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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1480–N]

RIN 0938–AN92

Medicare Program; Inpatient Rehabilitation Facility Compliance Criteria

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: In accordance with the provisions of the Consolidated Appropriations Act of 2005, this notice announces the Secretary's determination that the requirements for classification as an inpatient rehabilitation facility (IRF) specified in § 412.23(b)(2) are not inconsistent with a report that the Government Accountability Office (GAO) issued concerning classification of a facility as an IRF.

DATES: Effective Date: This notice is effective on June 24, 2005.

FOR FURTHER INFORMATION CONTACT: Pete Diaz, (410) 786–1235.

SUPPLEMENTARY INFORMATION:

I. Background

A. Classification as an Inpatient Rehabilitation Facility Under § 412.23(b)(2)

Sections 1886(d)(1)(B) and 1886(d)(1)(B)(ii) of the Social Security Act (the Act) give the Secretary the discretion to define a rehabilitation hospital and unit. A freestanding rehabilitation hospital and a rehabilitation unit of an acute care hospital are collectively referred to as an inpatient rehabilitation facility (IRF), and are paid under the IRF prospective payment system (PPS). Under the current regulations at 42 CFR 412.1(b)(2), a hospital or unit of a hospital, must first be deemed excluded from the diagnosis-related group (DRG)-based inpatient prospective payment system (IPPS) to be paid under the IRF PPS. A facility must meet the applicable requirements in subpart B of part 412. Secondly, the excluded hospital or unit of the hospital must meet the conditions for payment under the IRF PPS at § 412.604. *See* § 412.23(b). Moreover, a provider, among other requirements, must be in compliance with the criteria specified in § 412.23(b)(2) in order to be classified as an IRF, *see* § 412.604(b).

On May 7, 2004, we published a final rule in the **Federal Register** (69 FR 25752) that responded to public comments on the September 9, 2003 proposed rule (68 FR 26786), and revised the criteria for being classified as an IRF including the criteria at § 412.23(b)(2). The changes in the final rule were effective for cost reporting periods beginning on or after July 1, 2004. Under § 412.23(b)(2), a specific percentage, noted below, of an IRF's total inpatient population must meet at least one of the following medical conditions:

(1) Stroke.
(2) Spinal cord injury.
(3) Congenital deformity.
(4) Amputation.
(5) Major multiple trauma.
(6) Fracture of femur (hip fracture).
(7) Brain injury.
(8) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease.
(9) Burns.
(10) 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.
(11) 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.
(12) 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.)
(13) Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meets one or more of the following specific criteria:
(i) The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.
(ii) The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.
(iii) The patient is age 85 or older at the time of admission to the IRF.

The percentage of an IRF's inpatient population that must meet at least one of the above medical conditions is determined by the IRF's cost reporting period. The following are the percentages of an IRF's inpatient population that must meet at least one of the medical conditions specified above:

For cost reporting periods beginning on or after July 1, 2004, and before July 1, 2005, the compliance threshold will be 50 percent of the IRF's total inpatient population.

For cost reporting periods beginning on or after July 1, 2005, and before July 1, 2006, the compliance threshold will be 60 percent of the IRF's total inpatient population.

For cost reporting periods beginning on or after July 1, 2006 and before July 1, 2007, the compliance threshold will be 65 percent of the IRF's total inpatient population. Furthermore, for those cost reporting periods beginning before July 1, 2007, the regulations also permit certain comorbidities, as defined in § 412.602, to be counted towards the applicable inpatient population percentage, if certain requirements are met as specified in § 412.23(b)(2)(i). For cost reporting periods beginning on or after July 1, 2007, patient comorbidity as described in § 412.23(b)(2)(i) is not included in the inpatient population that counts toward the compliance threshold percentage.

For cost reporting periods beginning on or after July 1, 2007, the compliance

threshold will be 75 percent of the IRF's total inpatient population.

B. Verification of Compliance With § 412.23(b)(2)

The fiscal intermediaries (FIs) determine if an IRF met the requirements specified in § 412.23(b)(2). In order to provide guidance to the FIs regarding how they should determine compliance with § 412.23(b)(2), we issued Program Transmittal 221 on June 25, 2004. In order to clarify the instructions in Program Transmittal 221, we issued Program Transmittal 347 on October 29, 2004, and Program Transmittal 478 on February 18, 2005.

