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§ 412.10 Changes in the DRG classification system.

(a) *General rule.* CMS issues changes in the DRG classification system in a FEDERAL REGISTER notice at least annually. Except as specified in paragraphs (c) and (d) of this section, the DRG changes are effective prospectively with discharges occurring on or after the same date the payment rates are effective.

(b) *Basis for changes in the DRG classification system.* All changes in the DRG classification system are made using the principles established for the DRG system. This means that cases are classified so each DRG is—

(1) Clinically coherent; and

(2) Embraces an acceptable range of resource consumption.

(c) *Interim coverage changes—(1) Criteria.* CMS makes interim changes to the DRG classification system during the Federal fiscal year to incorporate items and services newly covered under Medicare.

(2) *Implementation and effective date.* CMS issues interim coverage changes through its administrative issuance system and makes the change effective as soon as is administratively feasible.

(3) *Publication for comment.* CMS publishes any change made under paragraph (c)(1) of this section in the next annual notice of changes to the DRG classification system published in accordance with paragraph (a) of this section.

(d) *Interim changes to correct omissions and inequities—(1) Criteria.* CMS makes interim changes to the DRG classification system to correct a serious omission or inequity in the system only if failure to make the changes would have—

(i) A potentially substantial adverse impact on the health and safety of beneficiaries; or

(ii) A significant and unwarranted fiscal impact on hospitals or the Medicare program.

(2) *Publication and effective date.* CMS publishes these changes in the FEDERAL REGISTER in a final notice with comment period with a prospective effective date. The change is also published for public information in the next annual notice of changes to the DRG clas-

sification system published in accordance with paragraph (a) of this section.

(e) *Review by ProPAC.* Changes published annually in accordance with paragraph (a) of this section are subject to review and comment by ProPAC upon publication. Interim changes to the DRG classification system that are made in accordance with paragraphs (c) and (d) of this section are subject to review by ProPAC before implementation.

[50 FR 35688, Sept. 3, 1985, as amended at 51 FR 31496, Sept. 3, 1986; 57 FR 39820, Sept. 1, 1992]

Subpart B—Hospital Services Subject to and Excluded From the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

§ 412.20 Hospital services subject to the prospective payment systems.

(a) Except for services described in paragraphs (b), (c), (d), and (e) of this section, all covered hospital inpatient services furnished to beneficiaries during the subject cost reporting periods are paid under the prospective payment system as specified in § 412.1(a)(1).

(b) Effective for cost reporting periods beginning on or after January 1, 2005, covered inpatient hospital services furnished to Medicare beneficiaries by an inpatient psychiatric facility that meets the conditions of § 412.404 are paid under the prospective payment system described in subpart N of this part.

(c)(1) Effective for cost reporting periods beginning on or after January 1, 2002, covered inpatient hospital services furnished to Medicare beneficiaries by a rehabilitation hospital or rehabilitation unit that meet the conditions of § 412.604 are paid under the prospective payment system described in subpart P of this part.

(2) CMS will not pay for services under subpart P of this part if the services are paid for by a health maintenance organization (HMO) or competitive medical plan (CMP) that elects not

to have CMS make payments to an inpatient rehabilitation facility for services, which are inpatient hospital services, furnished to the HMO's or CMP's Medicare enrollees, as provided under part 417 of this chapter.

(d) Effective for cost reporting periods beginning on or after October 1, 2002, covered inpatient hospital services furnished to Medicare beneficiaries by a long-term care hospital that meets the conditions for payment of §§ 412.505 through 412.511 are paid under the prospective payment system described in subpart O of this part.

(e) Inpatient hospital services will not be paid under the prospective payment systems specified in § 412.1(a)(1) under any of the following circumstances:

(1) The services are furnished by a hospital (or hospital unit) explicitly excluded from the prospective payment systems under §§ 412.23, 412.25, 412.27, and 412.29.

(2) The services are emergency services furnished by a nonparticipating hospital in accordance with § 424.103 of this chapter.

(3) The services are paid for by an HMO or competitive medical plan (CMP) that elects not to have CMS make payments directly to a hospital for inpatient hospital services furnished to the HMO's or CMP's Medicare enrollees, as provided in §§ 417.240(d) and 417.586 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 53 FR 6648, Mar. 2, 1988; 57 FR 39820, Sept. 1, 1992; 59 FR 45400, Sept. 1, 1994; 66 FR 41386, Aug. 7, 2001; 67 FR 56048, Aug. 30, 2002; 68 FR 45698, Aug. 1, 2003; 69 FR 66976, Nov. 15, 2004]

§ 412.22 Excluded hospitals and hospital units: General rules.

(a) *Criteria.* Subject to the criteria set forth in paragraph (e) of this section, a hospital is excluded from the prospective payment systems specified in § 412.1(a)(1) of this part if it meets the criteria for one or more of the excluded classifications described in § 412.23. For purposes of this subpart, the term "hospital" includes a critical access hospital (CAH).

(b) *Cost reimbursement.* Except for those hospitals specified in paragraph (c) of this section, and § 412.20(b), (c), and (d), all excluded hospitals (and ex-

cluded hospital units, as described in § 412.23 through § 412.29) are reimbursed under the cost reimbursement rules set forth in part 413 of this chapter, and are subject to the ceiling on the rate of hospital cost increases as specified in § 413.40 of this chapter.

