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(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

specified in § 412.1(a)(2) or the inpatient rehabilitation facility prospective payment system as specified in § 412.1(a)(3), a psychiatric or rehabilitation unit must meet the following requirements.

(1) Be part of an institution that—

(i) Has in effect an agreement under part 489 of this chapter to participate as a hospital;

(ii) Prior to October 1, 2019, is not excluded in its entirety from the prospective payment systems; and

(iii) Unless it is a unit in a critical access hospital, the hospital of which an IRF is a unit must have at least 10 staffed and maintained hospital beds that are paid under the applicable payment system under which the hospital is paid, or at least 1 staffed and maintained hospital bed for every 10 certified inpatient rehabilitation facility beds, whichever number is greater. Otherwise, the IRF will be classified as an IRF hospital, rather than an IRF unit. In the case of an inpatient psychiatric facility unit, the hospital must have enough beds that are paid under the applicable payment system under which the hospital is paid to permit the provision of adequate cost information, as required by § 413.24(c) of this chapter.

(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.

(3) Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.

(5) Meet applicable State licensure laws.

(6) Have utilization review standards applicable for the type of care offered in the unit.

(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds.

(8) Be serviced by the same fiscal intermediary as the hospital.

(9) Be treated as a separate cost center for cost finding and apportionment purposes.

(10) Use an accounting system that properly allocates costs.

(11) Maintain adequate statistical data to support the basis of allocation.

(12) Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.

(13) As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date.

(b) *Changes in the size of excluded units.* Except in the special cases noted at the end of this paragraph, changes in the number of beds or square footage considered to be part of an excluded unit under this section are allowed one time during a cost reporting period if the hospital notifies its Medicare contractor and the CMS RO in writing of the planned change at least 30 days before the date of the change. The hospital must maintain the information needed to accurately determine costs that are attributable to the excluded unit. A change in bed size or a change in square footage may occur at any time during a cost reporting period and must remain in effect for the rest of that cost reporting period. Changes in bed size or square footage may be made at any time if these changes are made necessary by relocation of a unit to permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility or because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(c) The status of a hospital unit may be changed from not excluded to excluded or excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the hospital unit. A change in the status of a hospital unit from not excluded to excluded or excluded to not excluded that is made during a cost reporting period must remain in effect

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for the rest of that cost reporting period.

(d) *Number of excluded units.* Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems specified in § 412.1(a)(1). A hospital excluded from the prospective payment systems as specified in § 412.1(a)(1) may not have an excluded unit (psychiatric or rehabilitation) that is excluded on the same basis as the hospital.

(e) *Satellite facilities.* (1) For purposes of paragraphs (e)(2) through (e)(5) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.

(2) Except as provided in paragraphs (e)(3) and (e)(6) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of State-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October 1, 1997.

(ii) The satellite facility independently complies with—

(A) For a rehabilitation unit, the requirements under § 412.29 of this subpart; or

(B) For a psychiatric unit, the requirements under § 412.27(a).

(iii) The satellite facility meets all of the following requirements:

(A) Except as provided in paragraph (e)(2)(iv) of this section, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the

control of the medical staff or chief medical officer of the hospital in which it is located.

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.

(D) It is serviced by the same fiscal intermediary as the hospital unit of which it is a part.

(E) It is treated as a separate cost center of the hospital unit of which it is a part.

(F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.

(iv) Effective for cost reporting periods beginning on or after October 1, 2019, the requirements of paragraph (e)(2)(iii)(A) of this section do not apply to a satellite facility of a unit that is part of a hospital excluded from the prospective payment systems specified in § 412.1(a)(1) that does not furnish services in a building also used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1).

(3) Except as specified in paragraphs (e)(4) and (e)(5) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit at the satellite facility on September 30, 1999.

(4) In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility—

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(5) For cost reporting periods beginning on or after October 1, 2006, in applying the provisions of paragraph (e)(3) of this section—

(i) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of this section, without affecting the provisions of paragraph (e)(3) of this section; and

(ii) If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of this section, it may subsequently increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.

(6) The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003.

(f) *Changes in classification of hospital units.* For purposes of exclusions from the prospective payment system under this section, the classification of a hospital unit is effective for the unit's en-

tire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period.

(g) *CAH units not meeting applicable requirements.* If a psychiatric or rehabilitation unit of a CAH does not meet the requirements of § 485.647 with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Payment to the CAH for services in the unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.25, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 412.27 Excluded psychiatric units: Additional requirements.

In order to be excluded from the prospective payment system as specified in § 412.1(a)(1), and paid under the prospective payment system as specified in § 412.1(a)(2), a psychiatric unit must meet the following requirements:

(a) Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the International Classification of Diseases, Tenth Revision, Clinical Modification.

(b) Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, and therapeutic activities.

(c) Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements:

(1) *Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.