7. Proposed Additional Hospital IQR Program Measures for the FY 2018 Payment Determination and Subsequent Years

We are proposing to add eight new measures to the Hospital IQR Program for the FY 2018 payment determination and subsequent years. We are proposing to adopt seven new claims-based measures and one new structural measure: (1) Hospital Survey on Patient Safety Culture (structural); (2) Kidney/UTI Clinical Episode-Based Payment Measure (claims-based); (3) Cellulitis Clinical Episode-Based Payment Measure (claims-based); (4) Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (claims-based); (5) Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment Measure (claims-based); (6) Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA (claims-based); (7) Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (claims-based); and (8) Excess Days in Acute Care after Hospitalization for Heart Failure (claims-based).

The proposed measures were included on a publicly available document entitled "List of Measures Under Consideration for December 1, 2014"[95] in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP as discussed in its MAP Pre-Rulemaking Report and Spreadsheet of MAP 2015 Final Recommendations.[96]

[95] Measure Applications Partnership: List of Measures Under Consideration (MUC) for December 1, 2014. Retrieved from http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78318.
[96] National Quality Forum "Process and Approach for MAP Pre-Rulemaking Deliberations 2015" found at: http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx and "Spreadsheet of MAP 2015 Final Recommendations" available at: http://www.qualityforum.org/map/.

For purposes of the Hospital IQR Program, section 1886(b)(3)(B)(IX)(aa) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act. The NQF currently holds this contract. However, section 1886(b)(3)(B)(IX)(bb) of the Act provides an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

a. Hospital Survey on Patient Safety Culture

(1) Background

For the FY 2018 payment determination and subsequent years, we are proposing to adopt the Hospital Survey on Patient Safety Culture. This proposed structural measure assesses whether a hospital administers a patient safety culture survey. Improving the safety of patient care is a priority and a quality improvement goal for CMS. We believe this structural measure will allow us to gain an understanding of whether hospitals are using a survey of patient safety culture in their hospitals. Because the number of questions in this measure is limited to five and can be completed using a Web-based tool, we believe this structural measure will not add undue reporting burden to hospitals.

We note that patient safety culture surveys are useful tools for measuring organizational conditions that can lead to adverse events and other incidences that can

cause harm to patients in health care organizations.[97] Patient safety culture surveys can be used to: (1) raise staff awareness about patient safety; (2) assess the current status of patient safety culture; (3) identify strengths and areas for improvement; and (4) examine trends in patient safety culture over time.[98]

There are multiple surveys that are currently used by the healthcare industry to assess patient safety culture including: the Pascal Metrics' Safety Attitudes Questionnaire (SAQ),[99] the Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture (HSOPSC),[100] the Patient Safety Climate in Healthcare Organizations (PSCHO),[101] and the Manchester Patient Safety Framework.[102] However, it is not clear which patient safety culture survey is used most frequently, or how many hospitals consistently assess their performance on these surveys. One example of use of a patient safety culture survey is the HSOPSC, which is nonproprietary and available to hospitals at no cost. AHRQ developed the survey, with CMS input, released it in 2004, and subsequently displayed results from 653 hospitals in 2014.[103] Use of the HSOPSC, as well as reporting results to AHRQ, was and continues to be voluntary. Among the

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[97] Nieva VF, Sorra J.: *Safety culture assessment: a tool for improving patient safety in healthcare organizations.* Qual Saf Health Care 2003; 12:ii17–23.

[98] Frequently Asked Questions: Surveys on Patient Safety Culture. October 2014. Agency for Healthcare Research and Quality, Rockville, MD. Available at: http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/pscfaq.html.

[99] Survey. (n.d.). Available at: http://www.pascalmetrics.com/solutions/survey/.

[100] Hospital Survey on Patient Safety Culture. (n.d.). Available at: http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/index.html.

[101] Measurement Instrument Database for the Social Sciences. (n.d.). Available at: http://www.midss.org/content/patient-safety-climate-healthcare-organizations-pscho.

[102] Dianne, P. (n.d.). Manchester Patient Safety Framework (MaPSaF). National Patient Safety Agency. Available at: http://www.nrls.npsa.nhs.uk/resources/?entryid45=59796.

[103] Hospital Survey on Patient Safety Culture: 2014 User Comparative Database Report: Executive Summary. March 2014. Agency for Healthcare Research and Quality, Rockville, MD. Available at: http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/2014/hosp14summ.html.

reporting hospitals, there was variation in frequency of survey use, format of administration (Web versus paper) and staff sampling scheme.[104]

Through the proposed Hospital Survey on Patient Safety Culture Measure, we will begin to understand how hospitals are using surveys, like the examples cited above, in improving their patient safety culture. This proposed measure will allow CMS to collect data on whether a hospital conducts a patient safety culture survey, and if so, which tool they use, how frequently the tool is administered, and the response rate. This structural measure will help inform CMS of whether a measure targeting the culture of patient safety using a specific survey is feasible.

Finally, we note that the MAP supports this measure and specifically highlighted that a patient safety culture survey is an important tool for hospitals to use to build a system of quality improvement within health care facilities.[105] While this measure is not currently NQF-endorsed, we are proposing this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered other existing measures related to patient safety that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess a patient safety culture, and found no other feasible and practical measures on this topic. We also are not aware

[104] Hospital Survey on Patient Safety Culture: 2014 User Comparative Database Report: Executive Summary. March 2014. Agency for Healthcare Research and Quality, Rockville, MD. Available at: http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/2014/hosp14summ.html.

[105] National Quality Forum Measure Application Partnership. "Spreadsheet of MAP 2015 Final Recommendations." Available at: http://www.qualityforum.org/map/.

of any other measures that assess whether a hospital administers a survey on patient safety.

(2) Overview of Measure

Reporting on a patient safety culture survey involves providing answers to the following questions listed below. Hospitals would submit answers via a Web-based tool on the QualityNet Web site:

(A) Does your facility administer a detailed assessment of patient safety culture using a standardized collection protocol and structured instrument?

(B) What is the name of the survey that is administered?

(C) How frequently is the survey administered?

(D) Does your facility report survey results to a centralized location? (Optional response options include the following: national data repository; State-based data repository; health system repository; other; and do not report the data outside the facility.)

(E) During the most recent assessment:

(a) How many staff members were requested to complete the survey?

(b) How many completed surveys were received?

(These questions can allow calculation of a response rate.)

(3) Data Sources

For FY 2018 payment determination and subsequent years, we are proposing that data collection for this structural measure for hospitals occur from January 1 through December 31 of each calendar year, with data submission occurring the following year. For the first year, data collection would be from January 1, 2016 through

December 31, 2016. These data will be collected via a Web-based tool available on the QualityNet Web site.

We are inviting public comment on our proposal to adopt the Hospital Survey on Patient Safety Culture measure for the FY 2018 payment determination and subsequent years.

b. Clinical Episode-Based Payment Measures

(1) Background

Clinical episode-based payment measures are clinically coherent groupings of healthcare services that can be used to assess providers' resource use. Combined with other clinical quality measures, they contribute to the overall picture of providers' clinical effectiveness and efficiency. Episode-based performance measurement allows meaningful comparisons between providers based on resource use for certain clinical conditions or procedures, as noted in the NQF report for the "Episode Grouper Evaluation Criteria" project available at: http://www.qualityforum.org/Publications/2014/09/Evaluating_Episode_Groupers__A_Report_from_the_National_Quality_Forum.aspx) and in various peer-reviewed articles.[106] Episode-based measurement further supports CMS' efforts in response to the mandate in section 3003 of the Affordable Care Act that the Secretary develop an episode grouper to improve care efficiency and quality.

We are proposing four clinical episode-based payment measures for inclusion in the Hospital IQR Program beginning with the FY 2018 payment determination: the

[106] For example: Hussey, P. S., Sorbero, M. E., Mehrotra, A., Liu, H., & Damberg, S. L.: (2009). Episode-Based Performance Measurement and Payment: Making It a Reality. *Health Affairs, 28*(5), 1406-1417. doi:10.1377/hlthaff.28.5.1406.

Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure, the Cellulitis Clinical Episode-Based Payment measure, the Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure, and the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure. The proposed measures evaluate the difference between observed and expected episode cost at the episode level before comparing at the provider level.

The MAP conditionally supported these measures pending NQF endorsement.[107] Once the call for measures for the Cost and Resource Use project at NQF is announced, these measures will be submitted for endorsement.

