

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]

§ 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;

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(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 vasculidities 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) 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 is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.

(e) Have in effect a procedure to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits 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.

(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—

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(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) Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.

(i) 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]

§ 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

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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—

(1) Withhold Medicare payment (in full or in part) to the hospital until the hospital provides adequate assurances of compliance; or

(2) Terminate the hospital's provider agreement.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39821, Sept. 1, 1992]

§ 412.42 Limitations on charges to beneficiaries.

(a) *Prohibited charges.* A hospital may not charge a beneficiary for any services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment systems.

(b) *Permitted charges—Stay covered.* A hospital receiving payment under the prospective payment systems for a covered hospital stay (that is, a stay that includes at least one covered day) may charge the Medicare beneficiary or other person only for the following:

(1) The applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter.

(2) Noncovered items and services, furnished at any time during a covered stay, unless they are excluded from coverage only on the basis of the following:

(i) The exclusion of custodial care under § 405.310(g) of this chapter (see paragraph (c) of this section for when charges may be made for custodial care).

(ii) The exclusion of medically unnecessary items and services under § 405.310(k) of this chapter (see paragraphs (c) and (d) of this section for when charges may be made for medically unnecessary items and services).

(iii) The exclusion under § 405.310(m) of this chapter of nonphysician services furnished to hospital inpatients by other than the hospital or a provider or supplier under arrangements made by the hospital.