospital claims data, HF and PN were first and second, respectively, as the most frequent diagnostic category for both total admissions and total readmissions. AMI was ninth among the 235 conditions in terms of frequency of admission and 8th in frequency of readmission. Therefore, we believe that AMI, HF and PN consitute high volume and high expenditure conditions particularly as this term relates to hospital admission and readmission.

With regards to the second criterion, we believe that measures of readmissions for these applicable conditions also meet the statutory requirements. Section 1886(q)(5)(A)(ii) of the Act requires that each ''applicable condition'' have ''measures of readmissions'' that ''(I) have been endorsed by the entity with a contract under section 1890(a) [of the Act]; and (II) such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).'' As discussed in section IV.C.3.c. of this preamble, we believe selecting AMI, HF, and PN as ''applicable conditions'' is consistent with this statutory requirement. The NQF (the entity with a contract under section 1890(a) of the Act) has endorsed ''measures of readmissions'' for each of these three conditions, and those NQF-endorsed measures ''have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).''

We believe AMI, HF, and PN meet both prongs of the definition of ''applicable condition.'' Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to include AMI, HF, and PN as ''applicable conditions'' for the Hospital Readmissions Reduction Program for FY 2013. We invited public comment on this proposal.

Comment: One commenter encouraged CMS to carefully review and address the selection of applicable conditions. One commenter urged CMS to exercise caution in implementing financial incentives to reduce readmission of patients for pneumonia and COPD because of the clinical variability and uncertainty involving the effectiveness of interventions for such patients.

Response: We note that we did not propose a COPD-based measure in the FY 2012 IPPS/LTCH PPS proposed rule, but we will take the comment into consideration should we consider

proposing COPD as an applicable condition in future rulemaking. In the case of pneumonia, we note that studies suggest optimal care for pneumonia during the index hospitalization may reduce the risk of subsequent readmission.[52][53] Furthermore, as we discussed above, pneumonia meets all of the statutory criteria to be included as a readmissions measure for the Hospital Readmissions Reduction Program for FY 2013.

As we discussed in the proposed rule, we believe the three applicable conditions that we have selected for the Hospital Readmissions Reduction Program for FY 2013 meet the stringent selection criteria as laid out in the statute and are conditions for which hospital interventions can lead to reduced readmissions. Specific interventions evaluated under the QIO 9th Statement of Work for reducing readmissions are listed at: *http://www. cfmc.org/caretransitions/files/toolkit/ intervention/QIO%20Developed% 20Tools/Interventions_by_Driver_ 031011.pdf.* We believe these three applicable conditions are most appropriate for the Hospital Readmissions Reduction Program.

Comment: One commenter stated that using only three applicable conditions in the FY 2013 Hospital Readmissions Reduction Program will create opportunities for gaming.

Response: We believe that the commenter was suggesting that hospitals might change coding practices to avoid identifying patients with AMI, HF, or PN. We plan to monitor trends in admissions and readmissions to ensure there no systematic shift in patients' primary discharge diagnoses codes occurs as a result of implementation of the Hospital Readmissions Reduction Program.

After consideration of the public comments we received, we are finalizing the proposed applicable

[52] Dean NC, Bateman KA, Donnelly SM, *et al.* 2006. Improved clinical outcomes with utilization of a community-acquired pneumonia guideline. Chest 130(3):794–799.

[53] Gleason PP, Meehan TP, Fine JM, *et al.* 1999. Associations between initial antimicrobial therapy and medical outcomes for hospitalized elderly patients with pneumonia. Arch Intern Med 159(21):2562–2572.

[54] Benbassat J, Taragin M. 2000. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Intern Med 160(8):1074–1081.

[55] Benbassat J, Taragin M. 2000. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Intern Med 160(8):1074–1081.

[56] Jonas M, Grossman E, Boyko V, *et al.* 1999. Relation of early and one-year outcome after acute myocardial infarction to systemic arterial blood pressure on admission. Am J Cardiol 84:162–165.

conditions of AMI, HF, and PN for use in the Hospital Readmissions Reduction Program for FY 2013.

b. Definition of "Readmission"

Section 1886(q)(5)(E) of the Act defines "readmission" as, "in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge." The definition further states that "[i]nsofar as the discharge relates to an applicable condition for which there is an endorsed measure * * * such time period (such as 30 days) shall be consistent with the time period specified for such measure."

The three NQF-endorsed readmission measures define a readmission as occurring when a patient is discharged from the applicable hospital to a non-acute setting (for example, home health, skilled nursing, rehabilitation or home) and then is admitted to the same or another acute care hospital within a specified time period from the time of discharge from the index hospitalization (*http://www.qualitynet.org/dcs/Content Server?c=Page&pagename= QnetPublic%2FPage%2FQnetTier4 &cid=1219069855841*. The time period specified for these measures is 30 days. Because the measures as endorsed by NQF are calculated based on readmissions occurring within 30 days, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25931 through 25932), we proposed 30 days as the time period specified from the date of discharge for the purpose of defining readmission for the Hospital Readmissions Reduction Program. The 30-day time period also meets the requirement set forth in section 1886(q)(5)(E) of the Act that the time period specified by the Secretary for defining a readmission be consistent with the time period specified for the endorsed measures. We invited public comment on our proposal to adopt, without revision, a proposed definition of readmission with a time period of 30 days from the date of discharge from the index hospitalization as set forth in the existing NQF-endorsed measures.

Comment: One commenter asked how multiple readmissions will be calculated.

Response: The readmissions measures are designed to measure whether a patient experienced at least one readmission within 30 days of an initial (or "index") discharge as a single binary (yes/no) event, rather than counting the number of readmissions experienced within 30 days of discharge as a

separate readmissions. For any given patient, only the first readmission they have will be counted for the Hospital Readmissions Reduction Program. In addition, only one readmission during the 30 days following the discharge from the initial hospitalization will count as a readmission for purposes of calculating the ratios set forth in section 1886(q) of the Act. For any given patient, none of the subsequent readmissions they experience within 30 days after discharge would be counted as a new "index" admission (that is, an admission evaluated in the measure for a subsequent readmission). Any eligible admission after the 30-day time period will be considered a new index admission.

Comment: One commenter recommended defining "readmission" to mean "readmission to the same hospital" because hospitals cannot control the admitting practices of other institutions.

Response: Section 1886(q)(5)(E) of the Act, as added by the Affordable Care Act, defines "readmission" as "in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital." We do not believe that the commenter's suggestion to limit the definition of readmission to only those readmissions to the same hospital is consistent with the statutory definition of "readmission." The statutory definition, which is consistent with the definition of "readmission" in the NQF-endorsed measures, captures the more than 20 percent of readmissions that occur at a hospital that is different from the hospital where the initial admission took place. We believe this is the appropriate approach. Although hospitals may not have influence over the admitting practices of outside institutions, we believe that hospitals can communicate effectively with post-acute care providers and take other measures that can better prepare a patient for discharge to reduce the risk of readmission.

