

(ii) Is located in a State that as of December 19, 1989, was not operating a demonstration project under section 1814(b) of the Act; and

(iii) Demonstrates that, for the 4-year period ending on December 31, 1996, at least 50 percent of its total discharges have a principal diagnosis that reflects a finding of neoplastic disease as defined in paragraph (f)(1)(iv) of this section.

(3) *PCHQR Program.* All hospitals classified as cancer hospitals under this paragraph must comply with the requirements of the PPS-Exempt Cancer Hospital Quality Reporting Program, as described in § 412.24.

(g) *Hospitals outside the 50 States, the District of Columbia, or Puerto Rico.* A hospital is excluded from the prospective payment systems if it is not located in one of the fifty States, the District of Columbia, or Puerto Rico.

(h) *Hospitals reimbursed under special arrangements.* A hospital must be excluded from prospective payment for inpatient hospital services if it is reimbursed under special arrangement as provided in § 412.22(c).

(i) *Changes in classification of hospitals.* For purposes of exclusions from the prospective payment system, the classification of a hospital is effective for the hospital's entire cost reporting period. Any changes in the classification of a hospital are made only at the start of a cost reporting period.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.23, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.govinfo.gov](http://www.govinfo.gov).

#### **§ 412.24 Requirements under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.**

(a) *Applicability.* The PCHQR Program applies to hospitals that are classified as cancer hospitals (PCHs) under the criteria described in § 412.23(f)(1) or (2).

(b) *Participation in the PCHQR Program.* In order to participate in the PCHQR Program, a PCH must do both of the following:

(1) Register with QualityNet (<http://qualitynet.cms.gov>) prior to reporting, including designating a QualityNet se-

curity official who completes all steps of the PCHQR Program registration process as described on the QualityNet website.

(2) Enroll in CDC's National Healthcare Safety Network (<https://www.cdc.gov/nhsn/enrollment/index.html>).

(c) *Submission of PCHQR Program data.* Except as provided in paragraph (e) of this section, PCHs that participate in the PCHQR Program must submit to CMS data on quality measures specified under section 1833(k)(3) of the Act in a form and manner, and at a time, specified by CMS. PCHs that participate in the PCHQR Program must also submit an annual online Data Accuracy and Completeness Acknowledgement via the Hospital Quality Reporting (HQR) system that attests to the accuracy and completeness of these data by the deadline specified by CMS on the QualityNet website (<http://qualitynet.cms.gov>).

(d) *Quality measure updates, retention, and removal—(1) Updating of measure specifications.* CMS uses rulemaking to make substantive updates to the specifications of measures used in the PCHQR Program. CMS announces technical measure specification updates through the QualityNet website (<http://qualitynet.cms.gov>) and listserv announcements.

(2) *Measure retention.* All quality measures specified under section 1866(k)(3) for the PCHQR Program measure set remain in the measure set unless CMS, through rulemaking, removes or replaces them.

(3) *Measure removal factors—(i) General rule.* CMS may remove or replace a quality measure based on one or more of the following factors:

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

(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.

## § 412.25

## 42 CFR Ch. IV (10–1–23 Edition)

(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.* The 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) *Exception.* CMS may retain a quality measure that meets one or more of the measure removal factors described in paragraph (d)(3)(i) of this section if the continued collection of data on the quality measure would align with a stated CMS or HHS policy objective, including, but not limited to, an objective to increase the number of quality measures that a PCH can report electronically, or an objective to collect data on the measure in one or more other CMS quality reporting programs.

(iii) *Patient safety exception.* Upon a determination by CMS that the continued requirement for PCHs to submit data on a measure raises specific patient safety concerns, CMS may elect to immediately remove the measure from the PCHQR measure set. CMS will, upon removal of the measure—

(A) Provide notice to PCHs and the public at the time CMS removes the measure, along with a statement of the specific patient safety concerns that would be raised if PCHs continued to submit data on the measure; and

(B) Provide notice of the removal in the FEDERAL REGISTER.

(e) *Extraordinary circumstances exceptions (ECEs).* (1) CMS may grant an ECE to a PCH that has requested an extension or exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the PCH.

(2) CMS may grant an ECE to one or more PCHs that has not requested an exception if CMS determines that—

(i) An extraordinary circumstance has affected an entire region or locale; or

(ii) A systemic problem with one of CMS' data collection systems has directly affected the ability of the PCH to submit data in accordance with paragraph (c) of this section.

(3) A PCH participating in the PCHQR Program that wishes to request an ECE must submit an ECE request to CMS via the QualityNet website (<https://qualitynet.cms.gov/pch/pchqr/resource>) within 90 days of the date that the extraordinary circumstances occurred, along with the following information:

(i) The PCH's CCN, name, reason for requesting an extension or exception, and evidence of the impact of extraordinary circumstances, including but not limited to photographs and media articles;

(ii) The date when the PCH will again be able to submit PCHQR Program data and a justification for that proposed date;

(iii) The following contact information for the PCH's CEO and any other designated personnel:

(A) Name.

(B) Email address.

(C) Telephone number.

(D) Physical mailing address (not a post office box); and

(iv) The signature of the PCH's CEO or designee on the ECE request.

(f) *Public reporting of PCHQR Program data.* CMS makes data submitted by PCHs under the PCHQR Program available to the public on the Provider Data Catalog website (<https://data.cms.gov/provider-data/>). Prior to making any such data submitted by a PCH available to the public, CMS gives the PCH an opportunity to review the data via the Hospital Quality Reporting (HQR) system (<https://hqr.cms.gov/hqrng/login>) and announces the timeline for review on the QualityNet website (<http://qualitynet.cms.gov>) and applicable listservs.

[86 FR 45518, Aug. 13, 2021, as amended at 87 FR 49403, Aug. 10, 2022]

### § 412.25 Excluded hospital units: Common requirements.

(a) *Basis for exclusion.* In order to be excluded from the prospective payment systems as specified in § 412.1(a)(1) and be paid under the inpatient psychiatric facility prospective payment system as