

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS-1262-P]

RIN 0938-AM72

Medicare Program; Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the classification criterion, commonly known as the "75 percent rule," used to classify a hospital as an inpatient rehabilitation facility (IRF). This proposed rule would also modify and expand the medical conditions listed in the 75 percent rule regulatory requirements as well as lower the percentage of patients required to fall within one of the specified list of medical criteria.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 3, 2003.

ADDRESSES: In commenting, please refer to file code CMS-1262-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail. Mail written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1262-P, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses: Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850. (Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Robert Kuhl, (410) 786-4597; or Pete Diaz, (410) 786-1235; or Nora Hoban, (410) 786-0675.

SUPPLEMENTARY INFORMATION:

Availability of Copies and Electronic Access

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 (or toll-free at 1-888-293-6498) or by faxing to (202) 512-2250. The cost for each copy is \$10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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I. Condition for Classification as an IRF Background

A. Overview of the Inpatient Rehabilitation Facility Prospective Payment System

Section 1886(j) of the Social Security Act (the Act) provides for the implementation of a prospective payment system (PPS) under Medicare for inpatient hospital services furnished by a rehabilitation hospital or a rehabilitation unit of a hospital (referred to as an inpatient rehabilitation facility (IRF)). Sections 1886(d)(1)(B) and 1886(d)(1)(B)(ii) of the Act give the Secretary the discretion to define a rehabilitation hospital and unit. The regulations at 42 CFR 412.23(b), 412.25, and 412.29, specify the criteria for a provider to be classified as a rehabilitation hospital or rehabilitation unit. Hospitals and units meeting those criteria are eligible to be paid on a

prospective payment basis as an IRF under the IRF PPS.

Payments made under the IRF PPS cover inpatient operating and capital costs of furnishing covered intensive rehabilitation services (that is, routine, ancillary, and capital costs), but do not cover costs of approved educational activities, bad debts, and other services or items outside the scope of the IRF PPS. Covered intensive rehabilitation services include services for which benefits are provided under Medicare Part A (Hospital Insurance).

Payments under the IRF PPS are made on a per discharge basis. A patient classification system is used to assign patients in IRFs into case-mix groups (CMGs). The IRF PPS uses Federal prospective payment rates across distinct CMGs. We construct a majority of the CMGs using rehabilitation impairment categories (RICs), functional status (both motor and cognitive), and age (though some CMGs do not use cognitive status or age in their definition). We construct special CMGs to account for very short stays and for patients who expire during the IRF stay.

For each CMG, we develop relative weighting factors to account for a patient's clinical characteristics and expected resource consumption. Thus, the weighting factors account for the relative difference in resource use across all CMGs. Within each CMG, the weighting factors are "tiered" based on the estimated effect that the comorbidities from appendix C of the August 7, 2001 final rule (66 FR 41414) have on resource use.

The Federal prospective payment rates are established using a standard payment amount (also referred to as the budget neutral conversion factor). For each of the tiers within a CMG, we apply the relative weighting factors to the budget neutral conversion factor to compute the unadjusted Federal prospective payment rates.

Adjustments that account for geographic variations in wages (wage index), for the percentage of low-income patients, and for facilities located in a rural area are applied to the unadjusted Federal prospective payment rates. In addition, adjustments are made for early transfers of patients to other facilities, interrupted stays, and high-cost outliers (cases with usually extraordinarily high costs).

The regulations implementing the IRF PPS provisions are presently in 42 CFR part 412, subpart P. Regulations governing the requirements for classification of hospitals as IRFs are located in § 412.22, § 412.23, § 412.25, and § 412.29. Section 412.23(b)(2) is commonly known as the "75 percent

rule” and specifies one of the criteria Medicare uses for classifying a hospital or unit of a hospital as an IRF. This regulation provides that during its most recent cost reporting period 75 percent of an IRF’s total patient population required intensive rehabilitation services for treatment of one or more of the medical conditions specified in § 412.23(b)(2).

For a more complete discussion of the development of the IRF PPS see our August 7, 2001 final rule (66 FR 41316). We also have established a CMS website that contains useful information regarding the IRF PPS. The website URL is <http://www.cms.hhs.gov/providers/irfpps/default.asp> and may be accessed to download or view publications, software, and other information pertinent to the IRF PPS.

