based on the exclusion and the amount that would have been paid under the prospective payment systems specified in §412.1(a)(1).

(2) For cost reporting periods beginning on or after January 1, 2002, the intermediary adjusts the payment to the hospitals described in paragraph (a) of this section as follows:

(i) The intermediary calculates the difference between the amounts actually paid under subpart P of this part during the cost reporting period for which the hospital, unit, or beds were first classified as a new hospital, new unit, or newly added beds under subpart B of this part, and the amount that would have been paid under the prospective payment systems specified in §412.1(a)(1) for services furnished during that period.

(ii) The intermediary makes a retroactive adjustment for the difference between the amount paid to the hospital under subpart P of this part and the amount that would have been paid under the prospective payment systems specified in §412.1(a)(1).

[56 FR 43241, Aug. 30, 1991, as amended at 57 FR 39825, Sept. 1, 1992; 59 FR 45400, Sept. 1, 1994; 60 FR 45848, Sept. 1, 1995; 66 FR 41387, Aug. 7, 2001; 70 FR 66977, Nov. 15, 2005; 78 FR 47934, Aug. 6, 2013]

§412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.

(a) *Participation in the Hospital IQR Program.* In order to participate in the Hospital IQR Program, a section 1886(d) of the hospital must–

(1) Register on QualityNet website, before it begins to report data;

(2) Identify and register a QualityNet security official as part of the registration process under paragraph (a)(1) of this section; and

(3) Submit a completed Notice of Participation Form to CMS if the hospital is participating in the program for the first time, has previously withdrawn from the program and would like to participate again, or has received a new CMS Certification Number (CCN).

(i) A hospital that would like to participate in the program for the first time (and to which paragraph (a)(3)(ii) of this section does not apply), or that previously withdrew from the program and would now like to participate again, must submit to CMS a completed Notice of Participation Form by December 31 of the calendar year preceding the first quarter of the calendar year in which data submission is required for any given fiscal year.

(ii) A hospital that has received a new CCN and would like to participate in the program must submit a completed Notice of Participation Form to CMS no later than 180 days from the date identified as the open date on the approved CMS Quality Improvement Evaluation System (QIES).

(b) *Withdrawal from the Hospital IQR Program.* CMS will accept Hospital IQR Program withdrawal forms from hospitals on or before—

(1) Prior to the FY 2016 payment determination, August 15 of the fiscal year preceding the fiscal year for which a Hospital IQR determination will be made.

(2) Beginning with the FY 2016 payment determination, May 15 of the fiscal year preceding the fiscal year for which a Hospital IQR payment determination will be made.

(c) *Submission and validation of Hospital IQR Program data.* (1) *General rule.* Except as provided in paragraph (c)(2) of this section, subsection (d) hospitals that participate in the Hospital IQR Program must submit to CMS data on measures selected under section 1886(b)(3)(B)(viii) of the Act in a form and manner, and at a time, specified by CMS. A hospital must begin submitting data on the first day of the quarter following the date that the hospital submits a completed Notice of Participation form under paragraph (a)(3) of this section.

(2) *Extraordinary circumstances exceptions.* CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the hospital. CMS may grant an exception as follows:

(i) For circumstances not relating to the reporting of electronic clinical quality measure data, a hospital participating in the Hospital IQR Program that wishes to request an exception with respect to quality data reporting

requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred. For circumstances relating to the reporting of electronic clinical quality measures, a hospital participating in the Hospital IQR Program that wishes to request an exception must submit its request to CMS by April 1 following the end of the reporting calendar year in which the extraordinary circumstances occurred. Specific requirements for submission of a request for an exception are available on QualityNet website.

(ii) CMS may grant an exception to one or more hospitals that have not requested an exception if: CMS determines that a systemic problem with CMS data collection systems directly affected the ability of the hospital to submit data; or if CMS determines that an extraordinary circumstance has affected an entire region or locale.