(c) *Special payment provisions.* The following classifications of hospitals are paid under special provisions and therefore are not generally subject to the cost reimbursement or prospective payment rules of this chapter.

(1) Veterans Administration hospitals.

(2) Hospitals reimbursed under State cost control systems approved under part 403 of this chapter.

(3) Hospitals reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90-248 (42 U.S.C. 1395b-1) or section 222(a) of Public Law 92-603 (42 U.S.C. 1395b-1 (note)).

(4) Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

(d) *Changes in hospitals' status.* For purposes of exclusion from the prospective payment systems under this subpart, the status of each currently participating hospital (excluded or not excluded) is determined at the beginning of each cost reporting period and is effective for the entire cost reporting period. Any changes in the status of the hospital are made only at the start of a cost reporting period.

(e) *Hospitals-within-hospitals.* A hospital-within-a-hospital is a hospital that occupies space in a building also used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital. Prior to October 1, 2017, except as provided in paragraphs (e)(1)(vi) and (f) of this section, a hospital-within-a-hospital must meet the following criteria in order to be excluded from the prospective payment systems specified in § 412.1(a)(1). On or after October 1, 2017, except as provided in paragraphs (e)(1)(vi) and (f) of this section, a hospital-within-hospital that is excluded from the prospective payment systems specified in § 412.1(a)(1) that occupies space in a building also used by a hospital which is not excluded from the prospective payment

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systems specified in § 412.1(a)(1), or in one or more separate buildings located on the same campus as buildings used by a hospital not excluded from the prospective payment systems specified in § 412.1(a)(1) must meet the following criteria in order to be excluded from the prospective payment systems specified in § 412.1(a)(1).

(1) Except as specified in paragraph (f) of this section, for cost reporting periods beginning on or after October 1, 1997—

(i) *Separate governing body.* The hospital has a governing body that is separate from the governing body of the hospital occupying space in the same building or on the same campus. The hospital's governing body is not under the control of the hospital occupying space in the same building or on the same campus, or of any third entity that controls both hospitals.

(ii) *Separate chief medical officer.* The hospital has a single chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of the hospital. The chief medical officer of the hospital is not employed by or under contract with either the hospital occupying space in the same building or on the same campus or any third entity that controls both hospitals.

(iii) *Separate medical staff.* The hospital has a medical staff that is separate from the medical staff of the hospital occupying space in the same building or on the same campus. The hospital's medical staff is directly accountable to the governing body for the quality of medical care provided in the hospital, and adopts and enforces by-laws governing medical staff activities, including criteria and procedures for recommending to the governing body the privileges to be granted to individual practitioners.

(iv) *Chief executive officer.* The hospital has a single chief executive officer through whom all administration authority flows, and who exercises control and surveillance over all administrative activities of the hospital. The chief executive officer is not employed by, or under contract with, either the hospital occupying space in the same building or on the same campus or any

third entity that controls both hospitals.

(v) *Performance of basic hospital functions.* Prior to October 1, 2017, the hospital meets one of the following criteria:

(A) The hospital performs the basic functions specified in §§ 482.21 through 482.27, 482.30, 482.42, 482.43, and 482.45 of this chapter through the use of employees or under contracts or other agreements with entities other than the hospital occupying space in the same building or on the same campus, or a third entity that controls both hospitals. Food and dietetic services and housekeeping, maintenance, and other services necessary to maintain a clean and safe physical environment could be obtained under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals.

(B) For the same period of at least 6 months used to determine compliance with the criterion regarding the age of patients in § 412.23(d)(2) or the length-of-stay criterion in § 412.23(e)(2), or for hospitals other than children's or long-term care hospitals, for a period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the cost of the services that the hospital obtains under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals, is no more than 15 percent of the hospital's total inpatient operating costs, as defined in § 412.2(c). For purposes of this paragraph (e)(1)(v)(B), however, the costs of preadmission services are those specified under § 413.40(c)(2) rather than those specified under § 412.2(c)(5).

(C) For the same period of at least 6 months used to determine compliance with the criterion regarding the age of inpatients in § 412.23(d)(2) or the length-of-stay criterion in § 412.23(e)(2), or for hospitals other than children's or long-term care hospitals, for the period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the hospital has an inpatient population of whom at least 75 percent were referred to the

hospital from a source other than another hospital occupying space in the same building or on the same campus.

(vi) Effective October 1, 2008, if a State hospital that is occupying space in the same building or on the same campus as another State hospital cannot meet the criterion under paragraph (e)(1)(i) of this section solely because its governing body is under the control of the State hospital with which it shares a building or a campus, or is under the control of a third entity that also controls the State hospital with which it shares a building or a campus, the State hospital can nevertheless qualify for an exclusion if it meets the other applicable criteria in this section and—

(A) Both State hospitals occupy space in the same building or on the same campus and have been continuously owned and operated by the State since October 1, 1995;

(B) Is required by State law to be subject to the governing authority of the State hospital with which it shares space or the governing authority of a third entity that controls both hospitals; and

(C) Was excluded from the inpatient prospective payment system before October 1, 1995, and continues to be excluded from the inpatient prospective payment system through September 30, 2008.

(2) Effective for long-term care hospitals-within-hospitals for cost reporting periods beginning on or after October 1, 2004, the hospital must meet the governance and control requirements at paragraphs (e)(1)(i) through (e)(1)(iv) of this section.