The measures we are proposing are described below, and detailed specifications can be found in the "Measure Methodology" report for proposed episodic payment measures, available at: http://www.qualitynet.org > Hospital-Inpatient > Claims-BasedMeasures > Proposed episodic payment measures > Measure Methodology. The measures follow the general construction of the previously adopted, NQF-endorsed, Hospital IQR Program measure, Payment-Standardized Medicare Spending per Beneficiary (MSPB), described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626) and include standardized payments for Medicare Part A and Part B services.[108] Similar to the MSPB measure, the episodes are risk adjusted for individual patient characteristics and other factors (for example, attributes of inpatient stays). Unlike the MSPB measure

[107] National Quality Forum. The report is available at: http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx and the "Spreadsheet of MAP 2015 Final Recommendations" is available at: http://www.qualityforum.org/map/.

[108] Detailed measure specifications can be found in the "Medicare Spending Per Beneficiary (MSPB) Measure Overview," available at: http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.

however, these clinical episode-based measures include only Medicare Part A and B services that are clinically related to the triggering diagnosis or procedure.

Mathematically, the methodology described below first computes the provider's Episode Amount (calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost) and then divides the provider's Episode Amount by the episode-weighted median of all providers' Episode Amounts (as shown in equation (A) below).

(A) $$Episode\ Measure_j = \frac{Episode\ Amount_j}{\substack{Episode-Weighted \\ Median\ of\ All\ Providers' \\ Episode\ Amounts}} = \frac{\frac{\sum_{i \in j}(\frac{O_{ij}}{E_{ij}})}{n_j} * \bar{O}_{i \in I}}{\substack{Episode-Weighted \\ Median\ of\ All\ Providers' \\ Episode\ Amounts}}$$

where

O_{ij} = observed episode cost for episode *i* in provider *j*,

E_{ij} = expected episode cost for episode *i* in provider *j*,

$\bar{O}_{i \in I}$ = average observed episode cost across all episodes *i* nationally, and

n_j = total number of episodes for provider *j*.

This methodology builds on that which was submitted to the MAP, in response to MAP feedback, and in order to yield a national episode-weighted measure. We are proposing these clinical episode-based payment measures because they meet the following episode selection criteria we established for the purpose of selecting the best conditions and procedures to begin with, for clinical episode-based payment measures: (1) the condition constitutes a significant share of Medicare payments and potential savings for hospitalized patients during and surrounding a hospital stay; (2) there was a high degree of agreement among clinical experts consulted for this project that

standardized Medicare payments for services provided during this episode can be linked to the care provided during the hospitalization; (3) episodes of care for the condition are comprised of a substantial proportion of payments and potential savings for postacute care, indicating episode payment differences are driven by utilization outside of the MS–DRG payment; (4) episodes of care for the condition reflect high variation in post-discharge payments, enabling differentiation among hospitals; and (5) the medical condition is managed by general medicine physicians or hospitalists and the surgical conditions are managed by surgical subspecialists, enabling comparison between similar practitioners.

(2) Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure

(A) Background

Inpatient hospital stays and associated services assessed by the Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure have high costs with substantial variation. In CY 2012, Medicare FFS beneficiaries experienced over 234,000 kidney/urinary tract infection episodes triggered by related inpatient stays.[109] Payment-standardized, risk-adjusted episode costs for these episodes (cost of the hospitalization plus the cost of clinically related services in the episode window) totaled more than $2.5 billion in 2012, with an average episode cost of over $10,000. There is substantial variation in kidney/urinary tract infection episode costs−ranging from approximately $4,800 at the 5th percentile to approximately $27,000 at the 95th−that is driven by

[109] The number of episodes and associated costs are calculated using the methodology for developing hospital-based episode measures proposed by Acumen LLC and outlined in the supplemental documentation for the FY 2015 IPPS and LTCH Prospective Payment System Proposed Rule. Available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html.

variation in post-discharge costs clinically-related to the inpatient hospitalization. These clinically-related post-discharge costs are an indicator of the quality of care provided during the hospitalization.

The MAP conditionally supported this measure pending NQF review and endorsement. Members noted that this measure addresses the cost of care for common conditions, but other members expressed caution that the most efficient providers may reduce overall hospitalizations and that the remaining hospitalizations may be a biased sample for measuring performance across providers. In response to this concern, we note that this measure is limited by design to the inpatient hospital, which means that resource use is evaluated only for patients that have been hospitalized for the episode condition, and providers are evaluated relative to other providers treating hospitalized patients. To address the concern that providers involved in the hospitalization of only the most complex cases might be disadvantaged under the measure, we note that the episode is risk-adjusted to account for differences in patient characteristics that may affect costs, such that expected costs for more complex patients will be higher and expected costs for less complex patients will be lower. Risk adjustment is described in section VIII.A.7.b.(7)(B) of the preamble of this proposed rule. Once the call for measures for the Cost and Resource Use project at NQF is announced, this measure will be submitted for endorsement.

We are proposing this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered other existing

measures related to efficiency that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess kidney/urinary tract infection. We also are not aware of any other measures that assess kidney/urinary tract infection treatment efficiency and found no other feasible and practical measures on this topic.

(B) Overview of Measure

The Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure includes the set of services provided to treat, manage, diagnose, and follow up on (including postacute care) a kidney/urinary tract infection-related hospital admission. This measure, like the NQF-endorsed MSPB measure, assesses the cost of services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the "episode window"). In contrast to the MSPB measure, however, this measure includes Medicare payments for services during the episode window only if they are clinically related to the health condition that was treated during the index hospital stay.

(C) Data Sources

The Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure is an administrative claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized with an MS-DRG that identifies a kidney/urinary tract infection.

(D) Measure Calculation

The measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the

hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted as described later in section VIII.A.7.b.(7)(B) of the preamble of this proposed rule. The period of performance for the measure is one year, beginning with calendar year 2016. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation or any potential changes in CMS payment policy. The numerator is the Episode Amount, calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost. The denominator is the episode-weighted median of all providers' Episode Amounts. A kidney/urinary tract infection episode begins 3 days prior to the initial (that is, index) admission and extends 30 days following the discharge from the index hospital stay.

(E) Cohort

The measure cohort includes Medicare FFS beneficiaries hospitalized with an MS-DRG that indicates a kidney/urinary tract infection. Additional details including the exclusion criteria are described in section VIII.A.7.b.(6) of the preamble of this proposed rule.

We are inviting public comment on our proposal to adopt the Kidney/Urinary Tract Infection Clinical Episode-Based Payment measure for the FY 2018 payment determination and subsequent years.

(3) Cellulitis Clinical Episode-Based Payment Measure

(A) Background

Inpatient hospital stays and associated services assessed by the Cellulitis Clinical Episode-Based Payment measure have high costs with substantial variation. In CY 2012, Medicare FFS beneficiaries experienced more than 143,000 cellulitis episodes triggered by related inpatient stays.[110] Payment-standardized, risk-adjusted episode costs for these episodes (cost of the hospitalization plus the cost of clinically related services in the episode window) totaled more than $1.4 billion in 2012, with an average episode cost of approximately $10,000. There is substantial variation in cellulitis episode costs−ranging from about $5,000 at the 5th percentile to about $24,000 at the 95th−that is driven by variation in post-discharge costs clinically-related to the inpatient hospitalization. These clinically related post-discharge costs are an indicator of the quality of care provided during the hospitalization.

The MAP conditionally supported this measure pending NQF review and endorsement. Members noted that this measure addresses the cost of care for an important condition. Other members expressed caution on the use of this measure noting that cellulitis is a highly variable condition that may be challenging to measure using an episode-based framework. Once the call for measures for the Cost and Resource Use project at NQF is announced, this measure will be submitted for endorsement. We note that there is substantial variation in cellulitis episode costs that is driven by variation in

[110]The number of episodes and associated costs are calculated using the methodology for developing hospital-based episode measures proposed by Acumen LLC and outlined in the supplemental documentation for the FY 2015 IPPS and LTCH Prospective Payment System Proposed Rule. Available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html.

post-discharge costs clinically-related to the inpatient hospitalization. This variation suggests that there may be opportunity to improve the efficiency of care for cellulitis treatment.

We are proposing this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered other existing measures related to efficiency that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess cellulitis. We also are not aware of any other measures that assess cellulitis treatment efficiency, and found no other feasible and practical measures on this topic.

(B) Overview of Measure

The Cellulitis Clinical Episode-Based Payment measure includes the set of services provided to treat, manage, diagnose, and follow up on (including post-acute care) a cellulitis-related hospital admission. The Cellulitis Clinical Episode-Based Payment measure, like the MSPB measure, assesses the cost of services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the "episode window"). In contrast to the MSPB measure, the Cellulitis Clinical Episode-Based Payment measure includes Medicare payments for services during the episode window only if they are clinically related to the health condition that was treated during the index hospital stay.