B. Recent Developments on the 75 Percent Rule

1. May 2003 Proposed Rule

On May 16, 2003, we published a proposed rule titled “Medicare Program; Changes to the Inpatient Rehabilitation Facility Prospective Payment System and Fiscal Year 2004 Rates” in the **Federal Register** (68 FR 26786) to propose updates to the IRF Federal prospective payment rates for FY 2004, to be effective for discharges occurring on or after October 1, 2003 and before October 1, 2004. We published the final rule on August 1, 2003 (68 FR 45674). The final rule specified the comments we received in response to our proposed policies and the final regulations regarding the proposed update to IRF PPS for FY 2004.

In the May 16, 2003 proposed rule, we solicited public comments on the regulatory requirements in § 412.23(b)(2). As stated previously and discussed more fully in section I.B.2. of this preamble, § 412.23(b)(2) provides that the requirements of 75 percent rule be met for a provider to be classified as an IRF. On May 19, 2003, we held a Town Hall meeting at our headquarters in Baltimore, MD, in which views regarding all aspects of the IRF PPS could be expressed. Hundreds of people participated in the Town Hall meeting either by attending at CMS headquarters or by a conference call. Most of the participants, however, limited their testimony to the 75 percent rule.

In response to the May 16, 2003 proposed rule, we received over 6,000 timely public comments regarding the regulatory requirements in § 412.23(b)(2). The primary issues discussed during the Town Hall meeting and in the public comments are summarized as follows:

- The regulatory requirement specifying the 10 medical conditions contained in § 412.23(b)(2) should be repealed or amended.
- The 10 medical conditions specified in § 412.23(b)(2) do not adequately reflect current care in IRFs.
- The medical conditions specified in § 412.23(b)(2) have not been updated in 20 years and should be revised or rewritten to include other diagnoses.
- Some of the medical conditions specified in § 412.23(b)(2) are vague; they have little clinical relevance; and are inconsistently interpreted by our fiscal intermediaries who are charged with enforcing the 75 percent rule.
- CMS administrative data indicate most IRFs are not in compliance with § 412.23(b)(2).
- Classification as an IRF should be based on 20 of the 21 RICs.
- Enforcement of the rule could force many IRFs to close.
- Enforcement of the rule limits access to care.
- Treatment in other rehabilitation treatment settings is inferior to treatment furnished in an IRF.

In the May 16, 2003 proposed rule, we did not propose amending the regulatory requirements in § 412.23(b)(2). In this proposed rule, we are proposing amending the requirements in § 412.23(b)(2) as discussed in section II of the preamble.

2. Classification as an IRF Under the 75 Percent Rule

As stated in the August 7, 2001 final rule, we did not change the survey and certification procedures for classification as an IRF. Currently, a hospital or unit of a hospital must first be deemed excluded from the diagnosis-related group (DRG)-based acute care hospital PPS to be paid under the IRF PPS and must meet the general 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. As specified at § 412.604(b), a provider, among other things, must be in compliance with all the criteria specified in § 412.23(b) to be classified as an IRF.

Under § 412.23(b)(2) of the existing regulations, a facility may be classified as an IRF if it can show that, during its most recent 12-month cost reporting period, it served an inpatient population of whom at least 75 percent required intensive rehabilitation services for the treatment of one or more of the following conditions:

- Stroke.
- Spinal cord injury.
- Congenital deformity.

- Amputation.
- Major multiple trauma.
- Fracture of femur (hip fracture).
- Brain injury.
- Polyarthritis, including rheumatoid arthritis.
- Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson’s disease.
- Burns.

C. Statutory and Regulatory Background on the 75 Percent Rule

We initially stipulated the “75 percent” requirement in the September 1, 1983, interim final rule with comment period entitled “Medicare Program; Prospective Payments for Medicare Inpatient Hospital Services” (48 FR 39752). That interim final rule implemented the Social Security Amendments of 1983 (Pub. L. 98–21), changing the method of payment for inpatient hospital services from a cost-based, retrospective reimbursement system to a diagnosis-specific inpatient PPS. However, the rule stipulated that, in accordance with sections 1886(d)(1)(B) and 1886(d)(1)(B)(ii) of the Act, both a rehabilitation unit, which is a distinct part of a hospital, and a rehabilitation hospital would be excluded from the IPPS. We noted that sections 1886(d)(1)(B) and 1886(d)(1)(B)(ii) of the Act also gave the Secretary broad discretion to define a “rehabilitation unit” and a “rehabilitation hospital.”