After consideration of the public comments we received, we are finalizing our proposal to adopt the definition of readmission as occurring when a patient is discharged from the applicable hospital and then is admitted to the same or another acute care hospital within a specified time period from the time of discharge from the index hospitalization.

c. Readmission Measures and Related Methodology

(1) Readmission Measures for Applicable Conditions

As explained above, section 1886(q)(5)(A)(ii) of the Act requires that each "applicable condition" selected by the Secretary has "measures of readmissions" that "have been endorsed by the entity with a contract under section 1890(a) [of the Act]" and that "such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge." In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25932), we proposed to adopt three NQF-endorsed, hospital risk-standardized readmission measures for AMI, HF, and PN which are currently included in the Hospital IQR Program. These existing measures are:

• Acute Myocardial Infarction [AMI] 30-day Risk Standardized Readmission Measure (NQF #0505);

• Heart Failure [HF] 30-day Risk Standardized Readmission Measure (NQF #0330); and

• Pneumonia [PN] 30-day Risk Standardized Readmission Measure (NQF #0506).

CMS adopted these measures for the Hospital IQR Program in the FY 2009 IPPS/LTCH PPS final rule for the FY 2010 payment determination (73 FR 48606) and the CY 2009 OPPS/ASC final rule with comment period (73 FR 68781). The NQF (the entity with a contract under section 1890(a) of the Act) has endorsed each of these "measures of readmissions" and, as explained in more detail below, those NQF-endorsed measures "have exclusions for readmissions that are unrelated to the prior discharge." Therefore, we believe these measures meet the statutory requirements for selection for the Hospital Readmissions Reduction Program, and we proposed them, without modification, as measures for the program.

Comment: Many commenters suggested changes to specific aspects of the three NQF-endorsed 30-day readmission measures for AMI, HF, and PN (for example, exclusions for unrelated readmissions and risk-adjustment of the readmission measures). These comments are summarized and included in the sections of this document that discuss those specific aspects of the measures.

Response: For the FY 2013 Hospital Readmission Reduction Program, the statute requires us to adopt NQF-endorsed measures for the 3 conditions selected. We have proposed to use the three measures as currently NQF endorsed. As we discuss below in the

section regarding NQF endorsement of the measures, we believe that altering specific aspects of the measures that are part of the NQF endorsed methodology (such as exclusions and risk adjustment) would be inconsistent with the statutory requirement to use NQF-endorsed readmission measures.

Comment: One commenter supported CMS' proposal to adopt, without alteration, the three NQF-endorsed 30-day readmission measures for AMI, HF, and PN.

Response: We appreciate the commenter's support of the readmission measures.

After consideration of the public comments we received, we are finalizing three readmission reduction measures for the FY 2013 Hospital Readmissions Reduction Program: AMI 30-day risk standardized readmission measure, HF 30-day risk standardized readmission measure, and PN 30-day risk standardized readmission measure.

(2) NQF Endorsement of Measures of Readmissions

We note that these measures and their underlying methodologies were NQF-endorsed. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25932), we proposed to adopt, for purposes of the Hospital Readmissions Reduction Program, the measures and related methodologies as they are currently endorsed by NQF. This includes the currently endorsed 30-day time window, risk-adjustment methodology, and exclusions for certain readmissions that comprise the measures. We stated our belief that our proposal to adopt, without modification, these measures of readmission is consistent with the statutory language, which requires the measures of readmissions to be "endorsed by the entity with a contract under section 1890(a) [of the Act]." If we were to modify the endorsed measures, we are concerned that they would no longer be considered "endorsed." If the NQF were to later endorse a revised measure for one of these conditions, we would then propose through notice and comment rulemaking that the revised measure be used prospectively for purposes of the Hospital Readmissions Reduction Program.

We welcomed public comment on our proposal to use, for each of the proposed applicable conditions, existing measures as endorsed by the NQF.

We did not receive any public comments specifically on the NQF-endorsement of the three proposed readmission measures. Therefore, we are finalizing the three NQF-endorsed Hospital Readmissions Reduction

Program measures as proposed for the FY 2013 Hospital Readmissions Reduction Program.

(3) Endorsed Measures With Exclusions for Unrelated Readmissions

Section 1886(q)(5)(A)(i)(ii)(II) of the Act requires that each of the readmission measures also have "exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital)." The three NQF-endorsed readmission measures that we proposed in the FY 2012 IPPS/LTCH PPS proposed rule for inclusion in the Hospital Readmissions Reduction Program have exclusions that meet this statutory requirement. Under each measure, certain unrelated readmissions are not taken into account when determining the number of readmissions under the measures.

The AMI 30-day risk standardized readmission measure, as endorsed by the NQF and as proposed in the FY 2012 IPPS/LTCH PPS proposed rule, has exclusions for certain unrelated readmissions. Because admissions for Percutaneous Transluminal Coronary Angioplasty (PTCA) or Coronary Artery Bypass Graft (CABG) may be staged or are typically scheduled readmissions for patients initially admitted for AMI, the AMI 30-day risk standardized readmission measure does not count as readmissions those admissions after discharge that include PTCA or CABG procedures, unless the principal discharge diagnosis for the readmission is one of the following diagnoses that are not consistent with a scheduled readmission: Heart failure, acute myocardial infarction, unstable angina, arrhythmia, and cardiac arrest (that is, readmissions with these diagnoses and a PTCA or CABG procedure are counted as readmissions). We adopted this approach when first developing this measure after consultation with clinical experts, including cardiologists, and review of relevant readmissions data.

During the development of the readmission measures for both HF and PN, we similarly asked clinical experts to identify planned readmissions for these conditions, that is, those which would not count as a readmission, after an admission for HF or PN. Specifically, the clinical experts were asked whether there were common follow-up causes of readmissions for a scheduled procedure that represented a continuation of care after either a HF or PN admission, respectively. No such related, planned procedures were identified as occurring commonly after the index admissions for HF or PN at the time of the development of the Hospital IQR

Program measures. Therefore, no similar exclusions exist for the HF and PN measures of readmissions as they are currently endorsed.

The three NQF-endorsed risk-standardized readmission measures that we proposed in the FY 2012 IPPS/LTCH PPS proposed rule exclude transfers to other acute care facilities from each of the readmission measures. The NQF-endorsed proposed measures consider these multiple contiguous hospitalizations to be a single acute episode of care. The measures attribute the readmission for transferred patients to the hospital that ultimately discharges the patient to a non-acute care setting (for example, to home or a skilled nursing facility). Thus, in the case of a patient who is transferred between two or more hospitals, if the patient is readmitted in the 30 days following the final hospitalization, the measures attribute such a readmission to the hospital that discharged the patient to a non-acute care setting. We believe that the exclusion of transfers to other applicable hospitals under the measures is sufficient to meet the requirement set forth in section 1886(q)(5)(A)(ii)(II) of the Act that certain "unrelated" readmissions be excluded from the measures selected for use in the program.

Comment: Many commenters stated that the current set of existing exclusions for unrelated readmissions did not meet Congress' intent, which they believed requires additional exclusions for certain readmissions. These commenters noted that although the AMI measure contains exclusion for certain planned procedures, neither the heart failure nor the pneumonia measures contain such exclusions.

Response: We thank the commenters for sharing their views on exclusions for the proposed readmission measures. Section 1886(q)(5)(A) of the Act requires us to select as the initial readmission measures those that are endorsed by the entity with a contract under section 1890(a) (currently the NQF), and that have exclusions for readmissions that are unrelated to the prior discharges (such as a planned readmission or transfer to another applicable hospital). The statute does not state that the measures must account for all possible unrelated readmissions. Moreover, adding exclusions would be inconsistent with the statute, which requires us to adopt the measures as endorsed by the NQF, and the endorsements currently include specific exclusions for unrelated readmissions, which include transfers.