(C) Data Sources

The Cellulitis Clinical Episode-Based Payment measure is an administrative claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized with an MS-DRG that identifies cellulitis.

(D) Measure Calculation

The measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during this episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted as described in section VIII.A.7.b.(7)(B) of the preamble of this proposed rule. The period of performance is one year, beginning with calendar year 2016. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation or any potential changes in CMS payment policy. The numerator is the Episode Amount, calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost. The denominator is the episode-weighted median of all providers' Episode Amounts. A cellulitis episode begins 3 days prior to the initial (that is, index) admission and extends 30 days following the discharge from the index hospital stay.

(E) Cohort

The measure cohort includes Medicare FFS beneficiaries hospitalized with an MS-DRG that indicates cellulitis. Additional details including the exclusion criteria are described in section VIII.A.7.b.(6) of the preamble of this proposed rule.

We are inviting public comment on our proposal to adopt the Cellulitis Clinical Episode-Based Payment measure for the FY 2018 payment determination and subsequent years.

(4) Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure

(A) Background

Inpatient hospital stays and associated services assessed by the GI Hemorrhage Clinical Episode-Based Payment measure have high costs with substantial variation. In calendar year 2012, Medicare FFS beneficiaries experienced 181,646 GI hemorrhage episodes triggered by related inpatient stays.[111] Payment-standardized, risk-adjusted episode costs for these episodes (cost of the hospitalization plus the cost of clinically related services in the episode window) totaled nearly $2 billion in 2012, with an average episode cost of about $11,000. There is substantial variation in GI hemorrhage episode costs−ranging from approximately $6,500 at the 5th percentile to approximately $23,000 at the 95th−that is driven by variation in post-discharge costs clinically related to the inpatient hospitalization. These clinically related post-discharge costs are an indicator of the quality of care provided during the hospitalization. For the purposes of reporting, and

[111] The number of episodes and associated costs are calculated using the methodology for developing hospital-based episode measures proposed by Acumen LLC and outlined in the supplemental documentation for the FY 2015 IPPS and LTCH Prospective Payment System Proposed Rule. Available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html.

as suggested by the MAP, the GI hemorrhage episodes may be split into those treating an upper GI bleed and those treating a lower GI bleed due to clinical differences in patterns of care for those treatments. More information can be found in the supplemental documentation for the FY 2016 IPPS and LTCH Prospective Payment System Proposed Rule available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html.

The MAP conditionally supported this measure pending NQF review and endorsement. MAP members noted that this measure addresses the cost of care for GI bleeding. Several members expressed caution that the most efficient providers may reduce overall hospitalizations thus those inpatient hospitalizations that remain are a biased sample for measuring performance across providers. In response to these concerns, we note that this measure is limited by design to GI hemorrhage episodes treated in the inpatient hospital, which means that resource use is evaluated only for patients that have been hospitalized for the episode condition, and providers are evaluated relative to other providers treating hospitalized patients. With regard to the concern that efficient providers may reduce hospitalizations, leaving a biased sample of less efficient providers, we note that the episode is risk-adjusted to account for differences in patient characteristics that may affect costs, thus to the extent that variation in treatment prior to hospitalization results in patterns of sicker (or healthier) GI hemorrhage patients admitted to certain hospitals, risk adjustment addresses these differences. For example, for providers who admit comparatively less complex patients to the inpatient hospital for treatment of GI bleeds, risk adjustment would cause their expected costs to be lower.

Risk adjustment is described in section VIII.A.7.b.(7)(B) of the preamble of this proposed rule. Once the call for measures for the Cost and Resource Use project at NQF is announced, this measure will be submitted for endorsement.

We are proposing this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered other existing measures related to efficiency that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess GI hemorrhage. We also are not aware of any other measures that assess GI hemorrhage treatment efficiency, and found no other feasible and practical measures on this topic.

(B) Overview of Measure

The Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure includes the set of services provided to treat, manage, diagnose, and follow up on (including postacute care) a gastrointestinal hemorrhage-related hospital admission. This measure, like the MSPB measure, assesses the cost of services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the "episode window"). In contrast to the MSPB measure, the Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure includes Medicare payments for services during the episode window only if they are clinically related to the health condition that was treated during the index hospital stay.

(C) Data Sources

The Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure is an administrative claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized with an MS-DRG that identifies a gastrointestinal hemorrhage.

(D) Measure Calculation

The measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted as described in section VIII.A.7.b.(7) of the preamble of this proposed rule. The period of performance is 1 year, beginning with CY 2016. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation or any potential changes in CMS payment policy. The numerator is the Episode Amount, calculated as the average of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost. The denominator is the episode-weighted median of all providers' Episode Amounts. A gastrointestinal hemorrhage episode begins 3 days prior to the initial (that is, index) admission and extends 30 days following the discharge from the index hospital stay.

(E) Cohort

The measure cohort includes Medicare FFS beneficiaries hospitalized with an MS-DRG that indicates gastrointestinal hemorrhage. Additional details including the exclusion criteria are described in section VIII.A.7.b.(6) of the preamble of this proposed rule.

We are inviting public comment on our proposal to adopt the Gastrointestinal Hemorrhage Clinical Episode-Based Payment measure for the FY 2018 payment determination and subsequent years.

(5) Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment Measure

(A) Background

Inpatient hospital stays and associated services assessed by the Spinal Fusion/Refusion Clinical Episode-Based Payment measure have high costs with substantial variation. In CY 2012, Medicare FFS beneficiaries experienced about 69,000 spinal fusion/refusion episodes triggered by related inpatient stays.[112] Payment-standardized, risk-adjusted episode costs for these episodes (cost of the hospitalization plus the cost of clinically related services in the episode window) totaled more than $2.6 billion in 2012, with an average episode cost of approximately $38,000. There is substantial variation in spinal fusion/refusion episode costs−ranging from approximately $28,000 at the 5th percentile to approximately $60,000 at the 95th−that is driven by variation in post-discharge costs clinically related to the inpatient

[112] The number of episodes and associated costs are calculated using the methodology for developing hospital-based episode measures proposed by Acumen LLC and outlined in the supplemental documentation for the FY 2015 IPPS and LTCH Prospective Payment System Proposed Rule. Available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html.

hospitalization. These clinically related post-discharge costs are an indicator of the quality of care provided during the hospitalization.

The MAP conditionally supported this measure pending NQF review and endorsement. Some members raised concerns that patients with cancer should be excluded from this measure. Once the call for measures for the Cost and Resource Use project at NQF is announced, this measure will be submitted for endorsement. We note that this measure is titled "Spine Fusion/Refusion Clinical Episode-Based Payment Measure" in the MAP spreadsheet. Also, the episode is risk-adjusted to account for differences in patient characteristics, including the presence of cancer in the patient's history, which may affect costs but are outside of providers' control. Risk adjustment is described in section VIII.A.7.b.(7)(B) of the preamble of this proposed rule.

We are proposing this measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered other existing measures related to efficiency that have been endorsed by the NQF and we were unable to identify any NQF-endorsed measures that assess spinal fusion/refusion. We also are not aware of any other measures that assess spinal fusion/refusion treatment efficiency, and found no other feasible and practical measures on this topic.

(B) Overview of Measure

The Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure includes the set of services provided to treat, manage, diagnose, and follow up on (including postacute care) a lumbar spine fusion/refusion-related hospital admission. The

Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure, like the MSPB measure, assesses the cost of services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the "episode window"). In contrast to the MSPB measure, the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure includes Medicare payments for services during the episode window only if they are clinically related to the health condition that was treated during the index hospital stay.

(C) Data Sources

The Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure is an administrative claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized with an MS-DRG and ICD-9-CM procedure code that identify a lumbar spine fusion/refusion.

(D) Measure Calculation

The measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted as described in section VIII.A.7.b.(7) of the preamble of this proposed rule. The period of performance is 1 year, beginning with calendar year 2016. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation or any potential changes in CMS payment policy. The numerator is the Episode Amount, calculated as the average

of the ratios of each episode's observed costs to its expected costs multiplied by the national average observed episode cost. The denominator is the episode-weighted median of all providers' Episode Amounts. A lumbar spine fusion/refusion episode begins 3 days prior to the initial (that is, index) admission and extends 30 days following the discharge from the index hospital stay.

(E) Cohort

The measure cohort includes Medicare FFS beneficiaries hospitalized with an MS-DRG and ICD-9 Procedure code that indicate lumbar spine fusion/refusion. Additional details including the exclusion criteria are described in section VIII.A.7.b.(6) of the preamble of this proposed rule.