We consulted with the Joint Commission on Accreditation of Hospitals (JCAH), and other accrediting organizations (JCAH is currently known as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) to define a rehabilitation hospital. The criteria we included in our definition of a rehabilitation hospital incorporated some of the accreditation requirements of these organizations. The definition also included other criteria, which we believed distinguished a rehabilitation hospital from a hospital that furnished general medical and surgical services as well as some rehabilitation services. One criterion was that “The hospital must be primarily engaged in furnishing intensive rehabilitation services as demonstrated by patient medical records showing that, during the hospital’s most recently completed 12-month cost reporting period, at least 75 percent of the hospital’s inpatients were treated for one or more conditions specified in these regulations that typically require intensive inpatient rehabilitation” (48 FR 39756). This requirement was originally specified in

§ 405.471(c)(2)(ii). We included this requirement, as a defining feature of a rehabilitation hospital, because we believed “that examining the types of conditions for which a hospital’s inpatients are treated, and the proportion of patients treated for conditions that typically require intensive inpatient rehabilitation, will help distinguish those hospitals in which the provisions of rehabilitation services is a primary, rather than a secondary, goal” (48 FR 39756). Likewise, the 75 percent rule was a criterion for a rehabilitation unit.

The original medical conditions specified in § 405.471(c)(2)(ii) were stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, fracture of femur (hip fracture), brain injury, and polyarthritis, including rheumatoid arthritis. This list of eight medical conditions was partly based upon the information contained in a document entitled “Sample Screening Criteria for Review of Admissions to Comprehensive Medical Rehabilitation Hospitals/Units.” This document was a product of the Committee on Rehabilitation Criteria for the Professional Standards Review Organization of the American Academy of Physical Medicine and Rehabilitation and the American Congress of Rehabilitation Medicine. In addition, we received input from the National Association of Rehabilitation Facilities and the American Hospital Association. The requirement that 75 percent of an IRF’s patient population must have one or more of the medical conditions listed in the regulation was due to the finding that the listed medical conditions accounted for approximately 75 percent of the admissions to IRFs at the time.

On January 3, 1984, we published a final rule entitled “Medicare Program; Prospective Payment for Medicare Inpatient Hospital Services” (49 FR 234). On page 240 of that final rule, we summarized comments that requested inclusion of neurological disorders, burns, chronic pain, pulmonary disorders, and cardiac disorders in the list of medical conditions under the 75 percent rule. Our analysis of these comments led us to agree that neurological disorders (including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson’s disease) and burns should be added to the original list of eight medical conditions under the 75 percent rule (49 FR 240). We did not agree with comments that we lower from 75 to 60 the percentage of patients that must meet one of the medical conditions. Nor did we agree with comments urging us to use IRF resource

consumption, instead of a percentage of patients that must have one or more of the specified medical conditions, to help define what is an IRF (49 FR 239–240). We also rejected suggestions that when an IRF could not meet the 75 percent rule, the facility should still be defined as an IRF based on the types of services it furnished.

On August 31, 1984, we published a final rule entitled “Medicare Program; Changes to the Inpatient Hospital Prospective Payment System and Fiscal Year 1985 Rates” (49 FR 34728). In that rule, we explained how the 75 percent rule applied to a new rehabilitation unit or rehabilitation hospital or to an increase in beds of an existing rehabilitation unit.

On March 29, 1985, we published a final rule entitled “Medicare Program; Prospective Payment System for Hospital Inpatient Services; Redesignation of Rules” (50 FR 12740). That rule redesignated provisions of § 405.471 that addressed the 75 percent rule as provisions under § 412.23.

On August 30, 1991, we published a final rule entitled “Medicare Program; Changes to the Inpatient Hospital Prospective Payment System and Fiscal Year 1992 Rates” (56 FR 43196). Since October 1, 1983, the regulations allowed a new rehabilitation hospital or a new rehabilitation unit, or an existing excluded rehabilitation unit that was to be expanded by the addition of new beds, to be excluded from the hospital inpatient PPS if, in addition to meeting other requirements, it submitted a written certification that during its first cost reporting period it would be in compliance with the 75 percent rule. The August 30, 1991, rule specified that, if these facilities were later found to have not complied with the 75 percent rule, we would determine the amount of actual payment under the exclusion, compute what we would have paid for the facility’s services to Medicare patients under the IPPS, and recover any difference in accordance with the rules on the recoupment of overpayments.

On September 1, 1992, we published a final rule entitled “Medicare Program; Changes to Hospital Inpatient Prospective Payment Systems and Fiscal Year 1993 Rates” (57 FR 39746). In the rule, we acknowledged that, for various reasons, a new rehabilitation hospital or a new rehabilitation unit might need to begin operations at some time other than at the start of its regular cost reporting period. Therefore, we specified that an IRF could submit a written certification that it would comply with the 75 percent rule for both a partial cost reporting period of up to

11 months and the subsequent full 12-month cost reporting period.