We recognize that there could conceivably be additional readmissions

that could properly be excluded from the readmission measures, and we intend to further explore if there are any such readmissions. If we determine that changes should be made to the measures used for the Hospital Readmissions Reduction Program in FY 2013, we will bring them to NQF for review for continued endorsement for the measures and would subsequently propose the revised measure for use in the Hospital Readmissions Reduction Program in future rulemaking.

Comment: Several commenters urged CMS to "* * * conduct a study to thoroughly determine the common reasons for planned readmissions, as well as determine a subset of readmissions that are unrelated to a patient's initial admission. * * *" These commenters also recommended three possible interim steps: (1) Not counting readmissions for certain patients (cancer, trauma, burns, end-stage renal disease, psychiatric disorders, substance abuse, and rehabilitation); (2) allowing a coding modifier on hospital claims to identify planned readmissions; or (3) using existing classification schemes such as MS–DRGs or AHRQ's classification system (*http://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp*), the clinical classification software, which "groups diagnoses and procedure codes into clinically meaningful groups" to identify related readmissions (and to exclude readmissions that are not identified as related).

Response: We appreciate the commenters' suggestions. As part of our ongoing implementation of the Hospital Readmissions Reduction Program, we intend to further explore whether there are other readmissions that could be excluded from the readmission measures finalized in this rule, and we expect that we will solicit public input on this issue in future rulemaking. However, again we note that because the FY 2013 measures must be NQF-endorsed, any changes to the measures used for the program in FY 2013 would have to be brought to NQF for review for continued endorsement before we could, in future rulemaking, propose the measures for use in the Hospital Readmissions Reduction Program.

Comment: Some commenters expressed concern that inappropriate transfers from acute care hospitals to a different acute care hospital might occur. Several of these commenters requested that CMS monitor transfers to ensure that potentially high-risk patients are not unnecessarily transferred in an attempt to artificially reduce hospital readmission rates.

Response: We note that the NQF-endorsed readmission measures as finalized in this rule are designed to count all readmissions unless they meet the planned procedure definition for AMI or involve a transfer to another acute care hospital. This approach is consistent with section 1886(q)(5)(ii)(II) of the Act which requires that "endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital)."

With regard to the commenters' concerns about hospitals transferring patients to another acute care institution to avoid being accountable for readmissions, we will consider future monitoring of transfer rates to assess if there are any unexpected changes in transfer patterns in response to the Hospital Readmissions Reduction Program.

Comment: Two commenters expressed concern regarding the appropriateness of the exclusion criteria for unrelated readmissions for use in measures when applied to hospitals that treat specialized patient populations, such as LTCHs and IPPS-exempt cancer hospitals. One commenter emphasized the importance to rural hospitals of not counting unrelated or planned readmissions. Another commenter suggested that CMS not count readmissions related to random events such as falls or readmissions that occur during natural disasters or states of emergency. One commenter suggested a method of reporting "nonreportable" admissions via the claims payment system. One commenter believed that the upcoming implementation of ICD–10 would enhance CMS' ability to identify and remove readmissions related to random events.

Response: We thank the commenters for their input on exclusion criteria, and we will consider these suggestions as we continue to implement the Hospital Readmissions Reduction Program. The proposed NQF-endorsed readmission measures were designed as "all-cause" readmission measures (that is, they count readmission regardless of the reason for readmission) because, from a patient perspective, readmission from any cause is an adverse event. Similarly, as we discussed above, many cases of seemingly unrelated diagnoses may, in fact, correspond to the original hospitalization, and differentiation is not always possible solely on the basis of the admitting diagnosis for the readmission. For instance, a patient with heart failure who develops a hospital-acquired infection may ultimately be readmitted with sepsis. In

this context, we believe that the NQF-endorsed readmission measure for heart failure appropriately considers the readmission to be related to the care the patient received for heart failure during the first hospitalization.

In our view, readmissions that are truly unrelated to the hospitalization should not affect some hospitals more than others, because these readmissions should have the same probability of occurring for similarly situated patients, regardless of where the patient was initially hospitalized. We also note that planned readmissions are easier to identify, especially those that are elective and scheduled in advance either as follow-on care for a procedure following a hospitalization or that have been scheduled by outpatient providers, and are not indicative of care quality.

Comment: One commenter stated there is another readmission measure available that has excludes greater numbers of unrelated readmissions and is in use in a State.

Response: The readmissions measure referred to by the commenter is 3M's Potentially Preventable Readmission measure and is in use in the State of Florida. This measure was reviewed by NQF in 2009 and was not endorsed (NQF # HOE–007–08). It is our understanding that the NQF's Steering Committee's decision not to endorse the measure reflected the Committee's concern about the measure's approach to identifying preventable readmissions. The measure developer specified over 98,000 admission–readmission diagnoses pairs (for example, a heart failure admission followed by readmission for a fall) as either clinically related and therefore preventable or not related and therefore not preventable. The NQF Steering Committee did not think these judgments were reliable, and it rejected the measure in part on this basis. We agree with the Steering Committee that this measure did not accurately specify what is related or unrelated simply by looking at the diagnoses for the admission and the readmission.

After consideration of the public comments we received, we are finalizing the NQF-endorsed measures with exclusions for unrelated conditions, as proposed.

(4) Methodology of Readmission Measures

In the following section, we describe the major components of the measure methodology of the three NQF-endorsed risk-standardized readmission measures for AMI, HF and PN that we proposed for the implementation of the Hospital Readmissions Reduction Program.

Additional details about each of these measures may be found online at *http://www.QualityNet.org*>Hospital-Inpatient>Readmission Measures>methodologies. This Web page is located at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

Briefly, as is described in more detail in the sections below, the measures are risk-standardized rates of readmission. For each hospital, qualifying index hospitalizations are identified based on the principal discharge diagnosis of the patient and the inclusion/exclusion criteria (section IV.C.3.c.(4)(A) of this preamble on index hospitalizations). Each hospitalization is evaluated for whether the patient had a readmission to an acute care setting in the 30-days following discharge (section IV.C.3.c.(4)(B) of this preamble on readmission). Patient-risk factors, including age, and chronic medical conditions are also identified from inpatient and outpatient claims for the 12-months prior to the hospitalization for risk-adjustment (section IV.C.3.c.(4)(D) of this preamble on risk-adjustment). The readmissions, sample size for each hospital, and patient risk-factors are then used to calculate a risk-standardized readmission ratio for each hospital. For the purposes of publicly-reporting the measures, this risk-standardized readmission ratio is then multiplied by the national crude rate of readmission for the given condition to produce a risk-standardized readmission rate (RSRR) (section IV.C.3.c.(5)(B) of this preamble).

(A) Index Hospitalization

An index hospitalization for each of the readmission measures is the hospitalization from which we evaluate the 30 days after discharge for possible readmissions. The measures, as endorsed by the NQF, evaluate eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital (as defined by section 1886(q)(5)(C) of the Act) having a principal discharge diagnosis for the measured condition in an applicable period. The NQF-endorsed measures, as specified, exclude patients under 65 year of age.