We are inviting public comment on our proposal to adopt the Lumbar Spine Fusion/Refusion Clinical Episode-Based Payment measure for the FY 2018 payment determination and subsequent years.

(6) Inclusion and Exclusion Criteria

A full list of the MS-DRG codes used to identify beneficiaries included in the final cohort for each of the proposed episode-based payment measures can be found in the "FY 2016 IPPS NPRM Episode Supplemental Documentation" report in the "Downloads" section at: "NPRM Episode Supplemental Documentation" report at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html.

The exclusion methodology applied to each of these measures is the same as the one used to calculate the previously adopted MSPB measure described in the FY 2012

IPPS/LTCH PPS final rule (76 FR 51626) and available in the "MSPB Measure Information Form" at: http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350. Episodes for beneficiaries that meet any of the following criteria are excluded from the measure:

- Lack of continuous enrollment in Medicare Parts A and B from 90 days prior to index admission through the end of the episode with Medicare as the primary payer.
- Death date during episode window.
- Enrollment in Medicare Advantage during the episode window.

In addition, claims that meet any of the following criteria do not trigger, or open, an episode:

- Claims with data coding errors, including missing date of birth or death dates preceding the date of the trigger event.
- Claims with payment ≤ 0.
- Acute inpatient stays that involved a transfer.
- Claims from a non-IPPS or non-subsection (d) hospital.

Claims that meet the following criterion will not be included in an episode:

- Claims with payment ≤ 0.

(7) Standardization and Risk-Adjustment

(A) Standardization

Standardization, or payment standardization, is the process of adjusting the allowed charge for a Medicare service to facilitate comparisons of resource use across

geographic areas. Medicare payments included in these proposed episode-based measures would be standardized according to the standardization methodology previously finalized for the Hospital IQR Program MSPB measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626) and used for all of the payment measures included in the Value-Based Payment Modifier Program. The methodology removes geographic payment differences, such as wage index and geographic practice cost index, incentive payment adjustments, and other add-on payments that support broader Medicare program goals, such as add-on payments for indirect graduate medical education (IME) and add-ons for serving a disproportionate share of uninsured patients (DSH).

(B) Risk Adjustment

Risk adjustment uses patient claims history to account for case-mix variation and other factors. The steps used to calculate risk-adjusted payments align with the NQF-endorsed MSPB method as specified in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51624 through 51626). Specifications for the risk-adjustment employed in the proposed episode-based payment measures are included in the "FY 2015 IPPS NPRM Episode Supplemental Documentation" report, Section 4, titled "Calculating the Hospital-Based Episode Measure," which can be found in the "FY 2016 IPPS NPRM Episode Supplemental Documentation" report at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html.

We are inviting public comment on our proposals.

c. Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)

(1) Background

Between 2009 and 2012, there were 337,419 total hip arthroplasty (THA) procedures and 750,569 total knee arthroplasty (TKA) procedures for Medicare FFS patients 65 years and older.[113] More than one-third of the US population 65 years and older suffers from osteoarthritis,[114] a disabling condition for which elective THA/TKAs are most commonly performed. Estimates place the annual insurer cost of osteoarthritis in the United States at $149 billion, with Medicare payments to hospitals for THA/TKA exceeding $15 billion annually.[115]

There is evidence of variation in payments at hospitals for patients undergoing THA and/or TKA. The mean 90-day risk-standardized payment among Medicare FFS patients aged 65 or older with a qualifying elective primary THA/TKA procedure in 2010–2012 was $23,248, and ranged from $16,421 to $35,123 across 2,614 hospitals.[116] However, high or low payments to hospitals are difficult to interpret in isolation. Some high payment hospitals may have better clinical outcomes when compared with low

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[113] Suter L, Grady JL, Lin Z et al.: 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). 2013. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

[114] Osteoarthritis. 2011; http://www.cdc.gov/arthritis/basics/osteoarthritis.html.

[115] Miller DC, Gust C, Dimick JB, Birkmeyer N, Skinner J, Birkmeyer JD.: Large variations in Medicare payments for surgery highlight savings potential from bundled payment programs. *Health Aff (Millwood).* Nov 2011;30(11):2107-2115.

[116] Kim N, Ott LS, Lin Z et al.: Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (Version 1.0). 2014. Available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

payment hospitals while other high payment hospitals may not have better outcomes. Thus, CMS believes that payment measures provide complementary information to quality measures.

Quality measures for THA/TKA, such as: (1) Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) (77 FR 53515 through 53518), and (2) Hospital-level risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) (77 FR 53519 through 53521), are already adopted in the Hospital IQR Program and publicly reported, making THA/TKA an ideal procedure for which to assess payments for Medicare patients and relative hospital value. Including this proposed measure in the Hospital IQR Program and publicly reporting it on *Hospital Compare* would provide stakeholders with additional information about a hospital's cost of care for THA/TKA that will complement information about a hospital's quality of care. By including payments for 90 days after admission, this hospital-level resource use measure can capture the full spectrum of care and encourage collaboration and shared responsibility for patients' health after their procedures.

We are proposing to include this non-NQF-endorsed measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed, we considered available measures that have been endorsed by the NQF, and were unable to identify any measures that

assess hospital risk-standardized payment associated with a 90-day episode-of-care for elective primary THA/TKA. We also are not aware of any other 90-day episode-of-care THA/TKA measures that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic.

The MAP conditionally supported this measure on December 10, 2014 pending a timely review by the NQF Cost and Resource Use Standing Committee. The MAP recommended harmonizing and determining the most parsimonious approach to measures the costs of hip and knee replacements to minimize the burden and confusion of competing methodologies.[117] Once the call for measures for the Cost and Resource Use project at NQF is announced, we will submit this measure for endorsement. In the meantime, we will consider ways to take these MAP recommendations into account.

(2) Overview of Measure and Rationale for Examining Payments for a 90-Day Episode-of-Care

The THA/TKA payment measure assesses hospital risk-standardized payment associated with a 90-day episode-of-care for elective primary THA/TKA for any hospital participating in the Hospital IQR Program.

When considering payments for Medicare patients, we focused on a 90-day episode-of-care triggered by admission for several key reasons. First, THA and TKA procedures require ongoing post-discharge care. Second, the 90-day preset window encourages hospitals to optimize post-discharge care. Third, mechanical complications

[117] National Quality Forum. The report is available at: http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx and the "Spreadsheet of MAP 2015 Final Recommendations" is available at: http://www.qualityforum.org/map/.

and wound or joint infections may present after 30 days and rates of these complications remain elevated for at least 90 days. Fourth, the 90-day post-admission timeframe is consistent with CMS' THA/TKA complication measure, which captures specific complications up to 90 days after admission. Furthermore, we obtained input from a national Technical Expert Panel (TEP) on the most appropriate window for the episode-of-care. Based on TEP feedback, we chose a measure follow-up period of 90 days that includes all payments for the initial 30 days of the episode, and all payments in a predefined set of care settings and services for days 31 through 90.

We refer readers to the measure methodology report and measure risk adjustment statistical model on our Measure Methodology page, under the "Downloads" section of the Web page. We refer readers to the "Hip and Knee Arthroplasty Payment" zip file on our Web site at: http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

(3) Data Sources

The proposed Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode-of-Care for Elective Primary THA and/or TKA measure uses Part A and Part B Medicare administrative claims data that contain payments for Medicare FFS beneficiaries who were hospitalized and underwent an elective THA/TKA. This measure will use 3 years of data.

(4) Outcome

The primary outcome of this measure is the hospital-level risk-standardized payment for an elective primary THA/TKA episode-of-care. This measure captures

payments for Medicare patients across multiple care settings, services, and supplies (inpatient, outpatient, skilled nursing facility, home health, hospice, physician/clinical laboratory/ambulance services, and durable medical equipment, prosthetics/orthotics, and supplies). This measure includes patient copayments as well as payments from coinsurance. While the approach to standardization in calculating payments over the episode is very similar to the previously adopted Hospital IQR measure, Payment-Standardized Medicare Spending Per Beneficiary (MSPB) as described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626), the THA/TKA measure has a different cohort and risk-model. For more information on how MSPB is calculated, we refer readers to the measure development reports found on the QualityNet Web site at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.

To isolate payment variation that reflects practice patterns rather than CMS payment adjustments, this measure excludes policy and geography payment adjustments unrelated to clinical care decisions. We achieve this by ‘‘stripping’’ or ‘‘standardizing’’ payments for each care setting. Stripping refers to removing geographic differences and policy adjustments in payment rates for individual services from the total payment for that service. Standardizing refers to averaging payments across geographic areas for those services where geographic differences in payment cannot be stripped. Stripping and standardizing the payment amounts allows for a fair comparison across hospitals based solely on payments for decisions related to clinical care of THA/TKA.