(d) *Validation of Hospital IQR Program data.* CMS may validate one or more measures selected under section 1886(b)(3)(B)(viii) of the Act by reviewing patient charts submitted by selected participating hospitals.

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS a sample of patient charts that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the patient charts to CMS or its contractor within 30 days of the date identified on the written request.

(2)(i) A hospital meets the chart-abstracted validation requirement with respect to a fiscal year if it achieves a 75-percent score, as determined by CMS.

(ii) A hospital meets the eCQM validation requirement with respect to a fiscal year if it submits at 100 percent of sampled eCQM measure medical records in a timely and complete manner, as determined by CMS.

(e) *Reconsiderations and appeals of Hospital IQR Program decisions.* (1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital IQR Program for a particular fiscal year. Except as provided in paragraph (c)(2) of this section, a hospital must submit a reconsideration request to CMS no later than 30 days from the date identified on the Hospital Inpatient Quality Reporting Program Annual Payment Update Notification Letter provided to the hospital.

(2) A reconsideration request must contain the following information:

(i) The hospital's CMS Certification Number (CCN);

(ii) The name of the hospital;

(iii) Contact information for the hospital's chief executive officer and QualityNet security official, including each individual's name, e-mail address, telephone number, and physical mailing address;

(iv) A summary of the reason(s), as set forth in the Hospital Inpatient Quality Reporting Program Annual Payment Update Notification Letter, that CMS concluded the hospital did not meet the requirements of the Hospital IQR Program;

(v) A detailed explanation of why the hospital believes that it complied with the requirements of the Hospital IQR Program for the applicable fiscal year;

(vi) Any evidence that supports the hospital's reconsideration request, including copies of patient charts, e-mails and other documents; and

(vii) If the hospital has requested reconsideration on the basis that CMS concluded it did not meet the validation requirement set forth in paragraph (d) of this section, the reconsideration request must contain the following additional information:

(A) A copy of each patient chart that the hospital timely submitted to CMS or its contractor in response to a request made under paragraph (d)(1) of this section; and

(B) A detailed explanation identifying which data the hospital believes was improperly validated by CMS and why the hospital believes that such data are correct.

(3) A hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R of this chapter.

(f) *Patient experience of care data (HCAHPS survey).* HCAHPS is the Hospital Consumer Assessment of

Healthcare Providers and Systems survey that measures patient experience of care after a recent hospital stay.

(1) Approved HCAHPS survey vendors and self-administering hospitals must fully comply with all HCAHPS oversight activities, including allowing CMS and its HCAHPS Project Team to perform site visits at the hospitals' and survey vendors' company locations.

(2) CMS approves an application for an entity to administer the HCAHPS survey as an approved HCAHPS survey vendor on behalf of one or more hospitals when an applicant has met the Minimum Survey Requirements and Rules of Participation that can be found on the official HCAHPS On-Line Web site, and agree to comply with the current survey administration protocols that can be found on the official HCAHPS On-Line Web site. An entity must be an approved HCAHPS survey vendor in order to administer and submit HCAHPS data to CMS on behalf of one or more hospitals.

(g) *Retention and removal of quality measures under the Hospital IQR Program*—(1) *General rule for the retention of quality measures.* Quality measures adopted for the Hospital IQR Program measure set for a previous payment determination year are retained for use in subsequent payment determination years, except when they are removed, suspended, or replaced as set forth in paragraphs (g)(2) and (3) of this section.

(2) *Immediate measure removal.* For cases in which CMS believes that the continued use of a measure raises specific patient safety concerns, CMS will immediately remove a quality measure from the Hospital IQR Program and will promptly notify hospitals and the public of the removal of the measure and the reasons for its removal through the Hospital IQR Program ListServ and the QualityNet website, as applicable.

(3) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (g)(2) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the Hospital IQR Program to allow for public comment.

(i) *Factors for consideration of removal of quality measures.* CMS will weigh whether to remove a measure based on the following factors:

(A) *Factor 1.* Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measure).

