

with the Secretary's requirements in this part.

(b) *Participation in the REHQR Program.* To participate in the REHQR Program, an REH as defined in section 1861(kkk)(2) of the Act must—

(1) Register on a CMS website before beginning to report data;

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

(3) Submit data on all quality measures to CMS as specified under paragraph (c) of this section.

(c) *Submission of REHQR Program data—(1) General rule.* REHs that participate in the REHQR Program must submit to CMS data on measures selected under section 1861(kkk)(7)(C) of the Act in a form and manner and at a time specified by CMS. REHs sharing the same CMS Certification Number (CCN) must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on a CMS website. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-work day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a non-work day for Federal employees by statute or Executive order.

(3) *Review and corrections period.* For all quality data submitted, REHs will have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, REHs can enter, review, and correct data submitted. However, after the submission deadline, these data cannot be changed.

(d) *Technical specifications and measure maintenance under the REHQR Program.* (1) CMS will update the specifications manual for measures in the REHQR Program at least every 12 months.

(2) CMS follows different procedures to update the measure specifications of a measure previously adopted under

the REHQR Program based on whether the change is substantive or non-substantive. CMS will determine what constitutes a substantive versus a non-substantive change to a measure's specifications.

(i) *Substantive changes.* CMS will use rulemaking to adopt substantive updates to measures in the REHQR Program.

(ii) *Non-substantive changes.* If CMS determines that a change to a measure previously adopted in the REHQR Program is non-substantive, CMS will use a sub-regulatory process to revise the specifications manual for the REHQR Program so that it clearly identifies the change to that measure and provide links to where additional information on the change can be found. When a measure undergoes sub-regulatory maintenance, CMS will provide notification of the measure specification update on a designated website and in the specifications manual and will provide sufficient lead time for REHs to implement the revisions where changes to the data collection systems would be necessary.

(e) *Retention and removal of quality measures under the REHQR Program—(1) General rule for the retention of quality measures.* Quality measures adopted for the REHQR Program measure set are retained for use, except when they are removed, suspended, or replaced as set forth in paragraphs (e)(2) and (3) of this section.

(2) *Immediate measure suspension from reporting.* In cases where CMS believes that the collection and reporting activities related to a quality measure as specified raises patient safety concerns, CMS will immediately suspend the measure from the REHQR Program and will promptly notify REHs and the public of the suspension of the measure. CMS will address the suspension and propose any permanent action regarding the measure in the next appropriate rulemaking cycle.

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

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

(A) *Factor 1.* Measure performance among REHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (“topped-out” measures);

(B) *Factor 2.* Performance or improvement on a measure does not result in better patient outcomes;

(C) *Factor 3.* A measure does not align with current clinical guidelines or practice;

(D) *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(G) *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(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 REHQR Program, a measure is considered to be topped-out under paragraph (e)(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 an REH’s measure is within two times the standard error of the full data set); and

(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 REHQR Program will be assessed on a case-by-case basis. Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor.

(f) *Public reporting of data under the REHQR Program.* Data that an REH submits for the REHQR Program will be made publicly available on a CMS website in an easily understandable format after providing the REH an opportunity to review the data to be made public. CMS will publicly display REH data by the CCN when data are submitted under the CCNs.

(g) *Exception.* CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS’ data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) *Upon request by the REH.* Specific requirements for submission of a request for an exception are available on a CMS website.

(2) *At the discretion of CMS.* CMS may grant exceptions to REHs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

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PART 420—PROGRAM INTEGRITY: MEDICARE

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