(3) *Notification of co-located status.* A long-term care hospital that occupies space in a building used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital and that meets the criteria of paragraphs (e)(1) or (e)(2) of this section must notify its fiscal intermediary and CMS in writing of its co-location and identify by name, address, and Medicare provider number those hospital(s) with which it is co-located.

(f) *Application for certain hospitals.* Except as provided in paragraph (f)(3) of this section, if a hospital was excluded

from the prospective payment systems under the provisions of this section on or before September 30, 1995, and at that time occupied space in a building also used by another hospital, or in one or more buildings located on the same campus as buildings used by another hospital, the criteria in paragraph (e) of this section do not apply to the hospital as long as the hospital—

(1) Continues to operate under the same terms and conditions, including the number of beds, unless the hospital is a children's hospital as defined at § 412.23(d), and square footage considered to be part of the hospital for purposes of Medicare participation and payment in effect on September 30, 1995; or

(2) In the case of a hospital that changes the terms and conditions under which it operates after September 30, 1995, but before October 1, 2003, continues to operate under the same terms and conditions, including the number of beds, unless the hospital is a children's hospital as defined at § 412.23(d), and square footage considered to be part of the hospital for purposes of Medicare participation and payment in effect on September 30, 2003.

(3) For cost reporting periods beginning on or after October 1, 2006, in applying the provisions of paragraph (f)(1) or (f)(2) of this section, any hospital that was excluded from the prospective payment systems under the provisions of this section on or before September 30, 1995, and at that time occupied space in a building also used by another hospital, or in one or more buildings located on the same campus as buildings used by another hospital may increase or decrease the square footage or decrease the number of beds considered to be part of the hospital at any time without affecting the provisions of paragraph (f)(1) or (f)(2) of this section.

(i) If a hospital to which the provisions of paragraph (f)(1) of this section applies decreases its number of beds below the number of beds considered to be part of the hospital on September 30, 1995, it may subsequently increase the number of beds at any time as long as the resulting total number of beds considered to be part of the hospital

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does not exceed the number of beds at the hospital on September 30, 1995.

(ii) If a hospital to which the provisions of paragraph (f)(2) of this section applies decreases its number of beds below the number of beds considered to be part of the hospital on September 30, 2003, it may subsequently increase the number of beds at any time as long as the resulting total number of beds considered to be part of the hospital does not exceed the number of beds at the hospital on September 30, 2003.

(g) *Definition of control.* For purposes of this section, control exists if an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

(h) *Satellite facilities.* (1) For purposes of paragraphs (h)(2) through (h)(5) of this section, a satellite facility is a part of a hospital 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 (h)(3), (h)(4), (h)(5), (h)(7) and (h)(8) 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 hospital (other than a children's hospital) that was excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the hospital's number of State-licensed and Medicare-certified beds, including those at the satellite facilities, does not exceed the hospital's number of State-licensed and Medicare-certified beds on the last day of the hospital's last cost reporting period beginning before October 1, 1997.

(ii) The satellite facility independently complies with—

(A) For psychiatric hospitals, the requirements under § 412.23(a);

(B) For rehabilitation hospitals, the requirements under § 412.23(b)(2);

(C) For the children's hospitals, the requirements under § 412.23(d)(2); or

(D) For long-term care hospitals, the requirements under §§ 412.23(e)(1) through (e)(3)(i).

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

(A) Effective for cost reporting periods beginning on or after October 1, 2002, 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.

(I) Except as provided in paragraph (h)(2)(iii)(A)(2) of this section, effective for cost reporting periods beginning on or after October 1, 2009, the governing body of the hospital of which the satellite facility is a part is not under the control of any third entity that controls both the hospital of which the satellite facility is a part and the hospital with which the satellite facility is co-located.

(2) If a hospital and its satellite facility were excluded from the inpatient prospective payment system under the provisions of this section for the most recent cost reporting period beginning prior to October 1, 2009, the hospital does not have to meet the requirements of paragraph (h)(2)(iii)(A)(I) of this section, with respect to that satellite facility, in order to retain its IPPS-excluded status.

(3) A hospital described in paragraph (h)(2)(iii)(A)(2) of this section that establishes an additional satellite facility in a cost reporting period beginning on or after October 1, 2009, must meet the criteria in this section, including the provisions of paragraph (h)(2)(iii)(A)(I) of this section with respect to the additional satellite facility, in order to be excluded from the inpatient prospective payment system.

(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 of which it is a part.

(E) It is treated as a separate cost center of the hospital 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.

(4) On or after October 1, 2018, a satellite facility that is part of a hospital excluded from the prospective payment systems specified in § 412.1(a)(1) that provides inpatient services in a building also used by another hospital that is 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 excluded from the prospective payment systems specified in § 412.1(a)(1), is not required to meet the criteria specified in paragraphs (h)(2)(iii)(A)(I) through (3) of this section in order to be excluded from the inpatient prospective payment system. A satellite facility that is part of a hospital excluded from the prospective payment systems specified in § 412.1(a)(1) which is located 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), is required to meet the criteria specified in paragraphs (h)(2)(iii)(A)(I) through (3) of this section in order to be excluded from the prospective payment systems specified in § 412.1(a)(1).

(3) Except as provided in paragraphs (h)(4) and (h)(5) of this section, the provisions of paragraph (h)(2) of this section do not apply to—

(i) Any hospital structured as a satellite facility on September 30, 1999, and excluded from the prospective pay-

ment systems on that date, to the extent the hospital continues operating under the same terms and conditions, including the number of beds and square footage considered, for the purposes of Medicare participation and payment, to be part of the hospital, in effect on September 30, 1999; or

(ii) Any hospital excluded from the prospective payment systems under § 412.23(e)(2)(ii).