By risk standardizing the payment measure, we are able to adjust for case-mix at any given hospital and compare a specific hospital's risk-standardized payment (RSP) to an average hospital with a similar case-mix. We define our analytic timeframe as beginning with the index admission for an elective primary THA/TKA to 90 days post-admission. The measurement includes all payments for the first 30 days after admission and only certain payments based on a pre-defined set of care settings and services for days 31-90.

(5) Cohort

The measure includes Medicare FFS patients aged 65 or older admitted for elective primary THA and/or TKA, and calculates payments made on behalf of these patients (including payments made by CMS, patients, and other insurers) over a 90-day episode-of-care beginning with the index admission. The measure cohort aligns with another previously adopted Hospital IQR Program measure – 90-day hospital-level risk-standardized complication rate (RSCR) following elective primary THA and/or TKA (NQF #1550) (77 FR 53516 through 53518). Consistent with this previously adopted measure, the proposed measure includes hospitalizations identified by a procedure code of either THA or TKA, as classified by the ICD-9-CM codes 81.51 and 81.54, respectively. The measure includes only those hospitalizations from short-stay acute care hospitals in the index cohort and restricts the cohort to patients enrolled in FFS Medicare Parts A and B (with no Medicare Advantage coverage).

(6) Inclusion and Exclusion Criteria

This proposed measure includes hospitalizations for patients 65 years and older at the time of index admission. An index admission/hospitalization is the initial admission for a qualifying elective primary THA/TKA that triggers the 90-day episode-of-care for this payment measure. An index admission is the hospitalization to which the RSP outcome is attributed and includes index admissions for patients having a qualifying elective primary THA/TKA procedure. The measure excludes the following admissions from the measure cohort: (1) admissions for patients without at least 90 days of post-admission enrollment in FFS Medicare Parts A and B because this is necessary to identify the outcome (payments) in the dataset over the analytic period; (2) admissions for patients discharged against medical advice (AMA) because hospitals had limited opportunity to implement high quality care; (3) admissions for patients transferred to federal hospitals because we do not have claims data for these hospitals, so including these patients would cause payments to be underestimated; (4) admissions for patients with more than two THA/TKA procedure codes during the index hospitalization because, although clinically possible, it is highly unlikely that patients would receive more than two elective THA/TKA procedures in one hospitalization, and this may reflect a coding error; (5) admissions that could not be matched to admissions in the THA/TKA complication measure because, as part of our data processing, we matched our index THA/TKA admissions to the THA/TKA complication measure cohort to obtain the risk-adjustment variables; and (6) admissions without a DRG weight and the provider

received no payment because, without either DRG weight or payment data, we cannot calculate a payment for the patient's index admission.

(7) Risk Adjustment

The measure adjusts for differences across hospitals in how payments are affected by patient comorbidities relative to patients cared for by other hospitals. We refer readers to the measure risk adjustment statistical model on our Measure Methodology Web page, under the "Downloads" section of the Web page. Please see the "Hip and Knee Arthroplasty Payment" zip file on our Web site at: http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

(8) Calculating the Risk-Standardized Payment (RSP)

The measure is calculated using a hierarchical generalized linear model with a log link and an inverse Gaussian distribution, which is a widely accepted statistical method that enables fair evaluation of relative hospital performance by taking into account patient risk factors as well as the number of patients that a hospital treats. This statistical model accounts for the structure of the data (patients clustered within hospitals) and calculates: (1) how much variation in hospital payment overall is accounted for by patients' individual risk factors (such as age and other medical conditions) and (2) how much variation is accounted for by hospital-specific performance. This approach appropriately models a positive, continuous, right-skewed outcome like payment and also accounts for the types of patients a hospital treats (that is, hospital case mix), the number of patients it treats, and the quality of care it provides. This hierarchical generalized linear model is an

appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals and sample sizes vary across hospitals. Clustered patients are within the same hospital, and the quality of care of the hospital affects all patients, so the outcomes for each hospital's patients are not fully independent (that is, completely unrelated) as is assumed by many statistical models. As noted above, the measure methodology defines hospital case mix based on the clinical diagnoses provided in the hospital claims for their patients' inpatient and outpatient visits for the 12 months prior to the THA/TKA hospitalization as well as select conditions indicated by secondary diagnosis codes on index admission. This methodology specifically does not, however, account for diagnoses present in the index admission that may indicate complications of care rather than patient comorbidities.

The RSP is calculated as the ratio of predicted payments to expected payments and then the ratio is multiplied by the national unadjusted average payment for an episode-of-care. The ratio is greater than one for hospitals that have higher payments than would be expected for an average hospital with similar cases and less than one if the hospital has lower payments than would be expected for an average hospital with similar cases. This approach is analogous to a ratio of "observed" or "crude" rate to an "expected" or "risk-adjusted" rate used in other similar types of statistical analyses. The RSP is a point estimate—the best estimate of a hospital's payment based on the hospital's case mix.

To calculate the measure result for the Hospital IQR Program, we computed an interval estimate, which is similar to the concept of a confidence interval, to characterize

the level of uncertainty around the point estimate. We use the point estimate and interval estimate to determine hospital performance (for example, higher than expected, as expected, or lower than expected). The interval estimate indicates that the true value of the payment ratio lies between the lower limit and the upper limit of the interval. For more detailed information on the calculation methodology, we refer readers to our Measure Methodology Web page, under the "Downloads" section. We refer readers to the "Hip and Knee Arthroplasty Payment" zip file on our Web site at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

We are inviting public comment on our proposal to adopt the Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode-of-Care for Elective Primary THA and/or TKA measure for the FY 2018 payment determination and subsequent years.

d. Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction

(1) Background

Acute myocardial infarction (AMI) is a priority area for outcomes measurement because it is a common condition associated with considerable morbidity, mortality, and healthcare spending. We note that AMI was the tenth most common principal discharge diagnosis among patients with Medicare in 2012.[118] AMI also accounts for a large

[118] Agency for Healthcare Research and Quality (AHRQ). *Healthcare Cost and Utilization Project (HCUP)* http://hcupnet.ahrq.gov/.

fraction of hospitalization costs, and it was the sixth most expensive condition billed to Medicare in 2011.[119]

Some of the costs for AMI can be attributed to high acute care utilization for post-discharge AMI patients in the form of readmissions, observation stays, and ED visits. We note that patients admitted for AMI have disproportionately high readmission rates, and that readmission rates following discharge for AMI are highly variable across hospitals in the United States.[120, 121] For the previously adopted Hospital IQR Program measure, Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (CY 2009 OPPS/ASC final rule with comment period; 73 FR 68780 through 68781) (hereinafter referred to as READM-30-AMI), publicly reported 30-day risk-standardized readmission rates for AMI ranged from 17.5 percent to 30.3 percent for the time period between July 2011 and June 2012.[122] However, patients are not only at risk of requiring readmission in the post-discharge period. ED visits represent a significant proportion of post-discharge acute care utilization. Two recent studies conducted in patients of all ages have shown that 9.5 percent of patients return to the ED within 30 days of hospital discharge and that

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[119] Torio CM, Andrews RM.: National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011. HCUP Statistical Brief #160. 2013; http://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.jsp.

[120] Krumholz HM, Merrill AR, Schone EM, et al.: Patterns of hospital performance in acute myocardial infarction and heart failure 30-day mortality and readmission. *Circulation. Cardiovascular Quality & Outcomes.* Sep 2009;2(5):407-413.

[121] Bernheim SM, Grady JN, Lin Z, et al.: National patterns of risk-standardized mortality and readmission for acute myocardial infarction and heart failure. Update on publicly reported outcomes measures based on the 2010 release. *Circulation. Cardiovascular Quality & Outcomes.* Sep 2010;3(5):459-467.