On September 1, 1994, we published a final rule entitled “Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and FY 1995 Rates” (59 FR 45330). In that final rule, we stated that we had miscellaneous comments requesting that oncology cases, pulmonary disorders, cardiac disorders, and chronic pain be added to the list of medical conditions under the 75 percent rule (59 FR 45393). We responded that, although the 75 percent rule had not been addressed in the associated May 27, 1994, proposed rule, we would take these miscellaneous comments into consideration if we decided to make changes to the 75 percent rule.

When we published the August 7, 2001 final rule (66 FR 41316), we acknowledged we had received comments requesting that we update the list of medical conditions specified in § 412.23(b)(2) or eliminate the regulation (66 FR 41321). We responded that in the November 3, 2000 IRF PPS proposed rule, we had not proposed amending the requirements in § 412.23(b)(2), and we believed the existing regulation was appropriate and, therefore, we would not be revising the requirements in § 412.23(b)(2). However, we also stated that data obtained after we implemented the IRF PPS could lead us to reconsider amending the requirements in § 412.23(b)(2).

D. CMS Evaluation of Compliance With the 75 Percent Rule Regulatory Requirements in § 412.23(b)(2)

In the spring of 2002, we surveyed the Medicare fiscal intermediaries (FIs) in order to ascertain what methods were being used to verify whether IRFs were complying with the requirements in § 412.23(b)(2). Analysis of the survey data made us aware that inconsistent methods were being used to determine whether an IRF was in compliance with the regulation. Also, some IRFs were not being reviewed to determine whether they were in compliance with the regulation. These survey results led us to become concerned that some IRFs may be out of compliance with the regulation and inappropriately classified as an IRF. In addition, we were concerned that some FIs might be using different methods to verify compliance with the requirements in § 412.23(b)(2). This practice may have resulted in an IRF being incorrectly considered out of compliance with the regulation. Thus, this practice had the potential to cause an IRF to inappropriately lose its classification as

an IRF. Therefore, on June 7, 2002, we suspended enforcement of the regulatory requirements § 412.23(b)(2) until we conducted a careful examination of this area and determined whether the regulation should be changed and the operating procedures to verify compliance with the regulation.

In addition to our review of the administrative procedures used by our FIs, we conducted an analysis of CMS administrative data to attempt to estimate overall compliance with the regulation. We examined both the inpatient rehabilitation facility-patient assessment instrument (IRF-PAI) data and claims from the years 1998, 1999, and 2002. The patient assessment data was from January to August of 2002. We estimated that the percent of facilities with 75 percent of cases falling into the 10 conditions was 13.35 percent. We note that the analysis has a number of limitations. For example, it is not possible to discern from the diagnosis data on IRF-PAI or the claim whether there was a medical need to furnish the patient "intensive rehabilitation." The diagnosis describes only some aspects of a patient's clinical status, but the diagnosis alone does not determine the medical necessity of treating a patient in an IRF as opposed to another type of treatment setting. In addition, all the information necessary to classify a case under 1 of the 10 conditions may not be present on the claim (for example, polyarthritis).

In the May 16, 2003 proposed rule, we indicated that we would be instructing FIs to re-institute appropriate enforcement action if they were to determine that an IRF has not complied with the requirements in § 412.23(b)(2). We realize that an IRF may need time to come into compliance with the regulation. An IRF's cost reporting period is the time period used to ascertain compliance with the requirements in § 412.23(b)(2). Therefore, we indicated that we were instructing the FIs that they must use cost reporting periods that begin on or after October 1, 2003, as the time period to ascertain an IRF's compliance with the requirements in § 412.23(b)(2). While in the May 16, 2003 proposed rule, we did not propose changes to § 412.23(b)(2), we indicated that we expect that improved enforcement and compliance with the existing rule will have varying impacts on providers and beneficiaries.

In the May 16, 2003 proposed rule, we indicated that while it is difficult to predict the aggregate impact of improved compliance on provider payments, we expect that IRFs or their

parent hospitals, or both (80 percent of IRFs are units of acute care hospitals), will change their behavior in a variety of ways. IRFs may change admission practices to alter their case-mix, either Medicare or total patient population, by admitting patients with more intensive rehabilitative needs that fall into the 10 conditions. This practice could have the effect of elevating the facility's revenues because cases requiring more intensive rehabilitation care generally receive higher Medicare payments than less complex cases. On the other hand, enforcement of the 75 percent rule may cause some IRFs to reduce the number of beds and/or reduce the number of admissions that may result in a reduction of the facility's revenues.