(4) For cost reporting periods beginning before October 1, 2006, in applying the provisions of paragraph (h)(3) of this section, any hospital 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 if these changes are made necessary by relocation of a facility—

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law; 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 (h)(3) of this section—

(i) Any hospital structured as a satellite facility on September 30, 1999, may increase or decrease the square footage or decrease the number of beds considered to be part of the satellite facility at any time without affecting the provisions of paragraph (h)(3) of this section; and

(ii) If the satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, it may subsequently increase the number of beds at any time 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) *Notification of co-located status.* A satellite of a long-term care hospital that occupies space in a building used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital and that meets the criteria of paragraphs (h)(1) through (h)(5) of this

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section must notify its fiscal intermediary and CMS in writing of its co-location and identify by name, address, and Medicare provider number, those hospital(s) with which it is co-located.

(7) The provisions of paragraph (h)(2)(i) of this section do not apply to any long-term care hospital that is subject to the long-term care hospital prospective payment system under Subpart O of this subpart, effective for cost reporting periods occurring on or after October 1, 2002, and that elects to be paid based on 100 percent of the Federal prospective payment rate as specified in § 412.533(c), beginning with the first cost reporting period following that election, or when the LTCH is fully transitioned to 100 percent of the Federal prospective rate, or to a new long-term care hospital, as defined in § 412.23(e)(4).

(8) The provisions of paragraph (h)(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.

(i)(1) *Requirements for extended neoplastic disease care hospitals.* For cost reporting periods beginning on or after January 1, 2015, an extended neoplastic disease care hospital is a hospital that was first excluded from the prospective payment system under this section in 1986 which has an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days and demonstrates that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in fiscal year 1997 have a principal diagnosis that reflects a finding of neoplastic disease as defined in paragraph (f)(1)(iv) of this section.

(2) *Payment to extended neoplastic disease care hospitals.* Payment for inpatient operating costs for hospitals classified under paragraph (i)(1) of this section is made as set forth in § 412.526(c)(3). Payment for capital costs for hospitals classified under paragraph (i)(1) of this section is made as set forth in § 412.526(c)(4).

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EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.22, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 412.23 Excluded hospitals: Classifications.

Hospitals that meet the requirements for the classifications set forth in this section are not reimbursed under the prospective payment systems specified in § 412.1(a)(1):

(a) *Psychiatric hospitals.* A psychiatric hospital must—

(1) Meet the following requirements to be excluded from the prospective payment system as specified in § 412.1(a)(1) and to be paid under the prospective payment system as specified in § 412.1(a)(2) and in subpart N of this part;

(2) Be primarily engaged in providing, by or under the supervision of a psychiatrist, psychiatric services for the diagnosis and treatment of mentally ill persons; and

(3) Meet the conditions of participation for hospitals and special conditions of participation for psychiatric hospitals set forth in part 482 of this chapter.

(b) *Rehabilitation hospitals.* A rehabilitation hospital or unit must meet the requirements specified in § 412.29 of this subpart to be excluded from the prospective payment systems specified in § 412.1(a)(1) of this subpart and to be paid under the prospective payment system specified in § 412.1(a)(3) of this subpart and in subpart P of this part.

(c) [Reserved]

(d) *Children's hospitals.* A children's hospital must—

(1) Have a provider agreement under part 489 of this chapter to participate as a hospital; and

(2) Be engaged in furnishing services to inpatients who are predominantly individuals under the age of 18.

(e) *Long-term care hospitals.* A long-term care hospital must meet the requirements of paragraph (e)(1) and (e)(2) of this section and, when applicable, the additional requirement of § 412.22(e), to be excluded from the prospective payment system specified in § 412.1(a)(1) and to be paid under the prospective payment system specified

in § 412.1(a)(4) and in Subpart O of this part.

(1) *Provider agreements.* The hospital must have a provider agreement under Part 489 of this chapter to participate as a hospital; and

(2) *Average length of stay.* (i) The hospital must have an average Medicare inpatient length of stay of greater than 25 days (which includes all covered and noncovered days of stay of Medicare patients) as calculated under paragraph (e)(3) of this section; or

(ii) For cost reporting periods beginning on or after August 5, 1997 and on or before December 31, 2014, a hospital that was first excluded from the prospective payment system under this section in 1986 meets the length-of-stay criterion if it has an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days and demonstrates that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in fiscal year 1997 have a principal diagnosis that reflects a finding of neoplastic disease as defined in paragraph (f)(1)(iv) of this section.

(3) *Calculation of average length of stay.* (i) Subject to the provisions of paragraphs (e)(3)(ii) through (vii) of this section and paragraphs (e)(4)(iv) and (v) of this section as applicable, the average Medicare inpatient length of stay specified under paragraph (e)(2)(i) of this section is calculated by dividing the total number of covered and noncovered days of stay of Medicare inpatients (less leave or pass days) by the number of total Medicare discharges for the hospital's most recent complete cost reporting period. Subject to the provisions of paragraphs (e)(3)(ii) through (vii) of this section, the average inpatient length of stay specified under paragraph (e)(2)(ii) of this section is calculated by dividing the total number of days for all patients, including both Medicare and non-Medicare inpatients (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period.