The discharge diagnoses for each applicable condition are based on a list of specific ICD–9–CM codes for that condition. These codes are listed in the *2010 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30-Day Risk-Standardized Readmission Measures.* They also are posted on the QualityNet Web site: *http://www.*

QualityNet.org>Hospital-Inpatient>Readmission Measures>methodologies. See *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

The current NQF-endorsed CMS 30-day risk standardized readmission measures exclude the following admissions from the group of index hospitalizations:

• Hospitalizations for patients with an in-hospital death (because they are not eligible for readmission);

• Hospitalizations for patients without at least 30 days post-discharge enrollment in Medicare FFS (because the 30-day readmission outcome cannot be assessed in this group);

• Hospitalizations for patients discharged against medical advice (because providers did not have the opportunity to deliver full care and prepare the patient for discharge).

• Hospitalizations for patients under the age of 65.

Comment: One commenter noted that admissions related to disaster preparedness or recovery should be excluded from the measures. One commenter noted that the nature of traumatic injuries is such that certain medical conditions are not always readily apparent upon admission and lead to the need for readmission.

Response: We appreciate the commenter's recommendation, and we intend to consider whether to it would be appropriate to allow waivers for extraordinary regional or local circumstances, such as natural disasters that are not in the control of the hospital. Any such process would be proposed in a future rulemaking.

(B) Readmission

As explained above, the initial hospitalization assessed for a readmission is called the index hospitalization. The proposed measures, as endorsed by the NQF, define readmission as a second admission to another acute care hospital within 30 days of the index hospitalization. Under the proposed measures, as endorsed by the NQF, a patient who is readmitted twice within 30 days simply is counted as having been readmitted; this patient's readmissions are not counted differently than a patient with a single readmission within 30 days of discharge.

With the exception of the exclusions discussed previously (transfers and planned readmissions, as discussed in the Exclusions for Unrelated Readmissions section above), the proposed measures, as currently endorsed by the NQF, include

readmissions for all causes, without regard to the principal diagnosis of the readmission. There are several reasons for this approach. First, from the patient's perspective, readmission from any cause is an adverse event. Second, although we would expect few hospitals to use gaming strategies, we strive to make sure that measures do not create incentives for hospitals to do so. Limiting the readmissions to particular diagnoses creates an opportunity for hospitals to potentially avoid having readmissions counted by changing coding practices. Further, doing so could create a perverse incentive whereby hospitals begin to avoid patients with conditions that are part of the readmissions measures. Third, as discussed above, there are not currently any clinically and technically sound and accepted strategies for accurately identifying readmission that are unrelated to hospital quality based on the documented cause of readmission. Finally, we believe it is important that hospitals strive to reduce readmissions from all causes, not just for patients with conditions that happen to be readmissions measures. While the measures do not presume that each readmission is preventable, interventions have generally shown reductions in all types of readmissions (including both related and unrelated readmissions). The NQF measures are intended to provide incentives for hospitals to reduce readmissions and not to achieve zero readmissions.

(C) Time Window

The three proposed measures, as endorsed by the NQF, count readmissions within a 30-day period from the date of the initial discharge from the index hospitalization. The timeframe of 30 days is a clinically meaningful period for hospitals, in collaboration with their medical communities, to reduce readmission risk. This time period for assessing readmission is an accepted standard in research and measurement. We believe that during this 30-day time period, hospital and community partners can take steps to reduce risk by ensuring patients are clinically ready to be discharged, improving communication across providers, reducing risks of infections, and educating patients on symptoms to monitor whom to contact with questions and where and when to seek follow-up care can influence readmission rates.

Comment: One commenter suggested the proposed 30-day time period (time window) is too long and should be reduced to 15 days. Another commenter

supported the 30-day time window, but indicated that they preferred 15 days.

Response: The proposed timeframe of 30 days from the date of the initial discharge from the index hospitalization is the timeframe that has been NQF-endorsed as part of the three readmission measures. The timeframe of 30 days is considered an acceptable standard in both the research and measurement communities as this time period is long enough to capture a substantial proportion of readmissions attributable to an index hospitalization, a greater proportion than captured in just 15 days, and yet it is short enough that outcomes can be attributed to and influenced by hospital care and the early transition to the outpatient setting. The use of the 30-day timeframe is also a clinically meaningful period for hospitals to collaborate with their communities in an effort to reduce readmissions. Multiple studies have shown that interventions by hospitals can make an impact on 30-day readmission rates.[54][55][56] Finally, we again note that, as required under the Act, we proposed the measures as they were endorsed by the NQF. Since the NQF-endorsed measures use a 30-day time period, we are finalizing our proposal to count readmissions within a 30-day period from the date of the initial discharge from the index hospitalization.

(D) Risk Adjustment

Section 1886(q)(4)(C)(i)(I) of the Act requires that the number of readmissions used in the Excess Readmission Ratio be risk adjusted. This language requires us, when comparing hospitals' readmission rates, to account for differences in the severity of illnesses of the patients that hospitals treat. Risk adjustment essentially ''levels the playing field'' for comparing hospital performance by taking into account that some hospitals' patients are sicker than others on admission and therefore have a higher risk of readmission.

The methodology for calculating the RSRRs under the NQF-endorsed measures that we proposed adjusts for key factors that are clinically relevant and have strong relationships with the

outcome (for example, patient demographic factors, patient co-existing medical conditions, and indicators of patient frailty). Under the current NQF-endorsed methodology, these covariates are obtained from Medicare claims extending 12 months prior to, and including, the index admission. This risk-adjustment approach adjusts for differences in the clinical status of the patient at the time of the index admission as well as for demographic variables.

A complete list of the variables used for risk adjustment and the clinical and statistical process for selecting the variables for each NQF-endorsed measure, as proposed, is available in the publicly-available technical documentation of the existing measures for AMI, HF, and PN. The risk adjustment variables for each condition are presented in the 2010 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30-Day Risk-Standardized Readmissions Measures that are posted on *http://www. QualityNet.org*>Hospital-Inpatient>Readmission Measures>Resources. The variables used are Condition Categories that group ICD–9–CM codes into clinically coherent variables. The 2010 Condition Category-ICD–9–CM Crosswalk provides a map to the specific ICD–9–CM codes in each variable and is also posted on *http://www.QualityNet.org*>Hospital-Inpatient>Readmission Measures>Measure Calculation Methodology or readers may use the following Web site address: *http://www.qualitynet.org/dcs/Content Server?c=Page&pagename=QnetPublic %2FPage%2FQnetTier4& cid=1219069855841.*

Comment: Many commenters argued that CMS should risk-adjust for patient characteristics beyond the medical diagnosis, age and gender currently included in the NQF-endorsed risk adjustment methodology. Specifically, commenters believed that patient race, language, life circumstances, environmental factors, and socioeconomic status (SES) should be included in the risk-adjustment methodology, because these factors also have an impact on health outcomes. Commenters expressed concern that without adding these adjustment factors, the Hospital Readmissions Reduction Program may disproportionately affect hospitals serving a large number of minorities, and by penalizing these hospitals, the program could in turn disproportionately harm minority patients. Commenters stated that failure

to account for these factors could result in ''disparate-impact discrimination,'' potentially violating Title VI of Civil Rights Act and 45 CFR 80.3.