[122] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook Performance Report on Outcome Measures September 2013. September 2013; http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/-Medicare-Hospital-Quality-Chartbook-2013.pdf.

about 12 percent of these patients are discharged from the ED and are not captured by the previously adopted Hospital IQR Program READM-30-AMI measure.[123, 124]

In addition, over the past decade, the use of observation stays has rapidly increased. Specifically, between 2001 and 2008, the use of observation services increased nearly three-fold,[125] and significant variation has been demonstrated in the use of observation services for conditions such as chest pain.[126] These rising rates of observation stays among Medicare beneficiaries have gained the attention of patients, providers, and policymakers.[127] For example, a report from OIG noted that in 2012, Medicare beneficiaries had 1.5 million observation stays.[128] Many of these observation stays lasted longer than the intended one day. This OIG report also noted the potential relationship between hospital use of observation stays as an alternative to short-stay inpatient hospitalizations as a response to changing hospital payment incentives.[129]

Thus, in the context of the previously adopted and publicly reported READM-30-AMI measure, the increasing use of ED visits and observation stays has raised concerns that the READM-30-AMI measure does not capture the full range of

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[123] Rising KL, White LF, Fernandez WG, Boutwell AE.: Emergency Department Visits After Hospital Discharge: A Missing Part of the Equation. *Annals of Emergency Medicine.* 2013(0).
[124] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA : the journal of the American Medical Association.* Jan 23 2013;309(4):364-371.
[125] Venkatesh AK GB, Gibson Chambers JJ, Baugh CW, Bohan JS, Schuur JD.: Use of Observation Care in US Emergency Departments, 2001 to 2008. *PLoS One.* September 2011;6(9):e24326.
[126] Schuur JD, Baugh CW, Hess EP, Hilton JA, Pines JM, Asplin BR.: Critical pathways for post-emergency outpatient diagnosis and treatment: tools to improve the value of emergency care. *Academic Emergency Medicine.* Jun 2011;18(6):e52-63.
[127] Feng Z, Wright B, Mor V.: Sharp rise in Medicare enrollees being held in hospitals for observation raises concerns about causes and consequences. *Health Affairs.* Jun 2012;31(6):1251-1259.
[128] Wright S.: *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries, OEI-02-12-00040*. Washington, DC: Department of Health and Human Services: Office of Inspector General July 29, 2013.
[129] Wright S.: *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries*, *OEI-02-12-00040.* Washington, DC: Department of Health and Human Services: Office of Inspector General July 29, 2013.

unplanned acute care in the post-discharge period. In particular, there exists concern that high use of observation stays could in some cases replace readmissions, and hospitals with high rates of observation stays in the post-discharge period may therefore have low readmission rates that do not accurately reflect the quality of care.[130]

In response to these concerns, CMS improved on a previously existing non-Hospital IQR Program measure entitled "30-Day Post-Hospital AMI Discharge Care Transition Composite" (NQF #0698). The improved measure (now called Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction) is a risk-adjusted outcome measure for AMI that incorporates the full range of acute care use that patients may experience post-discharge: hospital readmissions, observation stays, and ED visits.

The measure assesses all-cause acute care utilization for post-discharge AMI patients for several reasons. First, from the patient perspective, acute care utilization for any cause is undesirable. It is costly, exposes patients to additional risks of medical care, interferes with work and family care, and imposes significant burden on caregivers. Second, limiting the measure to inpatient utilization may make it susceptible to gaming. Finally, it is often hard to exclude quality concerns and accountability based on the documented cause of a hospital visit. Therefore, this measure includes all-cause utilization.

We are proposing to include this improved measure under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered existing measures

[130] Carlson J.: Faulty Gauge? Readmissions are down, but observational-status patients are up and that could skew Medicare numbers. *Modern Healthcare.* June 8, 2013 2013.

related to care transitions that have been endorsed by the NQF. Existing process measures capture many important domains of care transitions such as education, medication reconciliation and follow-up, but all require chart review and manual abstraction. Existing outcome measures are focused entirely on readmissions or complications and do not include observation stays or ED visits. We also are not aware of any other measures that assess the quality of transitional care by measuring 30-day risk-standardized days in acute care (hospital readmissions, observation stays, and ED visits) following hospitalization for AMI that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic.

The MAP conditionally supported this measure on the condition that this measure is reviewed by NQF and endorsed. We refer readers to the Spreadsheet of MAP 2015 Final Recommendations available at: http://www.qualityforum.org/map/, and note that in the document, this measure is entitled "Hospital 30-day, all-cause, unplanned risk-standardized days in acute care following acute myocardial infarction (AMI) hospitalization." In particular, MAP members noted that the measure should be considered for SDS adjustment in the upcoming NQF trial period, reviewed for the empirical and conceptual relationship between SDS factors and risk-standardized days following acute care, and endorsed with appropriate consideration of SDS factors as determined by NQF standing committees. Some MAP members noted this measure could help address concerns about the growing use of observation stays. We note that this measure will be submitted to NQF with appropriate consideration for SDS, if

required, for endorsement proceedings once an appropriate measure endorsement project has a call for measures.

(2) Overview of Measure

This Excess Days in Acute Care after Hospitalization for AMI measure is a risk-standardized outcome measure that compares the number of days that patients are predicted to spend in acute care across the full spectrum of possible acute care events (hospital readmissions, observation stays, and ED visits) after discharge from a hospital for AMI, compared to the days expected based on their degree of illness.

(3) Data Sources

The proposed measure is administrative claims-based and will use 3 years of data. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for AMI.

(4) Outcome

The outcome of the measure is the excess number of days patients spend in acute care (hospital readmissions, observation stays, and ED visits) per 100 discharges during the first 30 days after discharge from the hospital, relative to the number spent by the same patients discharged from an average hospital. The measure defines days in acute care as days spent: (1) in an ED, (2) admitted to observation status, or (3) admitted as an unplanned readmission for any cause within 30 days from the date of discharge from the index AMI hospitalization. Readmission days are calculated as the discharge date minus the admission date. Admissions that extend beyond the 30-day follow-up period are truncated on day 30. Observation days are calculated by the hours in observation,

rounded up to the nearest half day. On the advice of our TEP, an ED treat-and-release visit is counted as one half day. ED visits are not counted as a full day because the majority of treat-and-release visits last fewer than 12 hours.

"Planned" readmissions are those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. This measure excludes planned readmissions using the planned readmission algorithm previously developed for the READM-30-AMI measure. A more detailed discussion of exclusions follows below.

The measure counts all use of acute care occurring in the 30-day post-discharge period. For example, if a patient returns to the ED three times, the measure counts each ED visit as a half-day. Similarly, if a patient has two hospitalizations within 30 days, the days spent in each are counted. We take this approach to capture the full patient experience of need for acute care in the post-discharge period.

(5) Cohort

We defined the eligible cohort using the same criteria as the existing Hospital IQR Program measure, READM-30-AMI, except that this proposed measure does not include patients admitted to Veterans Administration hospitals. That is, the cohort includes Medicare FFS patients aged 65 years or older: (1) with a principal discharge diagnosis of AMI; (2) enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission, and enrolled in Part A during the index admission; (3) who were discharged from a non-Federal acute care hospital; (4) who were not transferred to

another acute care facility; and (5) were alive at discharge. We defined the cohorts using the following ICD-9-CM diagnosis codes identified in inpatient claims data:

- 410.00 (Acute myocardial infarction of anterolateral wall, episode of care unspecified);
- 410.01 (Acute myocardial infarction of anterolateral wall, initial episode of care);
- 410.10 (Acute myocardial infarction of other anterior wall, episode of care unspecified);
- 410.11 (Acute myocardial infarction of other anterior wall, initial episode of care);
- 410.20 (Acute myocardial infarction of inferolateral wall, episode of care unspecified);
- 410.21 (Acute myocardial infarction of inferolateral wall, initial episode of care);
- 410.30 (Acute myocardial infarction of inferoposterior wall, episode of care unspecified);
- 410.31 (Acute myocardial infarction of inferoposterior wall, initial episode of care);
- 410.40 (Acute myocardial infarction of other inferior wall, episode of care unspecified);
- 410.41 (Acute myocardial infarction of other inferior wall, initial episode of care);

- 410.50 (Acute myocardial infarction of other lateral wall, episode of care unspecified);
- 410.51 (Acute myocardial infarction of other lateral wall, initial episode of care);
- 410.60 (True posterior wall infarction, episode of care unspecified);
- 410.61 (True posterior wall infarction, initial episode of care);
- 410.70 (Subendocardial infarction, episode of care unspecified);
- 410.71 (Subendocardial infarction, initial episode of care);
- 410.80 (Acute myocardial infarction of other specified sites, episode of care unspecified);
- 410.81 (Acute myocardial infarction of other specified sites, initial episode of care);
- 410.90 (Acute myocardial infarction of unspecified site, episode of care unspecified);
- 410.91 (Acute myocardial infarction of unspecified site, initial episode of care).