(ii) Effective for cost reporting periods beginning on or after July 1, 2004, in calculating the hospital's average length of stay, if the days of a stay of

an inpatient involves days of care furnished during two or more separate consecutive cost reporting periods, that is, an admission during one cost reporting period and a discharge during a future consecutive cost reporting period, the total number of days of the stay are considered to have occurred in the cost reporting period during which the inpatient was discharged. However, if after application of this provision, a hospital fails to meet the average length of stay specified under paragraphs (e)(2)(i) and (ii) of this section, Medicare will determine the hospital's average inpatient length of stay for cost reporting periods beginning on or after July 1, 2004, but before July 1, 2005, by dividing the applicable total days for Medicare inpatients under paragraph (e)(2)(i) of this section or the total days for all inpatients under paragraph (e)(2)(ii) of this section, during the cost reporting period when they occur, by the number of discharges occurring during the same cost reporting period.

(iii) If a change in a hospital's average length of stay specified under paragraph (e)(2)(i) or (e)(2)(ii) of this section would result in the hospital not maintaining an average Medicare inpatient length of stay of greater than 25 days, the calculation is made by the same method for the period of at least 5 consecutive months of the immediately preceding 6-month period.

(iv) [Reserved]

(v) For periods beginning on or after October 1, 2011, a hospital that is excluded from the inpatient prospective payment system as a long-term care hospital that plans to undergo a change of ownership (as described in § 489.18 of this chapter) must notify its fiscal intermediary or MAC within 30 days of the effective date of such change of ownership, as specified in § 424.516(e) of this subchapter. The hospital will continue to be excluded from the inpatient prospective payment system as a long-term care hospital for the cost reporting period following the change of ownership only if, for the period of at least 5 months of the 6 months immediately preceding the change of ownership, the hospital meets the required average length of

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stay (calculated in accordance with paragraph (e)(3)(i) of this section).

(vi) For cost reporting periods beginning on or after October 1, 2015, the Medicare inpatient days and discharges that are paid at the site neutral payment rate specified at § 412.522(c)(1) or paid under a Medicare Advantage plan (Medicare Part C) will not be included in the calculation of the Medicare inpatient average length of stay specified under paragraph (e)(2)(i) of this section.

(vii) For cost reporting periods beginning on or after October 1, 2019, the Medicare inpatient days and discharges that are associated with patients discharged from a unit of the hospital will not be included in the calculation of the Medicare inpatient average length of stay specified under paragraph (e)(2)(i) of this section.

(4) For the purpose of calculating the average length of stay for hospitals seeking to become long-term care hospitals, with the exception of paragraphs (e)(3)(iii) and (v) of this section, the provisions of paragraph (e)(3) of this section apply.

(i) *Definition.* For the purpose of payment under the long-term care hospital prospective payment system under subpart O of this part, a new long-term care hospital is a provider of inpatient hospital services that meets the qualifying criteria in paragraphs (e)(1) and (e)(2) of this section; meets the applicable requirements of paragraphs (e)(4)(ii) through (v) of this section; and, under present or previous ownership (or both), its first cost reporting period as a LTCH begins on or after October 1, 2002.

(ii) *Satellite facilities and remote locations of hospitals seeking to become new long-term care hospitals.* Except as specified in paragraph (e)(4)(iii) of this section, a satellite facility (as defined in § 412.22(h)) or a remote location of a hospital (as defined in § 413.65(a)(2) of this chapter) that voluntarily reorganizes as a separate Medicare participating hospital, with or without a concurrent change in ownership, and that seeks to qualify as a new long-term care hospital for Medicare payment purposes must demonstrate through documentation that it meets the average length of stay requirement as spec-

ified under paragraphs (e)(2)(i) or (e)(2)(ii) of this section based on discharges that occur on or after the effective date of its participation under Medicare as a separate hospital.

(iii) *Provider-based facility or organization identified as a satellite facility and remote location of a hospital prior to July 1, 2003.* Satellite facilities and remote locations of hospitals that became subject to the provider-based status rules under § 413.65 as of July 1, 2003, that become separately participating hospitals, and that seek to qualify as long-term care hospitals for Medicare payment purposes may submit to the fiscal intermediary discharge data gathered during the period of at least 5 consecutive months of the immediate 6 months preceding the facility's separation from the main hospital for calculation of the average length of stay specified under paragraph (e)(2)(i) or paragraph (e)(2)(ii) of this section.

(iv) *Qualifying period for hospitals seeking to become long-term care hospitals.* A hospital may be classified as a long-term care hospital after a 6-month qualifying period, provided that the average length of stay during the period of at least 5 consecutive months of that 6-month qualifying period, calculated under paragraph (e)(2) of this section, is greater than 25 days. The 6-month qualifying period for a hospital is the 6 months immediately preceding the date of long-term care hospital classification.

(v) *Special rule for hospitals seeking to become long-term care hospitals that experience a change in ownership.* If a hospital seeks exclusion from the inpatient prospective payment system as a long-term care hospital and a change of ownership (as described in § 489.18 of this chapter) occurs within the period of at least 5 consecutive months of the 6-month period preceding its petition for long-term care hospital status, the hospital may be excluded from the inpatient prospective payment system as a long-term care hospital for the next cost reporting period if, for the period of at least 5 consecutive months of the 6 months immediately preceding the start of the cost reporting period for which the hospital is seeking exclusion

from the inpatient prospective payment system as a long-term care hospital (including time before the change of ownership), the hospital has met the required average length of stay, has continuously operated as a hospital, and has continuously participated as a hospital in Medicare.