Response: We do not agree that the use of the current NQF-endorsed risk adjustment methodology in the Hospital Readmissions Reduction Program will harm minorities. The proposed readmission measures are risk-standardized readmission measures that adjust for case-mix differences based on the clinical status of the patient at the time of admission to the hospital. That is, they are risk-adjusted for certain key variables (for example, age, sex, co-morbid diseases and indicators of patient frailty) that are clinically relevant and/or have been found to have strong relationships with the outcome. To the extent that race or SES results in certain patient groups having a greater disease burden, those factors are accounted for in the measure. A more complete description of the risk adjustment model and its development is available on the QualityNet Web site (*http://www.qualitynet.org/dcs/Content Server?c=Page&pagename=Qnet Public%2FPage%2FQnetTier4& cid=1219069855841*).

However, these measures are not adjusted for other factors such as race, English language proficiency or SES. We believe such additional adjustments are not appropriate because the association between such patient factors and health outcomes can be due, in part, to differences in the quality of health care received by groups of patients with varying race/language/SES. Differences in the quality of health care received by certain racial and ethnic groups may be obscured if the measures risk-adjust for race and ethnicity. Additionally, risk-adjusting for patient race, for instance, may suggest that hospitals with a high proportion of minority patients are held to different standards of quality than hospitals treating fewer minority patients.

We appreciate the concerns of hospitals that care for disproportionately large numbers of disadvantaged populations. Our analysis indicates that better quality of care is achievable regardless of the demographics of the hospital's patients. (See: *Medicare Hospital Quality Chartbook 2010*).

Although we believe the current risk-adjustment methodology properly accounts for different patient circumstances, we will monitor whether the Hospital Readmissions Reduction Program has a disparate impact on

---

[54] Benbassat J, Taragin M. 2000. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Intern Med 160(8):1074–1081.

[55] Benbassat J, Taragin M. 2000. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Intern Med 160(8):1074–1081.

[56] Jonas M, Grossman E, Boyko V, *et al.* 1999. Relation of early and one-year outcome after acute myocardial infarction to systemic arterial blood pressure on admission. Am J Cardiol 84:162–165.

[57] *http://www.cms.gov/HospitalQualityInits/ 20_OutcomeMeasures.asp#TopOfPage.*

hospitals that care for large numbers of disadvantaged patients. If such an impact is found, we will consider whether additional program modifications would be appropriate and consistent with the statutory requirements and intent of the program. For example, one option might be to refine the measures themselves to include factors such as SES in the risk adjustment. We also note that there are programs that provide technical and financial support that may assist hospitals in improving performance on the readmission measures included in the Hospital Readmissions Reduction Program such as the Community Based Care Transitions program authorized under section 3026 of the Affordable Care Act and the Partnership for Patients, a new public-private partnership that will help improve the quality, safety and affordability of health care. In addition, assistance in lowering readmission rates is available from the Quality Improvement Organizations.

Comment: Several commenters suggested that trauma hospitals and safety-net hospitals are at increased risk of being subject to a payment adjustment under the Hospital Readmissions Reduction Program because of insufficient risk-adjustment for ''case-mix'' or the fact that their patients are sicker, lack access to appropriate post-discharge care, may suffer numerous chronic conditions, and may have substance abuse or behavioral problems. Another commenter expressed concern that coding does not capture patients in palliative care or those readmitted from hospice, but acknowledged that CMS risk adjustment methodology is the state of the art at present.

Response: We thank the commenters for their input. As noted above, our analyses suggest that trauma and safety net hospitals caring for high proportions of at-risk patients can, and frequently do, perform as well on the readmission measures as those hospitals with fewer at-risk patients (see: *Medicare Hospital Quality Chartbook 2010,* pp 14–19).

We do not exclude hospice patients or those who have elected palliative care from the readmission measures because we do not believe that it is appropriate to differentiate, as to the appropriateness of care provided, between patients who have elected hospice or palliative care and those who have not.

After consideration of the public comments we received, we are finalizing the risk-adjustment methodology as proposed and endorsed by the NQF.

(E) Applicable Period

Section 1886 (q)(5)(D) of the Act authorizes the Secretary to specify the ''applicable period'' with respect to a fiscal year. Currently, for Hospital IQR Program public reporting purposes, we use 3 years of data (three 12-month increments) to calculate the three proposed readmission measures. This provides substantially more data than a 1- or 2-year timeframe and increases the precision of the measure in distinguishing performance among hospitals. Additionally, it is advantageous to have three years worth of data for purposes of displaying the three proposed readmission measures on *Hospital Compare* where we categorize hospital performance into one of three discrete categories: ''Better than the US national rate,'' ''No different than the US national rate,'' and ''Worse than the US national rate.''

For the FY 2013 Hospital Readmissions Reduction Program, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25934), we proposed to use 3 years of data for discharges from July 1, 2008 through June 30, 2011 as the applicable period upon which to calculate Excess Readmission Ratios for each of the three proposed measures. Based on our experience with the Hospital IQR Program, we believe that this timeframe increases the precision of the measures in distinguishing performance among hospitals. However, for purposes of the Hospital Readmissions Reduction Program, we will not be categorizing hospital performance in three categories; rather, we will be using the measures to calculate Excess Readmission Ratios for the three conditions. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25934), we proposed to use a 3-year data period spanning July 1, 2008 through June 30, 2011, as the applicable period for determining the FY 2013 Hospital Readmissions Reduction Program payment adjustment. We indicated that we are currently conducting analyses to determine an appropriate data period (for example, 1 year, 2 years, 3 years) that will yield reliable Excess Readmission Ratios for the three proposed measures, and that we intend to consider both the positive and negative consequences of using longer or shorter data periods for this program. We also indicated that should our analysis or public comment indicate that a shorter data period yields Excess Readmission Ratios with acceptable reliability, we may consider finalizing a shorter time period.

We invited public comment and suggestions on the topic of an appropriate length for the applicable period to consider for the three proposed readmission measures for FY 2013.

Comment: Many commenters recommended that CMS shorten the proposed applicable period of 3 years so that only more recent data would be used for the Hospital Readmissions Reduction Program. Some commenters urged CMS to shorten the timeframe because the commenters believed it was unfair to assess hospital performance on data that occurred during 2008, which is ''long before [the Hospital Readmissions Reduction Program provision] was passed * * *''

Response: We thank the commenters' for their views regarding the data used for the measures. We proposed 3 years as the applicable period because we believe that this time period would ensure the proposed measures covers a sufficient number of applicable patients for hospital performance to be fairly portrayed. For example, from 2006 through 2008, only 2,500 of the 4,500 qualifying hospitals for the Hospital Readmissions Reduction Program reported at least 25 discharges for AMI during that time period.

As stated above, we indicated that we are currently conducting analyses to determine if a different data period (for example, 1 or 2 years) might also yield reliable Excess Readmission Ratios for the three proposed measures. We intend to consider both the positive and negative consequences of using longer or shorter data periods for this program. If our analysis or public comments indicate that a shorter data period yields Excess Readmission Ratios with acceptable reliability, we may consider finalizing a shorter time period.

Because we did not receive any public comments demonstrating that a shorter period would yield reliable and meaningful results upon which differences in hospital performance could be appropriately distinguished, and because our own analysis indicated that 3 years continues to be an appropriate period, we are finalizing 3 years as the applicable period for the FY 2013 Hospital Readmissions Reduction Program.