(B) *Factor 2.* A measure does not align with current clinical guidelines or practice.

(C) *Factor 3.* The availability of a more broadly applicable measure (across settings or populations), or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(D) *Factor 4.* Performance or improvement on a measure does not result in better patient outcomes.

(E) *Factor 5.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(F) *Factor 6.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Criteria to determine topped-out measures.* For the purposes of the Hospital IQR Program, a measure is considered to be topped-out under paragraph (g)(3)(i)(A) of this section when it meets both of the following criteria:

(A) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for a hospital's measure is within 2 times the standard error of the full data set).

(B) A truncated coefficient of variation less than or equal to 0.10.

(iii) *Application of measure removal factors.* The benefits of removing a

measure from the Hospital IQR Program will be assessed on a case-by-case basis.

[76 FR 51782, Aug. 18, 2011, as amended at 77 FR 53674, Aug. 31, 2012; 78 FR 50966, Aug. 19, 2013; 79 FR 50354, Aug. 22, 2014; 81 FR 57267, Aug. 22, 2016; 82 FR 38511, Aug. 14, 2017; 86 FR 45520, Aug. 13, 2021; 87 FR 49404, Aug. 10, 2022; 88 FR 59332, Aug. 28, 2023]

Subpart I—Adjustments to the Base Operating DRG Payment Amounts Under the Prospective Payment Systems for Inpatient Operating Costs

SOURCE: 77 FR 53674, Aug. 31, 2012, unless otherwise noted.

§ 412.150 Basis and scope of subpart.

(a) Section 1886(q) of the Act requires the Secretary to establish a Hospital Readmissions Reduction program, under which payments to applicable hospitals are reduced in order to account for certain excess readmissions, effective for discharges beginning on October 1, 2012. The rules for determining the payment adjustment under the Hospital Readmission Reductions Program are specified in §§ 412.152 and 412.154.

(b) Section 1886(o) of the Act requires the Secretary to establish a Value-Based Purchasing (VBP) Program for inpatient hospitals (Hospital VBP Program), which requires CMS to make value-based incentive payments to hospitals that meet performance standards for applicable performance periods, effective for discharges beginning on October 1, 2012. The rules for determining the payment adjustment under the Hospital Value-Based Purchasing Program are specified in §§ 412.160 through 412.167.

(c) Section 1886(p) of the Act requires the Secretary to establish an adjustment to hospital payments for hospital-acquired conditions, or a Hospital-Acquired Condition Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions, effective for discharges beginning on October 1, 2014. The rules for determining the payment adjustment under the Hospital-Acquired Condition Reduction Program are specified in §§ 412.170 and 412.172.

[77 FR 53674, Aug. 31, 2012, as amended at 78 FR 50966, Aug. 19, 2013]

PAYMENT ADJUSTMENTS UNDER THE HOSPITAL READMISSIONS REDUCTION PROGRAM

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

As used in this section and in § 412.154, the following definitions apply:

Aggregate payments for all discharges is, for a hospital for the applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.

Aggregate payments for excess readmissions is, for a hospital for the applicable period, the sum, for the applicable conditions, of the product for each applicable condition of:

(1) The base operating DRG payment amount for the hospital for the applicable period for such condition or procedure;

(2) The number of admissions for such condition or procedure for the hospital for the applicable period;

(3) The excess readmission ratio for the hospital for the applicable period minus the peer-group median excess readmission ratio (ERR); and

(4) The neutrality modifier, a multiplicative factor that equates total Medicare savings under the current stratified methodology to the previous non-stratified methodology.

Applicable condition is a condition or procedure selected by the Secretary—

(1) Among the conditions and procedures for which—

(i) Readmissions represent conditions or procedures that are high volume or high expenditures; and

(ii) Measures of such readmissions have been endorsed by the entity with a contract under section 1890(a) of the Act and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital); or

(2) Among other conditions and procedures as determined appropriate by