(5) *Freestanding long-term care hospital.* For purposes of this paragraph, a freestanding long-term care hospital means a hospital that meets the requirements of paragraph (e)(1) and (2) of this section and all of the following:

- (i) Does not occupy space in a building also used by another hospital.
- (ii) Does not occupy space in one or more separate or entire buildings located on the same campus as buildings used by another hospital.
- (iii) Is not part of a hospital that provides inpatient services in a building also used by another hospital.

(6) *Moratorium on the establishment of new long-term care hospitals and long-term care hospital satellite facilities—(i) General rule.* Except as specified in paragraphs (e)(6)(ii) and (e)(6)(iii) of this section for the period beginning December 29, 2007 and ending December 28, 2012, and the period beginning April 1, 2014 and ending September 30, 2017, a moratorium applies to the establishment and classification of a long-term care hospital as described in paragraphs (e) and (e)(1) through (e)(5) of this section or a long-term care hospital satellite facility as described in § 412.22(h).

(ii) *Exception.* The moratorium specified in paragraph (e)(6)(i) of this section is not applicable to the establishment and classification of a long-term care hospital that meets the requirements of paragraphs (e) introductory text and (e)(1) through (e)(5) of this section, or a long-term care hospital satellite facility that meets the requirements of § 412.22(h), if the long-term care hospital or long-term care satellite facility meets one or more of the following criteria on or before December 27, 2007, or prior to April 1, 2014, as applicable:

(A) Began its qualifying period for payment in accordance with paragraph (e) of this section.

(B)(1) Has a binding written agreement with an outside, unrelated party

for the actual construction, renovation, lease or demolition for a long-term care hospital; and

(2)(i) Has expended prior to December 29, 2007, at least 10 percent (or, if less, \$2.5 million) of the estimated cost of the project specified in paragraph (e)(6)(ii)(B)(1) of this section; or

(ii) Has expended, before April 1, 2014, at least 10 percent (or, if less, \$2.5 million) of the estimated cost of the project specified in paragraph (e)(6)(ii)(B)(1) of this section.

(C) Had obtained an approved certificate of need from the State, when required by State law.

(7) *Moratorium on increasing the number of beds in existing long-term care hospitals and existing long-term care hospital satellite facilities.* (i) For purposes of this paragraph, an existing long-term care hospital or long-term care hospital satellite facility means a long-term care hospital that meets the requirements of paragraph (e) of this section or a long-term care hospital satellite facility that meets the requirements of § 412.22(h) that received payment under the provisions of subpart O of this part prior to the dates noted in the following moratorium clauses.

(ii) December 29, 2007, through December 28, 2007—

(A) Except as specified in paragraph (e)(7)(ii)(B) and (C) of this section, the number of Medicare-certified beds in an existing long-term care hospital or an existing long-term care hospital satellite facility as defined in paragraph (e)(7)(i) of this section must not be increased beyond the number of Medicare-certified beds on December 29, 2007.

(B) Except as specified in paragraph (e)(7)(ii)(C) of this section, the moratorium specified in paragraph (e)(7)(ii)(A) of this section is not applicable to—

(1) An existing long-term care hospital or existing long-term care hospital satellite facility as defined in paragraph (e)(7)(i) of this section that meets both of the following requirements:

(i) Is located in a State where there is only one other long-term care hospital that meets the criteria specified in § 412.23(e) of this subpart.

(ii) Requests an increase in the number of Medicare-certified beds after the

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closure or decrease in the number of Medicare-certified beds of another long-term care hospital in the State; or

(2) An existing long-term care hospital or existing long-term care hospital satellite facility as defined in paragraph (e)(7)(i) of this section that obtained a certificate of need for an increase in beds and that meets both of the following requirements:

(i) Is in a State for which such certificate of need is required, and

(ii) Such certificate was issued on or after April 1, 2005, and before December 29, 2007.

(C) The exceptions specified in paragraph (e)(7)(ii)(B) of this section do not affect the limitation on increasing beds under § 412.22(f) and § 412.22(h)(3) of subpart.

(iii) April 1, 2014 through September 30, 2017—The number of Medicare-certified beds in an existing long-term care hospital or an existing long-term care hospital satellite facility must not be increased beyond the number of Medicare-certified beds prior to April 1, 2014, unless one of the exceptions specified in paragraph (e)(6)(ii) of this section is met.

(8) *Application of LTCH moratorium on the increase in beds at section 114(d)(1)(B) of Public Law 110–173 to LTCHs and LTCH satellite facilities established or classified as such under section 114(d)(2) of Public Law 110–173.* Effective for the period beginning October 1, 2011, and ending December 28, 2012, for long-term care hospitals and long-term care hospital satellite facilities established under paragraph (e)(6)(ii) of this section for the period beginning December 29, 2007, and ending September 30, 2011, the moratorium under paragraph (e)(7) of this section applies and the number of Medicare-certified beds must not be increased beyond the number of beds that were certified by Medicare at the long-term care hospital or the long-term care hospital satellite facility as of October 1, 2011.

(f) *Cancer hospitals—(1) General rule.* Except as provided in paragraph (f)(2) of this section, if a hospital meets the following criteria, it is classified as a cancer hospital and is excluded from the prospective payment systems beginning with its first cost reporting period beginning on or after October 1,

1989. A hospital classified after December 19, 1989, is excluded beginning with its first cost reporting period beginning after the date of its classification.