In accordance with the instructions in the above-noted Program Transmittals, the FI reports an IRF's compliance percentage to the appropriate CMS Regional Office (RO). If the IRF did not meet the compliance percentage threshold, then the RO terminates the facility's classification as an IRF and notifies the FI and the facility of this action. The facility would then be paid as an acute care hospital under the IPPS if the facility met the requirements to be paid under the IPPS. In the case of the termination of the classification of a critical access hospital (CAH) rehabilitation distinct part unit (DPU) as an IRF, the DPU may be paid in accordance with the payment system Medicare uses to pay CAHs, but only if such payment to the DPU does not violate any of Medicare's CAH regulations or operational policies.

C. Effect of the Consolidated Appropriations Act of 2005

Section 219 of the Consolidated Appropriations Act of 2005 (Pub. L. 108–447), enacted on December 8, 2004, specifies that if a facility was classified as an IRF as of June 30, 2004, we could not change the classification of the facility and treat it as an acute care hospital to be paid under the IPPS until the Secretary either: (1) Determined that the requirements specified in § 412.23(b)(2) are not inconsistent with a report that the Government Accountability Office (GAO) would issue concerning the clinically appropriate standard for the IRF classification criteria under § 412.23(b)(2); or (2) In accordance with the provisions of that GAO report, we issue an interim final rule revising the classification criteria specified in § 412.23(b)(2). Accordingly, under the Consolidated Appropriations Act of 2005, we have not changed the classification of facilities classified as IRFs as of June 30, 2004 on the basis of any non-compliance with § 412.23(b)(2), but we continued to have the FIs perform their classification compliance reviews.

D. The GAO Report

In April 2005 the GAO issued its report and recommended the following:

- We should ensure that FIs routinely conduct targeted reviews for medical necessity for IRF admissions.
- We should conduct additional activities to encourage research on the effectiveness of intensive inpatient rehabilitation and the factors that predict patient need for intensive inpatient rehabilitation.
- We should use the information obtained from reviews for medical necessity, research activities, and other sources to refine the rule to describe more thoroughly the subgroups of patients within a condition that are appropriate for IRFs rather than other settings, and may consider using other factors in the descriptions, such as functional status.

We share GAO's view that it would be beneficial to obtain information from the reviews for medical necessity, research activities, and other sources to describe subgroups of patients within a condition in order to better delineate which patients can most appropriately be treated in an IRF and those that can be more appropriately cared for in other settings. To obtain this information, we have expanded our efforts to provide greater oversight of IRF admissions through a number of Local Coverage Decisions that are now in effect or in advance stages of development. In addition, we are actively encouraging government clinical research organizations, academic institutions, and industry rehabilitation groups to conduct both general and targeted research that would inform all interested parties regarding the types of patients that would most benefit from intensive inpatient rehabilitation. We also requested that the National Institute of Health (NIH) convene a research panel to recommend future research regarding the types of patients that would most benefit from intensive inpatient rehabilitation. The agency is currently evaluating the recommendations of this panel. The recommendations will be used to guide research that will help determine which facility and patient factors may be considered to classify a facility as an IRF. We will collaborate with NIH to determine how best to promote this research.

E. Results of CMS' Review of the GAO Recommendations

Medicare covers rehabilitation care in a variety of settings, including the home, skilled nursing facilities, outpatient facilities, hospitals and IRFs. We are committed to ensuring that beneficiaries have access to high quality rehabilitation services in the most appropriate setting. Medicare's payments to IRFs are made at a level commensurate with the type of intensive inpatient rehabilitation services these facilities are intended to provide. Consequently, Medicare maintains the compliance criteria and other policies to ensure its higher payments to IRFs are appropriately directed to this more intense level of service. We believe the regulations as revised in the May 7, 2004 final rule reflect the need for Medicare payments to be appropriately directed towards those beneficiaries who require intensive rehabilitation.

II. Provisions of the Notice

After careful consideration, the Secretary has determined that the recommendations in the GAO's IRF report are not inconsistent with our regulations as revised in the May 7, 2004 final rule. Therefore, we will immediately enforce the procedures specified in Program Transmittals 221, 347, and 478, as well as any additional Program Transmittals or instructions that we may issue if the facility does not meet the requirements specified in § 412.23(b)(2).

Authority: Section 1886(j) of the Social Security Act (42 U.S.C. 1395ww(j)).

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 17, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 10, 2005.

Michael O. Leavitt,

Secretary.

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