The existing regulation reflects the fact that up to 25 percent of medically necessary admissions may fall outside of the 10 conditions. These cases can continue to be admitted and treated under the regulation. Other cases may appropriately receive rehabilitative care in alternative settings. For certain medically complex cases, it may be appropriate to lengthen the patient's stay in an acute care setting in order to stabilize his or her condition to prepare the patient to participate in rehabilitation. Alternative settings for rehabilitative care could include the acute care hospital, skilled nursing facilities, long-term care hospitals, outpatient rehabilitation facilities, and home health care. For this reason, we did not expect to see reduced access to care for Medicare beneficiaries as a result of improved compliance. In addition, because many hospitals having a Medicare certified IRF unit also have one or more other subunits that provide rehabilitation, revenues from these cases may be generated elsewhere within the same hospital.

As noted above, on June 7, 2002, we suspended enforcement of the 75 percent rule under § 412.23(b)(2). We accomplished the suspension of enforcement by the issuance of instructions to the FIs and, therefore, it was a method that was administrative and operational. The suspension of enforcement was communicated to the IRFs by CMS Regional Offices, the FIs, or other means such as regular telephone conferences between CMS and providers. Although the May 16, 2003 proposed rule stated that we would be re-instituting enforcement of § 412.23(b)(2) for cost reporting periods that start on or after October 1, 2003, we decided to revisit this issue due to the extensive public comments received on this issue. We are now proposing to amend § 412.23(b)(2) in this proposed rule. Therefore, we will not be re-

instituting enforcement of the regulation for cost reporting periods beginning on or after October 1, 2003 as stated in the May 16, 2003 proposed rule. Instead, we are now proposing that the proposed amendments in § 412.23(b)(2) would be applicable to cost reporting periods that start on or after the effective date specified in the final rule that will be published subsequent to this proposed rule. We anticipate that the effective date of the final rule would be January 1, 2004.

The intent of the policy specified at § 412.23(b)(2), and of other policy criteria for IRFs, is to ensure that these facilities are unique compared to other hospitals in that they provide intensive rehabilitative services in an inpatient setting. The uniqueness of these facilities is the justification for paying them under a separate payment system rather than paying them with the same payment system for acute care inpatient PPS. We believe it is crucial that Medicare maintain criteria to ensure that only facilities providing intensive rehabilitation are identified as IRFs so that services are paid appropriately under the IRF PPS. In addition, we believe it is imperative to identify conditions that would "typically require intensive inpatient rehabilitation" in IRFs because rehabilitation in general can be delivered in a variety of settings such as acute care hospitals, skilled nursing facilities, and outpatient settings.

II. Provisions of the Proposed Rule

For the reasons set forth in the preamble, in section II.A., we are proposing in § 412.23(b)(2) "Excluded hospitals: Classifications," to remove the reference to "75 percent." We are proposing a new § 412.23(b)(2)(i) that specifies for cost reporting periods beginning on or after January 1, 2004 and before January 1, 2007, the hospital has served an inpatient population of whom at least 65 percent required intensive rehabilitative services for treatment of one or more of the conditions specified at paragraph (b)(2)(iii) of this section. A patient with a comorbidity, as defined at § 412.602, may be included in the inpatient population that counts towards the required 65 percent if—

- The patient is admitted for inpatient rehabilitation for a condition that is not one of the conditions specified at paragraph (b)(2)(iii) of this section;
- The patient has a comorbidity that falls in one of the conditions specified at paragraph (b)(2)(iii) of this section; and

- The comorbidity has caused significant functional ability decline in the individual such 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 which cannot be appropriately performed in another care setting covered under this title.

We are also proposing a new § 412.23(b)(2)(ii) that specifies for cost reporting periods beginning on or after January 1, 2007, the hospital has served an inpatient population of whom at least 75 percent required intensive rehabilitative services for treatment of one or more of the conditions specified at paragraph (b)(2)(iii) of this section.

In proposed § 412.23(b)(2)(iii), we are proposing to retain the existing conditions except for polyarthritides, which we are proposing to replace with the following three new conditions:

- Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living, which has 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 which results from a systemic disease activation immediately before admission, but has the potential to improve with more intensive rehabilitation.

- Systemic vasculitides with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living, which has 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 which results from a systemic disease activation immediately before admission, but has the potential to improve with more intensive rehabilitation.

- Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving three or more major joints (elbow, shoulders, hips, or knees) with joint deformity and substantial loss of range of motion, atrophy, significant functional impairment of ambulation and other activities of daily living, which has 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 but has 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.)

Furthermore, in section II.C., we are proposing the possible use of comorbidities to verify compliance with proposed § 412.23(b)(2).

We are also proposing to phase-out the reduction from 75 percent to 65 percent and the use of comorbidities to verify compliance, as discussed in section II.D., on January 1, 2007 with the intention of using data acquired and analysis performed during this period to revise the rule, if necessary, prior to the phase-out date. Lastly, in section II.E., we are proposing to change the time period used to determine compliance with the proposed 65 percent rule.

A. Change of the Percentage of the Inpatient Population

Under proposed § 412.23(b)(2)(i), we are proposing, starting with the effective date of the final rule and subject to the proposed phase-out provision discussed in section II.D., to change the percentage of the total IRF patient population used as a criterion to distinguish an IRF from an acute care hospital from 75 percent to 65 percent.

We recognize that rehabilitation practice may have changed since we developed the original list of conditions. We are, however, concerned that in some cases, patients may have been transferred inappropriately from the inpatient setting and, thus, these inappropriate responses may be responsible for some of these changes in rehabilitation practice rather than medical advances.

We believe that the list of medical conditions we are proposing in this rule identifies patients who typically can benefit from the type of intensive inpatient rehabilitation services provided by IRFs. We do, however, recognize that there may be certain atypical patients admitted for other conditions who may be appropriate for care in an IRF. As a precaution to mitigate any unintended effects on access to care while we perform the analysis discussed in section II.D., we are proposing to lower the percentage of cases to 65 percent. We welcome the development and presentation of objective evidence that shows the type of patients most appropriately treated in the IRF setting, compared to other settings.

As reflected in both the present and now proposed policies, we do not

believe it is necessary that an IRF must treat patients only with the medical conditions listed in proposed § 412.23(b)(2)(iii) to distinguish it from other inpatient settings as an inpatient hospital setting that is primarily engaged in furnishing intensive rehabilitation services. Patients may have a variety of medical conditions that require rehabilitation treatment and the rehabilitation treatment may be furnished by a variety of rehabilitation programs. However, while an IRF is one of the settings that is available to furnish rehabilitation, it may not be the most appropriate setting to treat a medical condition not listed in proposed § 412.23(b)(2)(iii).

Patients with the medical conditions not listed in proposed § 412.23(b)(2)(iii) have always had, and will continue to have, rehabilitation programs in IRFs and other settings available to them that we believe can furnish the type of treatment that is commensurate to the need they have for rehabilitation. While being a prudent purchaser of health care services for Medicare beneficiaries is an important factor, the most important determination is which rehabilitation program is the most appropriate in relation to the patient's medical condition and rehabilitation needs, that is, the rehabilitation services furnished by the most appropriate rehabilitation program.

Although the previous analysis of impairment group and diagnoses data from the IRF-PAI suggests that IRFs are treating a patient population with more than 35 percent of cases with medical conditions other than those specified in proposed § 412.23(b)(2)(iii), this does not in and of itself provide evidence that the IRF is the most appropriate rehabilitation treatment modality for these patients. We welcome evidence or studies demonstrating that patients with medical conditions not included in proposed § 412.23(b)(2)(iii) generally require intensive inpatient rehabilitation and have better outcomes compared to other settings.

Although there may have been "medical advances" in rehabilitation or at least changes in practice patterns since the medical conditions listed at proposed § 412.23(b)(2)(iii) were developed, it is not clear that there is evidence supporting a clinical basis for these changes. Instead, in some cases, patients may have been transferred inappropriately from the inpatient setting which may have played a major role in changing practice patterns and in deciding which patients are admitted to IRFs. We note that the general trend has been the migration of care from the acute inpatient hospital setting to

another treatment setting. However, we recognize that the conditions listed in proposed § 412.23(b)(2)(iii) describe groups of patients who typically require intensive inpatient rehabilitation. To allow IRFs to care for some atypical patients who require intensive inpatient rehabilitation and still maintain their status as an IRF, we would allow the percentage of cases in the conditions specified in proposed § 412.23(b)(2)(iii) to be lowered to 65 percent. As part of our ongoing analysis described in section II.D., we would both periodically monitor the literature and analyze the data obtained from assessments of beneficiaries to determine whether it would be appropriate to modify any of the conditions that are listed in proposed § 412.23(b)(2)(iii).