(i) It was recognized as a comprehensive cancer center or clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of April 20, 1983.

(ii) It is classified on or before December 31, 1990, or, if on December 19, 1989, the hospital was located in a State operating a demonstration project under section 1814(b) of the Act, the classification is made on or before December 31, 1991.

(iii) It demonstrates that the entire facility is organized primarily for treatment of and research on cancer (that is, the facility is not a subunit of an acute general hospital or university-based medical center).

(iv) It shows that at least 50 percent of its total discharges have a principal diagnosis that reflects a finding of neoplastic disease. (The principal diagnosis for this purpose is defined as the condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital. For the purposes of meeting this definition, only discharges with ICD–9–CM principal diagnosis codes of 140 through 239, V58.0, V58.1, V66.1, V66.2, or 990 will be considered to reflect neoplastic disease.)

(2) *Alternative.* A hospital that applied for and was denied, on or before December 31, 1990, classification as a cancer hospital under the criteria set forth in paragraph (f)(1) of this section is classified as a cancer hospital and is excluded from the prospective payment systems beginning with its first cost reporting period beginning on or after January 1, 1991, if it meets the criterion set forth in paragraph (f)(1)(i) of this section and the hospital is—

(i) Licensed for fewer than 50 acute care beds as of August 5, 1997;

(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.

§ 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 security 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.

(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.

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(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 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

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§ 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 entire 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 reha-

bilitation 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.

(i) The identification data must include the inpatient's legal status.

(ii) A provisional or admitting diagnosis must be made on every inpatient

at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(iii) The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both.

(iv) The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(v) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(2) *Psychiatric evaluation.* Each inpatient must receive a psychiatric evaluation that must—

(i) Be completed within 60 hours of admission;

(ii) Include a medical history;

(iii) Contain a record of mental status;

(iv) Note the onset of illness and the circumstances leading to admission;

(v) Describe attitudes and behavior;

(vi) Estimate intellectual functioning, memory functioning, and orientation; and

(vii) Include an inventory of the inpatient's assets in descriptive, not interpretative fashion.

(3) *Treatment plan.* (i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include a substantiated diagnosis; short-term and long-term goals; the specific treatment modalities utilized; the responsibilities of each member of the treatment team; and adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out; and

(ii) The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included.

(4) *Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient, a nurse, social worker and, when appropriate, others significantly involved in active treat-

ment modalities. The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first two months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan.

(5) *Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

(d) Meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning, as follows:

(1) *Personnel.* The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—

(i) Evaluate inpatients;

(ii) Formulate written, individualized, comprehensive treatment plans;

(iii) Provide active treatment measures; and

(iv) Engage in discharge planning.

(2) *Director of inpatient psychiatric services: Medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(i) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(ii) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(3) *Nursing services.* The unit must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient.

(i) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(ii) The staffing pattern must ensure the availability of a registered nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program.

(4) *Psychological services.* The unit must provide or have available psychological services to meet the needs of the inpatients. The services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures.

(5) *Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures. Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

(6) *Therapeutic activities.* The unit must provide a therapeutic activities program.

(i) The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(ii) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39820, Sept. 1, 1992; 59 FR 45397, 45400, Sept. 1, 1994; 69 FR 66976, Nov. 15, 2004; 71 FR 27086, May 9, 2006; 83 FR 38619, Aug. 6, 2018]

§ 412.29 Classification criteria for payment under the inpatient rehabilitation facility prospective payment system.

To be excluded from the prospective payment systems described in § 412.1(a)(1) and to be paid under the prospective payment system specified in § 412.1(a)(3), an inpatient rehabilitation hospital or an inpatient rehabilitation unit of a hospital (otherwise referred to as an IRF) must meet the following requirements:

(a) Have (or be part of a hospital that has) a provider agreement under part 489 of this chapter to participate as a hospital.

(b) Except in the case of a "new" IRF or "new" IRF beds, as defined in paragraph (c) of this section, an IRF must show that, during its most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the Medicare contractor), it served an inpatient population that meets the following criteria:

(1) For cost reporting periods beginning on or after July 1, 2004, and before July 1, 2005, the IRF served an inpatient population of whom at least 50 percent, and for cost reporting periods beginning on or after July 1, 2005, the IRF served an inpatient population of whom at least 60 percent required intensive rehabilitation services for treatment of one or more of the conditions specified at paragraph (b)(2) of this section. A patient with a comorbidity, as defined at § 412.602 of this part, may be included in the inpatient

population that counts toward the required applicable percentage if—

(i) The patient is admitted for inpatient rehabilitation for a condition that is not one of the conditions specified in paragraph (b)(2) of this section;

(ii) The patient has a comorbidity that falls in one of the conditions specified in paragraph (b)(2) of this section; and

(iii) The comorbidity has caused significant decline in functional ability in the individual that, even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities paid under subpart P of this part and that cannot be appropriately performed in another care setting covered under this title.

(2) List of conditions.

(i) Stroke.

(ii) Spinal cord injury.

(iii) Congenital deformity.

(iv) Amputation.

(v) Major multiple trauma.

(vi) Fracture of femur (hip fracture).

(vii) Brain injury.

(viii) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease.

(ix) Burns.

(x) Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(xi) Systemic vasculitides with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding

the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(xii) Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

(xiii) Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet one or more of the following specific criteria:

(A) The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.