(6) Exclusion Criteria

The measure excludes the following admissions from the measure cohort: (1) hospitalizations without at least 30 days of post-discharge enrollment in Part A and Part B FFS Medicare because the 30-day outcome cannot be assessed in this group since claims data are used to determine whether a patient was readmitted, was placed under observation, or visited the ED; (2) discharged against medical advice (AMA) because

providers did not have the opportunity to deliver full care and prepare the patient for discharge; (3) hospitalizations for patients admitted and discharged on the same day (and not transferred or deceased) because these patients likely did not suffer clinically significant AMI; and (4) hospitalizations for patients with an index admission within 30 days of a previous index admission because additional AMI admissions within 30 days are part of the outcome, and we choose not to count a single admission both as an index admission and a readmission for another index admission.

(7) Risk-Adjustment

The measure adjusts for variables that are clinically relevant and have strong relationships with the outcome. The measure seeks to adjust for case-mix differences among hospitals based on the clinical status of the patient at the time of the index admission. Accordingly, only comorbidities that convey information about the patient at that time or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk adjustment. The measure does not adjust for patients' admission source or their discharge disposition (for example, skilled nursing facility) because these factors are associated with the structure of the healthcare system, not solely patients' clinical comorbidities. Regional differences in the availability of post-acute care providers and practice patterns might exert undue influence on model results. In addition, these data fields are not audited and are not as reliable as diagnosis codes.

The outcome is risk adjusted using a two-part random effects model. This statistical model, often referred to as a "hurdle" model, accounts for the structure of the

data (patients clustered within hospitals) and the observed distribution of the outcome. Specifically, it models the number of acute care days for each patient as: (a) a probability that they have a non-zero number of days; and (b) a number of days, given that this number is non-zero. The first part is specified as a logit model, and the second part is specified as a Poisson model, with both parts having the same risk-adjustment variables and each part having a random effect. This is an accepted statistical method that explicitly estimates how much of the variation in acute care days is accounted for by patient risk factors, how much by the hospital where the patient is treated, and how much is explained by neither. This model is used to calculate the predicted (including random effects) and expected (assuming random effects are zero) number of days for each patient, and the average difference between these for each hospital is used to construct the risk-standardized Excess Acute Care Days.

(8) Calculating Excess Acute Care Days (EACDs)

The EACD is calculated as the difference between the average of the predicted number of days spent in acute care for patients discharged from each hospital and the average number of days that would have been expected if those patients had been cared for at an average hospital, and then the difference is multiplied by 100 so that EACD represents EACD per 100 discharges. We multiply the final measure by 100 to be consistent with the reporting of the existing READM-30-AMI measure. A positive result indicates that patients spend more days in acute care post-discharge than expected; a negative result indicates that patients spend fewer days in acute care than expected.

We are inviting public comment on our proposal to adopt the Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction measure for the FY 2018 payment determination and subsequent years.

e. Excess Days in Acute Care after Hospitalization for Heart Failure

(1) Background

Heart failure is a priority area for outcomes measurement because it is a common condition associated with considerable morbidity, mortality, and healthcare spending. Heart failure was the second most common principal discharge diagnosis among patients with Medicare in 2012.[131] Heart failure also accounts for a large fraction of hospitalization costs, and it was the third most expensive condition billed to Medicare in 2011.[132]

Some of the costs for heart failure can be attributed to high acute care utilization for post-discharge heart failure patients in the form of readmissions, observation stays, and ED visits. Patients admitted for heart failure have disproportionately high readmission rates. Readmission rates following discharge for heart failure are highly variable across hospitals in the United States.[133, 134] For the previously adopted Hospital IQR Program measure, Hospital 30-Day All-Cause Risk-Standardized Readmission Rate

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[131] Agency for Healthcare Research and Quality (AHRQ). *Healthcare Cost and Utilization Project (HCUP)* http://hcupnet.ahrq.gov/.

[132] Torio CM, Andrews RM. National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011. HCUP Statistical Brief #160. 2013; Available at: http://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.jsp.

[133] Krumholz HM, Merrill AR, Schone EM, et al.: Patterns of hospital performance in acute myocardial infarction and heart failure 30-day mortality and readmission. *Circulation. Cardiovascular Quality & Outcomes.* Sep 2009;2(5):407-413.

[134] Bernheim SM, Grady JN, Lin Z, et al.: National patterns of risk-standardized mortality and readmission for acute myocardial infarction and heart failure. Update on publicly reported outcomes measures based on the 2010 release. *Circulation. Cardiovascular Quality & Outcomes.* Sep 2010;3(5):459-467.

(RSRR) following Heart Failure Hospitalization (NQF #0330) (READM-30-HF) (73 FR 46806 through 48610), publicly reported 30-day risk-standardized readmission rates for heart failure ranged from 17.5 percent to 30.3 percent for the time period between July 2011 and June 2012.[135] However, patients are not only at risk of requiring readmission in the post-discharge period. ED visits represent a significant proportion of post-discharge acute care utilization. Two recent studies conducted in patients of all ages have shown that 9.5 percent of patients return to the ED within 30 days of hospital discharge and that about 12 percent of these patients are discharged from the ED and are not captured by the previously adopted Hospital IQR Program READM-30-HF measure.[136, 137] Patients returning to the ED after heart failure hospitalization most commonly return for heart failure recurrence and chest pain.[138]

In addition, over the past decade, the use of observation stays has rapidly increased. Specifically, between 2001 and 2008, the use of observation services increased nearly three-fold,[139] and significant variation has been demonstrated in the use of observation services for conditions such as chest pain.[140] These rising rates of observation stays among Medicare beneficiaries have gained the attention of patients,

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[135] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook Performance Report on Outcome Measures September 2013. September 2013; Available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/-Medicare-Hospital-Quality-Chartbook-2013.pdf.

[136] Rising KL, White LF, Fernandez WG, Boutwell AE.: Emergency Department Visits After Hospital Discharge: A Missing Part of the Equation. *Annals of Emergency Medicine.* 2013(0).

[137] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA : the journal of the American Medical Association.* Jan 23 2013;309(4):364-371.

[138] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA :The journal of the American Medical Association.* Jan 23 2013;309(4):364-371.

[139] Venkatesh AK GB, Gibson Chambers JJ, Baugh CW, Bohan JS, Schuur JD.: Use of Observation Care in US Emergency Departments, 2001 to 2008. *PLoS One.* September 2011;6(9):e24326.

[140] Schuur JD, Baugh CW, Hess EP, Hilton JA, Pines JM, Asplin BR.: Critical pathways for post-emergency outpatient diagnosis and treatment: tools to improve the value of emergency care. *Academic Emergency Medicine.* Jun 2011;18(6):e52-63.

providers, and policymakers.[141, 142, 143] For example, a report from the OIG noted that in 2012, Medicare beneficiaries had 1.5 million observation stays.[144] Many of these observation stays lasted longer than the intended one day. The OIG report also noted the potential relationship between hospital use of observation stays as an alternative to short-stay inpatient hospitalizations as a response to changing hospital payment incentives.

Thus, in the context of the currently adopted and publicly reported Hospital IQR Program READM-30-HF measure, the increasing use of ED visits and observation stays has raised concerns that the READM-30-HF measure does not capture the full range of unplanned acute care in the post-discharge period. In particular, there exists concern that high use of observation stays could in some cases replace readmissions, and hospitals with high rates of observation stays in the post-discharge period may therefore have low readmission rates that do not accurately reflect the quality of care.[145]

In response to these concerns, we improved on an existing non-Hospital IQR Program measure entitled "30-Day Post-Hospital HF Discharge Care Transition Composite" (NQF #0699). The improved measure (now called Excess Days in Acute Care after Hospitalization for Heart Failure) is a risk-adjusted outcome measure for heart

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[141] Rising KL, White LF, Fernandez WG, Boutwell AE.: Emergency Department Visits After Hospital Discharge: A Missing Part of the Equation. *Annals of Emergency Medicine.* 2013(0).
[142] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA : The Journal of the American Medical Association.* Jan 23 2013;309(4):364-371.
[143] Feng Z, Wright B, Mor V.: Sharp rise in Medicare enrollees being held in hospitals for observation raises concerns about causes and consequences. *Health Affairs.* Jun 2012;31(6):1251-1259.
[144] Wright S.: *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries, OEI-02-12-00040.* Washington, DC: Department of Health and Human Services: Office of Inspector General July 29, 2013.
[145] Carlson J.: Faulty Gauge? Readmissions are down, but observational-status patients are up and that could skew Medicare numbers. *Modern Healthcare.* June 8, 2013 2013.

failure that incorporates the full range of acute care use that patients may experience post-discharge: hospital readmissions, observation stays, and ED visits.

The measure assesses all-cause acute care utilization for post-discharge heart failure patients for several reasons. First, from the patient perspective, acute care utilization for any cause is undesirable. It is costly, exposes patients to additional risks of medical care, interferes with work and family care, and imposes significant burden on caregivers. Second, limiting the measure to inpatient utilization may make it susceptible to gaming. Finally, it is often hard to exclude quality concerns and accountability based on the documented cause of a hospital visit. Therefore, this measure includes all-cause utilization.