(F) Data Sources

As discussed above, the adjustment under section 1886(q) of the Act is made to the ''base operating DRG payment amount,'' and components of the ratio used to determine a hospital's adjustment factor also use that payment amount. Payments under section 1886 of the Act, including the ''base operating DRG payment amount,'' are made for services furnished to Medicare's fee-for-

service population under part A. Therefore, for purposes of implementing the Hospital Readmissions Reduction Program under section 1886(q) of the Act, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25934), we proposed to use Medicare claims data for the Medicare FFS population over the age of 65 only. This is the same universe of claims used for calculating the NQF-endorsed measures for the purposes of the Hospital IQR Program.

The administrative data sources for the risk adjustment analyses are Medicare administrative claims datasets that contain FFS inpatient and outpatient (Medicare Parts A and B) claims information in the prior 12 months and subsequent one month for patients admitted in each of these years. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25934), we proposed to use claims from the index hospitalization included the measure and from the prior 12 months from all of these data sources to gather risk factors. If the patient does not have any claims in the 12 months prior to the index hospitalization admission, only comorbidities from the included admission are used.

We welcomed public comment on this proposal.

We did not receive any public comments on this proposal. Therefore, we are finalizing the data sources used for the Hospital Readmissions Reduction Program as proposed in the FY 2012 IPPS/LTCH PPS proposed rule.

(G) Minimum Number of Discharges for Applicable Conditions

Section 1886(q)(4)(C)(II)(ii) of the Act authorizes the Secretary to exclude readmissions for an applicable condition for which there are "fewer than a minimum number (as determined by the Secretary)." Currently, for public reporting purposes under the Hospital IQR Program, only hospitals with at least 25 discharges for each of the three proposed applicable conditions are included in the display of the three proposed readmission measures on *Hospital Compare.* We chose this number of discharges for the Hospital IQR Program based on our findings that using fewer cases did not provide sufficiently reliable information on hospital performance. In general, the larger the number of cases, the more reliable the information. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25935), we indicated that we are currently conducting additional analyses to further evaluate the appropriate minimum number of discharges needed to yield reliable Excess Readmission Ratios for the three

proposed measures. However, based on our experience with the Hospital IQR Program, in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25934 through 25935), we proposed to use the current threshold of 25 discharges for each of the three measures for the Hospital Readmissions Reduction Program. However, we indicated that should our analysis or public comment indicate that a different minimum number of discharges would be more appropriate for this program, we would consider finalizing a different number. We invited public comment and suggestions on the topic of appropriate minimum number of discharges to consider for the three proposed readmission measures.

Comment: Several commenters supported the proposed minimum number of 25 discharges. Other commenters stated that 25 discharges is too small a number to reliably profile hospitals.

Response: We appreciate hearing from commenters regarding the proposed minimum number of discharges. We continue to believe that 25 discharges is the appropriate cut-off. As noted in the proposed rule, we have been using 25 cases as the minimum sample size for publicly reporting hospital quality measures on *Hospital Compare* Web site for the Hospital IQR Program. Hospitals are familiar with this threshold. We also proposed to use this threshold of 25 discharges for each of the three measures to calculate the Excess Readmission Ratios because we believe this number helps maximize hospital participation and at the same time ensures that we achieve reasonable reliability for profiling hospital performance.

After consideration of the public comments we received, we are finalizing our proposal to use 25 discharges as the minimum number of discharges for applicable conditions for the FY 2013 Hospital Readmissions Reduction Program. We note that analyses to determine appropriate sample size to yield reliable Excess Readmission Ratios for the three readmission measures are ongoing. If the results of our analyses suggest that a different minimum number of discharges would be more appropriate, we will propose to revise the minimum number accordingly through future rulemaking.

(H) Reporting Hospital-Specific Readmission Rates

Section 1886(q)(6)(A) of the Act requires the Secretary to "make information available to the public regarding readmission rates of each

subsection (d) hospital under the [readmissions reduction] program." Section 1886(q)(6)(B) of the Act requires the Secretary to "ensure that a subsection (d) hospital has the opportunity to review and submit corrections for, the information to be made public with respect to the hospital * * * prior to such information being made public." Section 1886(q)(6)(C) of the Act requires the Secretary to post the hospital-specific readmission information on the *Hospital Compare* Web site in an easily understandable format.

We currently report information on the three readmission rates that we are finalizing in this rule on the *Hospital Compare* Web site for each subsection (d) hospital. We provide hospitals with an opportunity to preview their readmission rates for 30 days prior to posting on the Web site. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25935), we proposed to use a similar process and timeframe for the rates calculated for the Hospital Readmissions Reduction Program. Through this process, hospitals will be able to review the information and submit to CMS corrections in advance of the information to be made public. We will review all such correction submissions and determine the appropriateness of any revisions. We will inform the hospital requesting corrections of our findings, and we will make any appropriate revisions to the information to be made available to the public regarding the hospital's readmission rates.

We invited public comment on this proposal.

Comment: Several commenters supported our proposal to use a preview period and public reporting process that is similar to that used in the Hospital IQR Program. Two commenters requested more information about how the information will be presented on the *Hospital Compare* Web site. One recommended that more specific data on actual readmission rates be portrayed.

Response: We appreciate the commenters' support for the proposed reporting procedure for hospital-specific readmission rates. This reporting procedure will be different from what is reported with the Hospital IQR Program. The Hospital IQR Program identifies hospitals on *Hospital Compare* as being better than, no different than, or worse than the national rate for readmission. However, the Hospital Readmissions Reduction Program will include hospital-specific readmission rates.

Comment: One commenter requested clarification on "what grounds and with

what data'' a hospital might appeal its calculated expected readmissions ratio.

Response: As stated earlier, hospitals will be able to review the information and submit to CMS corrections related to their readmission rate in advance of the information to be made public. We will review all such correction submissions and determine the appropriateness of any revisions. The policies regarding what aspects of the readmission rates are subject to corrections, as well as specifics regarding the review and correction process will be proposed in future rulemaking. We will consider the commenter's concern as we develop our proposal.

After consideration of the public comments we received, we are finalizing the proposed reporting procedure for hospital-specific readmission rates for the FY 2013 Hospital Readmissions Reduction Program.

(I) Readmission Rates for All Patients

Section 1886(q)(8)(A) of the Act requires the Secretary to calculate readmission rates for all patients for a ''specified hospital'' for an applicable condition and ''other conditions deemed appropriate by the Secretary for an applicable period.'' Section 1886(q)(8)(D)(ii) of the Act defines ''specified hospital'' as: ''a subsection (d) hospital; hospitals described in clauses (i) through (v) of subsection (d)(1)(B) (psychiatric hospitals, rehabilitation hospitals, children's hospitals, LTCHs, and cancer hospitals); and, as determined feasible and appropriate by the Secretary, other hospitals not otherwise described. * * *'' Such information is to be calculated in the same manner as used to calculate readmission rates for hospitals with respect to the postings on the CMS *Hospital Compare* Web site.

Section 1886(q)(8)(C) of the Act requires specified hospitals, or a State or an appropriate entity on behalf of the hospitals, to submit to the Secretary, in a form, manner and time specified by the Secretary, data and information determined necessary to calculate the all patient readmission rates. Section 1886(q)(8)(D) of the Act defines ''all patients'' to mean patients who are treated on an inpatient basis and discharged from a specified hospital. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25935), we did not propose any specific policies to implement section 1886(q)(8) of the Act, but we invited public comment and suggestions for issues related to implementation of these provisions, such as the mechanisms to collect the all-patient

data, the collection of patient identifiers to track patient care history across multiple settings to conduct risk adjustment for outcome measures, what entities could submit all patient data on behalf of hospitals, and more generally, the requirement for all patient data submission.