Various commenters have suggested that we add cancer, cardiac, pulmonary, and pain to the list of conditions defining IRFs. We note that patients with cancer affecting the brain and spinal cord may be considered under the proposed clarification of the existing conditions to have non-traumatic brain or spinal cord injuries and can be counted in defining IRFs.

As has been commented on in the past, the result of adding cancer, cardiac, pulmonary, and pain conditions would be that almost all patients admitted to acute hospitals would qualify as being the types of patients that would be used to distinguish IRFs from acute care hospitals. Furthermore, we have seen no studies that demonstrate that patients from these categories have improved outcomes when cared for in IRFs as compared to other settings. We have reviewed studies that show that cardiac and pulmonary patients improve when treated in IRFs, but none of the studies provided evidence that the improvement required the unique characteristics of IRFs and compared the improvements of equivalent patients in other settings.

We continue to believe it is the total patient population that should determine whether a facility is classified as an IRF. This is the best indication that a facility (as a whole) is primarily engaged in furnishing intensive rehabilitation services. For a provider to be primarily engaged in furnishing intensive rehabilitation services implies that it is furnishing these services to its entire patient population. Therefore, we believe it is appropriate for Medicare to continue to use the entire IRF patient population as one of the criteria used to classify a facility as an IRF. This approach is part of CMS' existing policy that we plan to maintain.

In proposing 65 percent of an IRF's total patient population to determine compliance with proposed § 412.23(b)(2)(i) we still wanted to find methods of verification for the FIs that were not difficult operationally to automate. RAND's analysis of IRF compliance with existing requirements at § 412.23(b)(2) found that Medicare cases were highly predictive of the percentage of an IRF's total patient population with respect to the medical conditions specified in the regulation. We plan to instruct the FIs to initially utilize a presumptive eligibility test that uses Medicare data to assess compliance with proposed § 412.23(b)(2)(i). However, if an IRF appears to comply with proposed § 412.23(b)(2)(i) using only Medicare data, we may still consider other available information before making a final compliance determination. If the IRF does not comply with proposed § 412.23(b)(2)(i) based on the presumptive eligibility test that uses Medicare data, we would consider the IRF's total case-mix. In any case, we expect individual IRFs to notify their FI if the IRF believes that its Medicare population is not wholly representative of the total facility patient population. We believe that the compliance verification method described above offers Medicare adequate program protection and may reduce the burden on IRFs and the FIs related to enforcement of proposed § 412.23(b)(2)(i).

B. Change in the Medical Conditions

As noted in the May 16, 2003 proposed rule, we were concerned that some FIs inappropriately were using methods to verify compliance with the 75 percent rule. These inappropriate methods included incorrectly interpreting which patient diagnoses met the medical conditions listed in the 75 percent rule.

As in the present policies under the proposed IRF-PPS policies, Medicare will pay for the services an IRF furnishes to some patients who have a medical need for intensive inpatient rehabilitation services but do not have one of the medical conditions specified in proposed § 412.23(b)(2)(iii). The medical conditions specified in proposed § 412.23(b)(2)(iii) are used to determine whether a facility qualifies as an IRF and, thus, may be paid under the IRF PPS. However, the criteria for admission of any individual patient is based upon medical necessity; as a result, some patients with conditions listed in proposed § 412.23(b)(2)(iii) may still not meet the medical necessity criteria. Providers also have discretion over which patients are admitted, so we

believe an IRF can manage its case-mix and, thus, ensure that its patient population during a cost reporting period would allow it to achieve compliance with proposed § 412.23(b)(2)(i).

We recognize, however, that one of the listed conditions in the existing regulation at § 412.23(b)(2), specifically polyarthritis, has been a source of confusion and is acknowledged by many not to represent any clearly defined clinical condition. We are proposing to remove this term from the list of 10 conditions and substitute instead 3 more clearly defined arthritis-related conditions, as specified above in the introduction to section II of this preamble, that comprise the range of diagnoses that the term "polyarthritis" was intended to encompass. This clarification was developed in part from information gathered from experts in rheumatology and rehabilitation as well as a review of the literature. We are proposing to adopt in § 412.23(b)(2)(iii) the other conditions currently listed in § 412.23(b)(2) because we believe these other conditions are the most appropriate conditions for treatment in an IRF. We are limiting the conditions to those that are sufficiently severe and in which intensive inpatient rehabilitation may be an appropriate modality of treatment. Although we acknowledge that "arthritis" may affect joints other than those specified (shoulders, elbows, hips and knees), such as those in the hands or spine, we do not believe these conditions require intensive rehabilitation care. Thus, we are limiting the focus to conditions that more commonly require intensive inpatient rehabilitation treatment. For this reason, conditions other than the types specified in this proposed rule are not included in the identified conditions to be listed in proposed § 412.23(b)(2)(iii). If a patient has a type of "arthritis" not included in the proposed conditions that we described earlier in this section then that patient would be included in the percent of cases that IRFs can admit which are not included in the proposed 65 percent of the proposed § 412.23(b)(2)(iii) conditions (assuming the care is medically necessary).