We are proposing this improved measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section VIII.A.7. of the preamble of this proposed rule. We considered other existing measures related to care transitions that have been endorsed by the NQF. Existing process measures capture many important domains of care transitions such as education, medication reconciliation and follow-up, but all require chart review and manual abstraction. Existing outcome measures are focused entirely on readmissions or complications and do not include observation stays or ED visits. We also are not aware of any other measures that assess the quality of transitional care by measuring 30-day risk-standardized days in acute care (hospital readmissions, observation stays and ED visits) following hospitalization for heart failure that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic.

The MAP conditionally supported this measure on the condition that it is reviewed by NQF and endorsed. We note that this measure was entitled "Hospital 30-day, all-cause, unplanned risk-standardized days in acute care following heart failure hospitalization," in the MAP Spreadsheet. In particular, MAP members noted that the measure should be considered for SDS adjustment in the upcoming NQF trial period, reviewed for the empirical and conceptual relationship between SDS factors and risk-standardized days following acute care, and endorsed with appropriate consideration of SDS factors as determined by NQF standing committees. Some MAP members noted this measure could help address concerns about the growing use of observation stays. We note that this measure will be submitted to NQF with appropriate consideration for SDS, if required, for endorsement proceedings once an appropriate measure endorsement project has a call for measures.

(2) Overview of Measure

This Excess Days in Acute Care after Hospitalization for Heart Failure measure is a risk-standardized outcome measure that compares the number of days that patients are predicted to spend in acute care across the full spectrum of possible acute care events (hospital readmissions, observation stays, and ED visits) after discharge from a hospital for heart failure, compared to the days expected at an average hospital, based on their degree of illness.

(3) Data Sources

The proposed measure is administrative claims-based and will use 3 years of data. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for heart failure.

(4) Outcome

The outcome of the measure is the excess number of days patients spend in acute care (hospital readmissions, observation stays, and ED visits) per 100 discharges during the first 30 days after discharge from the hospital, relative to the number spent by the same patients discharged from an average hospital. The measure defines days in acute care as days spent: (1) in an ED, (2) admitted to observation status, or (3) admitted as an unplanned readmission for any cause within 30 days from the date of discharge from the index heart failure hospitalization. Readmission days are calculated as the discharge date minus the admission date. Admissions that extend beyond the 30-day follow-up period are truncated on day 30. Observation days are calculated by the hours in observation, rounded up to the nearest half day. On the advice of our TEP, an ED treat-and-release visit is counted as one half day. ED visits are not counted as a full day because the majority of treat-and-release visits last fewer than 12 hours.

"Planned" readmissions are those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. This measure excludes planned readmissions using the planned readmission algorithm (78 FR 50786 through 50787), a set of criteria for classifying readmissions that are likely to be planned among the general Medicare population using Medicare claims data, previously

developed for Hospital IQR Program 30-day readmission measures, including the previously adopted READM-30-HF measure.

The measure counts all use of acute care occurring in the 30-day post-discharge period. For example, if a patient returns to the ED three times, the measure counts each ED visit as a half-day. Similarly, if a patient has two hospitalizations within 30 days, the days spent in each are counted. We take this approach to capture the full patient experience of need for acute care in the post-discharge period.

(5) Cohort

We defined the eligible cohort using the same criteria as the previously adopted Hospital IQR Program READM-30-HF measure (73 FR 46806 through 48610). The READM-30-HF cohort criteria are included in a report posted on our Measure Methodology Web page, under the "Downloads" section in the "AMI, HF, PN, COPD, and Stroke Readmission Updates" zip file on our Web site at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html. This measure differs from the READM-30-HF measure cohort in that this measure does not include patients admitted to Veterans Administration hospitals. That is, the cohort includes Medicare FFS patients aged 65 years or older: (1) with a principal discharge diagnosis of heart failure; (2) enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission, and enrolled in Part A during the index admission; (3) who were discharged from a non-Federal acute care hospital; (4) who were not transferred to another acute care

facility; and (5) were alive at discharge. We defined the cohorts using the following ICD-9-CM diagnosis codes identified in inpatient claims data:

- 402.01 (Malignant hypertensive heart disease with heart failure);
- 402.11 (Benign hypertensive heart disease with heart failure);
- 402.91 (Unspecified hypertensive heart disease with heart failure);
- 404.01 (Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified);
- 404.03 (Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease);
- 04.11 (Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified);
- 404.13 (Hypertensive heart and chronic kidney disease, benign, with heart failure and chronic kidney disease stage V or end stage renal disease);
- 404.91 (Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified);
- 404.93 (Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease);
- 428.0 (Congestive heart failure, unspecified);
- 428.1 (Left heart failure);
- 428.20 (Systolic heart failure, unspecified);
- 428.21 (Acute systolic heart failure);
- 428.22 (Chronic systolic heart failure);

- 428.23 (Acute on chronic systolic heart failure);
- 428.30 (Diastolic heart failure, unspecified);
- 428.31 (Acute diastolic heart failure);
- 428.32 (Chronic diastolic heart failure);
- 428.33 (Acute on chronic diastolic heart failure)
- 428.40 (Combined systolic and diastolic heart failure, unspecified);
- 428.41 (Acute combined systolic and diastolic heart failure);
- 428.42 (Chronic combined systolic and diastolic heart failure);
- 428.43 (Acute on chronic combined systolic and diastolic heart failure);
- 428.9 (Heart failure, unspecified).

(6) Exclusion Criteria

The measure excludes the following admissions from the measure cohort: (1) hospitalizations without at least 30 days of post-discharge enrollment in Part A and Part B FFS Medicare because the 30-day outcome cannot be assessed in this group because claims data are used to determine whether a patient was readmitted, was placed under observation, or visited the ED; (2) discharged against medical advice (AMA) because providers did not have the opportunity to deliver full care and prepare the patient for discharge; and (3) hospitalizations for patients with an index admission within 30 days of a previous index admission because additional heart failure admissions within 30 days are part of the outcome, and we choose not to count a single admission both as an index admission and a readmission for another index admission.

(7) Risk-Adjustment

The measure adjusts for variables that are clinically relevant and have strong relationships with the outcome. The measure seeks to adjust for case-mix differences among hospitals based on the clinical status of the patient at the time of the index admission. Accordingly, only comorbidities that convey information about the patient at that time or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk adjustment. The measure does not adjust for patients' admission source or their discharge disposition (for example, skilled nursing facility) because these factors are associated with the structure of the health care system, not solely patients' clinical comorbidities. Regional differences in the availability of post-acute care providers and practice patterns might exert undue influence on model results. In addition, these data fields are not audited and are not as reliable as diagnosis codes.

The outcome is risk adjusted using a two-part random effects model. This statistical model, often referred to as a "hurdle" model, accounts for the structure of the data (patients clustered within hospitals) and the observed distribution of the outcome. Specifically, it models the number of acute care days for each patient as: (a) a probability that they have a non-zero number of days and (b) a number of days, given that this number is non-zero. The first part is specified as a logit model, and the second part is specified as a Poisson model, with both parts having the same risk-adjustment variables and each part having a random effect. This is an accepted statistical method that explicitly estimates how much of the variation in acute care days is accounted for by

patient risk factors, how much by the hospital where the patient is treated, and how much is explained by neither. This model is used to calculate the predicted (including random effects) and expected (assuming random effects are zero) number of days for each patient, and the average difference between these for each hospital is used to construct the risk-standardized Excess Acute Care Days.

(8) Calculating Excess Acute Care Days (EACDs)

The EACD is calculated as the difference between the average of the predicted number of days spent in acute care for patients discharged from each hospital and the average number of days that would have been expected if those patients had been cared for at an average hospital, and then the difference is multiplied by 100 so that EACD represents EACD per 100 discharges. We multiply the final measure by 100 to be consistent with the reporting of the existing READM-30-HF measure. A positive result indicates that patients spend more days in acute care post-discharge than expected; a negative result indicates that patients spend fewer days in acute care than expected.

We are inviting public comment on our proposal to adopt the Excess Days in Acute Care after Hospitalization for Heart Failure measure for the FY 2018 payment determination and subsequent years.

f. Summary of Previously Adopted and Proposed Hospital IQR Program Measure Set for the FY 2018 Payment Determination and Subsequent Years

The table below outlines the Hospital IQR Program measure set for the FY 2018 payment determination and subsequent years and includes both previously adopted and proposed measures.