Comment: One commenter supported the calculation of all-patient readmission rates. Another commenter supported the decision to defer proposals for the collection of data necessary for readmission rates of all patients to allow CMS enough time to put the underlying infrastructure in place. One commenter suggested allowing hospitals to either submit data directly to CMS, or through a third party that is not another payer.

Response: We appreciate the comments provided on this issue. As we stated in the proposed rule, we will take them into account in the calculation and reporting of readmission rates for all patients in future rulemaking.

(5) Excess Readmission Ratio

(A) Statutory Background

Section 1886(q)(4)(C) of the Act requires the Secretary to develop a risk-adjusted ''Excess Readmission Ratio.'' The Excess Readmission Ratio will be used in the calculation of ''aggregate payments for excess readmissions'' as required under section 1886(q)(4)(A)(iii) of the Act, which, in turn, is used to determine the adjustment factor under section 1886(q)(3) of the Act. Specifically, section 1886(q)(4)(C)(i) of the Act states that the term '' 'excess readmission ratio' means, with respect to an applicable condition for a hospital for an applicable period, the ratio * * * of * * * the risk adjusted readmissions based on actual readmissions * * * to * * * the risk adjusted expected readmissions. * * *'' The Act also requires that the numerator and denominator of the ratio, that is, ''risk adjusted readmissions based on actual readmissions'' and the ''risk adjusted expected readmissions,'' be determined ''consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I) [of the Act].''

(B) Excess Readmission Ratio Methodology

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25935 through 25936), we proposed to use the risk-standardized ratio calculated for the NQF-endorsed measures for AMI, HF, and PN as the ''Excess Readmission Ratio.'' This risk-standardized ratio (Excess Readmission Ratio), as required

by the Act, is a ratio of ''risk adjusted readmission based on actual'' to ''risk adjusted expected readmissions.'' Moreover, use of this ratio meets the statutory requirement that the numerator and denominator of the ratio be determined in a manner that is ''consistent with'' an NQF-endorsed readmission measure methodology.

The proposed ratio is a measure of relative performance. If a hospital performs better than an average hospital that admitted similar patients (that is, patients with the same risk factors for readmission such as age and comorbidities), the ratio will be less than one. If a hospital performs worse than average, the ratio will be greater than one. Hospitals with a ratio greater than one have excess readmissions relative to average quality hospitals with similar types of patients.

As part of the Hospital IQR Program, the risk-standardized ratio is used to generate the measure results for these three measures that are reported on *Hospital Compare* Web site. The risk-standardized ratio is the unique result produced by the measures for each hospital for each condition to assess relative hospital performance. Hospitals may not be familiar with this ratio because the measure result reported on *Hospital Compare* for each hospital and each condition is this ratio multiplied by a constant (the national raw rate of readmission for the condition), and it is currently presented as the risk-standardized readmission rate (RSRR). Multiplying by a constant transforms the ratio into a rate (the risk-standardized readmission rate) that is better understood by the public. Thus *Hospital Compare* results for CMS readmission measures are computed as follows:

[Hospital risk-standardized ratio] X [national raw readmission rate]

(i) Numerator and Denominator of the Risk-Standardized Ratio (Excess Readmission Ratio)

The NQF-endorsed measures, which we are finalizing in this rule for the Hospital Readmissions Reduction Program, calculate this risk-standardized ratio (Excess Readmission Ratio) using hierarchical logistic modeling, which is a widely accepted statistical method that evaluates relative hospital performance based on outcomes such as readmission. The method adjusts for variation across hospitals in how sick their patients are when admitted to the hospital (and therefore variation in hospitals' patients' readmission risk) as well as the variation in the number of patients that a hospital treats to reveal difference in

quality. The detailed methodology for these measures is publicly-available and the calculation "SAS packs" are made available upon request. This is the calculation software that permits the measures to be calculated. We describe the key details of the methodology here.

In order to model the extent to which hospitals affect patients' risk of readmission, this statistical model first analyzes data on all the patients discharged from all hospitals for a given condition that indicate for each patient what comorbidities were present when the patient was admitted and whether or not the patient was readmitted and calculates:

• How much variation in hospital readmission rates overall is accounted for by variation across hospitals in patients' individual risk factors (such as age and other medical conditions); a risk weight (beta-coefficient) is calculated for each patient risk factor at all hospitals. The specific approach and variables used in the risk adjustment are discussed below.

• How much variation in readmission rates is accounted for by hospitals' contribution to readmission risk, after adjusting for differences in readmission due to differences in patients' risk factors. The model estimates the amount by which a specific hospital increases or decreases patients' risk of readmission relative to an average hospital based on the hospitals actual readmission relative to hospitals with similar patients. The estimated amount each hospital contributes (or subtracts) from its patients readmission risk compared to hospitals with similar patients is called the "hospital-specific readmission

effect." It is used only in the numerator to estimate the adjusted actual readmissions. The hospital-specific effect will be negative for a hospital above the national average (that is, with lower than average adjusted rates of readmissions), positive for a hospital below the national average (that is, with higher than average adjusted rates of readmissions), and close to zero for an average hospital. If there are no quality differences resulting in excess readmissions among hospitals (if all hospitals had the same readmission rates relative to hospitals with similar patients), the hospital-specific effects for all hospitals will be zero and the ratio for all hospitals will be one.

Comment: One commenter expressed concern that multiplying the ratio by the national raw rate of readmissions could inflate the readmission rate for a given hospital.

Response: As discussed above, the Excess Readmission Ratio is calculated using hierarchical logistic regression which produces an adjusted actual (or "predicted") number in the numerator and an "expected" number in the denominator. The expected calculation is similar to that for logistic regression— it is the sum of all patients' expected probabilities of readmission given their risk factors and the risk of readmission at an average hospital. The excess readmissions ratio is multiplied by the national readmission rate for reporting of risk-standardized readmission rates to the public as a part of the Hospital IQR Program for ease of interpretation. This serves to standardize all hospitals rates to the national rate but should not be

interpreted as the unadjusted rate for a given hospitals. Depending on the hospital's performance it may be higher or lower than the hospital's raw readmission rate. The Hospital Readmissions Reduction Program uses the Excess Readmission Ratio rather than the raw readmission rate.

(ii) Numerator Calculation—Adjusted Actual Readmissions

For each hospital, the numerator of the ratio used in the NQF-endorsed methodology (actual adjusted readmissions) is calculated by estimating the probability of readmission for each patient at that hospital and summing up over all the hospital's patients to get the actual adjusted number of readmissions for that hospital. This estimated probability of readmission for each patient is calculated using:

• The hospital-specific effect (probability of readmission relative to the probability of readmission at an average hospital);

• The intercept term for the model (this is the average hospital-specific effect and is the same for all hospitals and for both numerator and denominator equations). The intercept term is the probability of readmission for each patient when the value of all the patient risk factors is zero;

• The probability of readmission contributed by each of the patients' risk factors (risk adjustment coefficients multiplied by the patient's risk factors, X)

Mathematically, the numerator equation can be expressed as:

Mathematically, the numerator equation can be expressed as:

Numerator: Adjusted Actual Readmissions

Step 1:

Calculate each patient's predicted probability of readmission $= \dfrac{1}{1 + e^{-Z_a}}$

Z_a = hospital-specific effect + Xβ

↑

intercept + risk-adjustment coefficients

Step 2:

To get the numerator result, add all patients' predicted probabilities of readmission

Comment: One commenter requested clarification on how the numerator calculation of probable readmissions is related to the adjusted actual readmission. The commenter suggested that CMS take actual readmissions (observed) divided by the expected readmission.