(B) The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.

(C) The patient is age 85 or older at the time of admission to the IRF.

(c) In the case of new IRFs (as defined in paragraph (c)(1) of this section) or new IRF beds (as defined in paragraph (c)(2) of this section), the IRF must provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b) of this section. This written certification will apply until the end of the IRF's first full 12-month cost reporting period or, in the case of new IRF beds, until the end of the cost

reporting period during which the new beds are added to the IRF.

(1) *New IRFs.* An IRF hospital or IRF unit is considered new if it has not been paid under the IRF PPS in subpart P of this part for at least 5 calendar years. A new IRF will be considered new from the point that it first participates in Medicare as an IRF until the end of its first full 12-month cost reporting period.

(2) *New IRF beds.* Any IRF beds that are added to an existing IRF must meet all applicable State Certificate of Need and State licensure laws. New IRF beds may be added one time at any point during a cost reporting period and will be considered new for the rest of that cost reporting period. A full 12-month cost reporting period must elapse between the delicensing or decertification of IRF beds in an IRF hospital or IRF unit and the addition of new IRF beds to that IRF hospital or IRF unit. Before an IRF can add new beds, it must receive written approval from the appropriate CMS RO, so that the CMS RO can verify that a full 12-month cost reporting period has elapsed since the IRF has had beds delicensed or decertified. New IRF beds are included in the compliance review calculations under paragraph (b) of this section from the time that they are added to the IRF.

(3) *Change of ownership or leasing.* An IRF hospital or IRF unit that undergoes a change of ownership or leasing, as defined in § 489.18 of this chapter, retains its excluded status and will continue to be paid under the prospective payment system specified in § 412.1(a)(3) before and after the change of ownership or leasing if the new owner(s) of the IRF accept assignment of the previous owners' Medicare provider agreement and the IRF continues to meet all of the requirements for payment under the IRF prospective payment system. If the new owner(s) do not accept assignment of the previous owners' Medicare provider agreement, the IRF is considered to be voluntarily terminated and the new owner(s) may re-apply to participate in the Medicare program. If the IRF does not continue to meet all of the requirements for payment under the IRF prospective payment system, then the IRF

loses its excluded status and is paid according to the prospective payment systems described in § 412.1(a)(1).

(4) *Mergers.* If an IRF hospital (or a hospital with an IRF unit) merges with another hospital and the owner(s) of the merged hospital accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit retains its excluded status and will continue to be paid under the prospective payment system specified in § 412.1(a)(3) before and after the merger, as long as the IRF hospital or IRF unit continues to meet all of the requirements for payment under the IRF prospective payment system. If the owner(s) of the merged hospital do not accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit is considered voluntarily terminated and the owner(s) of the merged hospital may reapply to the Medicare program to operate a new IRF.

(d) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in § 400.200 of this chapter, have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program. This procedure must ensure that the preadmission screening for each Medicare Part A fee-for-Service patient is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.

(e) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622, during the Public Health Emergency, as defined in § 400.200 of this chapter, have in effect a procedure to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits

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per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process except that during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act). Beginning with the second week, as defined in § 412.622, of admission to the IRF, a non-physician practitioner who is determined by the IRF to have specialized training and experience in inpatient rehabilitation may conduct 1 of the 3 required face-to-face visits with the patient per week, provided that such duties are within the non-physician practitioner's scope of practice under applicable state law.

(f) Furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech-language pathology, social services, psychological services (including neuropsychological services), and orthotic and prosthetic services.

(g) Have a director of rehabilitation who—

(1) Provides services to the IRF hospital and its inpatients on a full-time basis or, in the case of a rehabilitation unit, at least 20 hours per week;

(2) Is a doctor of medicine or osteopathy;

(3) Is licensed under State law to practice medicine or surgery; and

(4) Has had, after completing a one-year hospital internship, at least 2 years of training or experience in the medical-management of inpatients requiring rehabilitation services.

(h) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in § 400.200 of this chapter, have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in con-

sultation with other professional personnel who provide services to the patient.

(i) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in § 400.200 of this chapter, use a coordinated interdisciplinary team approach in the rehabilitation of each inpatient, as documented by the periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment and discharge plans, and that team conferences are held at least once per week to determine the appropriateness of treatment.

(j) *Retroactive adjustments.* If a new IRF (or new beds that are added to an existing IRF) are excluded from the prospective payment systems specified in § 412.1(a)(1) and paid under the prospective payment system specified in § 412.1(a)(3) for a cost reporting period under paragraph (c) of this section, but the inpatient population actually treated during that period does not meet the requirements of paragraph (b) of this section, we adjust payments to the IRF retroactively in accordance with the provisions in § 412.130.

[76 FR 47891, Aug. 5, 2011, as amended at 78 FR 47934, Aug. 6, 2013; 85 FR 19287, Apr. 6, 2020; 85 FR 27621, May 8, 2020; 85 FR 48462, Aug. 10, 2020]

§ 412.30 [Reserved]

Subpart C—Conditions for Payment Under the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

§ 412.40 General requirements.

(a) A hospital must meet the conditions of this subpart to receive payment under the prospective payment systems for inpatient hospital services furnished to Medicare beneficiaries.

(b) If a hospital fails to comply fully with these conditions with respect to inpatient hospital services furnished to one or more Medicare beneficiaries, CMS may, as appropriate—