Response: As explained in the FY 2012 IPPS/LTCH PPS proposed rule and this final rule, consistent with the requirements in section 1886(q)(4)(C)(i)(I) of the Act, the numerator is the adjusted actual number of readmissions, which is the sum of the probability of readmission for all patients admitted at the particular hospital given the patients' risk factors and the hospitals estimated contribution to readmission risk. This estimated contribution to readmission risk—the

hospital-specific effect discussed in the rule—is derived from the hospital's actual readmission rate relative to hospitals with similar patients. Thus, the numerator is each hospital's adjusted actual readmissions. This approach to calculating the numerator, although more complex than that used for logistic regression, is the method traditionally used in hierarchical regression modeling and is statistically more accurate given the type of data being used. Other methods may overestimate the differences between hospitals.

(iii) Denominator Calculation— Expected Readmissions (at an Average Quality Hospital Treating the Same Patients)

The denominator of the risk-standardized ratio (Excess Readmission

Ratio) under this NQF-endorsed methodology sums the probability of readmission for each patient at an average hospital. This probability is calculated using:

• The intercept term for the model (the same for all hospitals and for both numerator and denominator equations); and

• The increase or decrease in the probability of readmission contributed by each of the patients' risk factors (risk adjustment coefficients multiplied by the patient's risk factors, X).

This can be expressed mathematically as:

This can be expressed mathematically as:

Denominator: Expected Readmissions

Step 1:

Calculate each patient's expected probability of readmission $= \dfrac{1}{1 + e^{-Z_e}}$

$Z_e = X\beta$

intercept + risk-adjustment coefficients

Step 2:

To get the denominator result, add all patients' expected probabilities of readmission

Thus, the ratio compares the total adjusted actual readmissions at the hospital to the number that would be expected if the hospital's patients were treated at an average hospital with similar patients. Hospitals with more adjusted actual readmissions than expected readmissions will have a risk-standardized ratio (Excess Readmission Ratio) greater than one.

Because the ratio is risk-adjusted, a hospital may have high crude readmission rates (number of 30-day readmissions among patients with the applicable condition divided by number of admissions for patients with the applicable condition) yet have a risk-standardized ratio (Excess Readmission Ratio) less than one. For example, if a

hospital with a higher than average raw readmission rate cares for very sick patients, the ratio may show that the adjusted actual number of readmissions (the numerator), which accounts for the case-mix, is actually lower than what would be expected for an average hospital caring for these patients (denominator) and therefore the Excess Readmission Ratio, as proposed, will be less than one, demonstrating that this hospital performs better than average, despite having a high crude readmission rate. Similarly, if a hospital has a seemingly low unadjusted readmission rate but cares for a very low risk population of patients, it may be found to have an adjusted actual number of readmissions that is higher than the

expected number of readmissions, and therefore a ratio greater than one.

In summary, in the FY 2012 IPPS/ LTCH PPS proposed rule, we proposed to use the risk-standardized readmission ratio of the NQF-endorsed readmission measures as the Excess Readmission Ratio. The ratio is a measure of relative performance. If a hospital performs better than an average hospital that admitted similar patients (that is, patients with the same risk factors for readmission such as age and comorbidities), the ratio will be less than 1.0. If a hospital performs worse than average, the ratio will be greater than 1.0.

We welcomed public comment on our proposal to use this methodology for

calculating the ''risk adjusted readmissions based on actual readmissions'' as well as the ''risk adjusted expected readmissions'' used to determine the Excess Readmission Ratio, as set forth in section 1886(q)(5)(C) of the Act.

Comment: Some commenters interpreted the Affordable Care Act as requiring CMS to calculate observed and expected rates and, therefore, these commenters suggested that CMS revise the measures to use the calculation of observed and expected rates. Some commenters compared the hierarchical modeling approach to the logistic regression model, which produces an expected rate for the denominator and uses the observed (raw count of readmission) for the numerator. One commenter requested CMS to provide reasons for not using a conventional observed over expected ratio in the methodology.

Response: We appreciate the commenter's thoughts on the Excess Readmission Ratio. Consistent with the statutory requirement that the Secretary must develop a risk-adjusted Excess Readmission Ratio that is the ratio of ''the risk adjusted readmissions based on actual readmission, as determined consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I) * * * to the risk adjusted expected readmissions,'' we proposed to calculate the Excess Readmission Ratio using hierarchical modeling (rather than logistic regression, which produces an observed over expected ratio).

We believe that hierarchical modeling is a more appropriate statistical approach for hospital outcomes measures than the calculation of observed over expected ratio using the logistic regression model for various reasons. First, the hierarchical model meets the requirement under section 1886(q)(4)(C)(i)(I) of the Act for NQF-endorsement and risk-adjustment. Second, we believe that hierarchical modeling is a more appropriate statistical approach given the structure of the data and the underlying assumption of such measures which is that hospital quality of care influences 30-day readmission rates. Patients are clustered within hospitals and, as such, have a shared exposure to the hospital's quality processes. The advantage of using the hierarchical modeling is that it accounts for the clustering of patients within hospitals. Third, hierarchical models distinguish within-hospital variation and between-hospital variation in the estimation of the hospital's contribution to the risk of mortality. The estimation of the hospital's influence on

patient outcomes is more noticeable. Finally, within hierarchical models, we can account for both differences in case mix and sample size to more fairly profile hospital performance. If we did not use hierarchical modeling, we may overestimate variation and potentially mischaracterize hospitals' performance with respect to readmissions.

After consideration of the public comments we received, we are finalizing the proposed methodology for readmission measures, including the definitions of ''index hospitalization,'' ''readmission,'' ''time window,'' ''risk adjustment methodology,'' ''applicable periods,'' ''data sources,'' ''minimum number of discharges for applicable conditions,'' and ''reporting hospital-specific readmission rates,'' as proposed, for use in the FY 2013 Hospital Readmissions Reduction Program.

D. Rural Referral Centers (RRCs) (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as an RRC. For discharges that occurred before October 1, 1994, RRCs received the benefit of payment based on the other urban standardized amount rather than the rural standardized amount (as discussed in the FY 1993 IPPS final rule (59 FR 45404 through 45409)). Although the other urban and rural standardized amounts are the same for discharges occurring on or after October 1, 1994, RRCs continue to receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs are also not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area where the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, ''[a]ny hospital classified as an RRC by the Secretary * * * for fiscal year 1991 shall be classified as such an RRC for fiscal year 1998 and each subsequent year.'' In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), CMS reinstated RRC status for all hospitals that lost the status due to triennial review or MGCRB

reclassification. However, CMS did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in Subpart D of 42 CFR Part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum CMI and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (c)(5) and the September 30, 1988 **Federal Register** (53 FR 38513).) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

• The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and

• The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. (The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.)

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The national median CMI value for FY 2012 includes data from all urban hospitals nationwide, and the regional values for FY 2012 are the median CMI values of urban hospitals within each census region, excluding those hospitals with