We acknowledge that the industry has interpreted polyarthritis to include hip and knee joint replacement cases and these should be included in the conditions counted in existing § 412.23(b)(2). Although some joint replacement cases are currently being treated in IRFs, we are not aware of any research that identifies the factors determining which patients are more appropriately treated in the intensive

inpatient rehabilitation setting provided in an IRF. Although it has been asserted that patients at risk for thrombosis, pressure ulcers, or infections should be treated in IRFs, all hip and knee joint replacement patients are at risk for those conditions. Likewise the presence of comorbidities such as diabetes and hypertension are common conditions that can generally be managed in the outpatient setting. We believe that there have been strong reimbursement incentives to send patients to IRFs and that these considerations have influenced the choice of setting for patients' care. We welcome data or studies that might provide evidence about whether certain patients had better outcomes as a result of care in IRFs.

We are also aware of proposals from the public that Medicare should count cases with lower functional status in RICs for joint replacement, cardiac, osteoarthritis, and pulmonary as cases that meet proposed § 412.23(b)(2)(iii). We are not proposing such a policy because the lower score of function on admission does not generally reflect a need for intensive inpatient rehabilitation services for patients with these medical conditions. Some patients may improve without rehabilitation, and others may not have the capability to improve even with rehabilitation.

We believe other conditions listed in proposed § 412.23(b)(2)(iii) also need to be clarified. The categories of brain and spinal cord injuries could appropriately be defined to include neoplasms of the brain, spinal cord, or meninges that result in substantial functional deficits as non-traumatic brain injuries and non-traumatic spinal cord injuries, since the course of rehabilitation for these conditions is very similar to the rehabilitation for other brain or spinal cord injuries. Although patients presenting with these conditions are currently paid under RIC 20, we believe that these patients can be counted towards the categories of cases listed in proposed § 412.23(b)(2)(iii) and invite comments of our interpretation.

Another category described in proposed § 412.23(b)(2)(iii) that requires clarification is major multiple trauma. Our contractors have noticed that some patients with relatively minor injuries at times are counted as having this condition. To clarify which patients should be counted, the IRF can determine if the acute care hospital service for a patient at the time of the initial injury was identified by diagnosis-related groups 484, 485, 486, or 487. We recognize that not all patients whose acute hospitalization was classified into DRG 484, 485, 486,

or 487 will be admitted to an IRF immediately after the injury, because some may require a period of recuperation and healing before beginning the intensive inpatient rehabilitation care. We are soliciting comments regarding this methodology.

C. Proposal To Consider Using a Comorbidity To Verify Compliance

In this section of the proposed rule, we discuss the possible use of comorbidities to verify compliance with proposed § 412.23(b)(2)(i). Under the IRF PPS, we defined a comorbidity at § 412.602 as a specific patient condition that is secondary to the patient's principal diagnosis that is the primary reason for the inpatient rehabilitation stay.

Section II.C.1 below describes a proposed methodology in which cases other than those admitted with a principal diagnosis matching one or more of the 12 conditions specified in proposed § 412.23(b)(2)(iii) could be considered to satisfy the proposed 65 percent rule if certain additional criteria are met. Section II.C.2 below describes another alternative, in which a case that has a comorbidity that matches one of the conditions in proposed § 412.23(b)(2)(iii) could be considered to satisfy the proposed 65 percent rule only if the patient is admitted to an IRF for postoperative care immediately following a hip or knee replacement. We are soliciting comments on both of these proposed methodologies.

1. Proposed Methodology

Under proposed § 412.23(b)(2)(i), we are proposing that starting with the effective date of the final rule and subject to the proposed phase-out provision discussed in section II.D., a case with a principal diagnosis that does not match one of the proposed 12 conditions be considered as meeting proposed § 412.23(b)(2)(i) if *all* of the following criteria are met: (1) The patient is admitted for rehabilitation for a condition that is not one of the conditions listed in proposed § 412.23(b)(2)(iii); (2) The patient also has a comorbidity that falls in one of the conditions listed in proposed § 412.23(b)(2)(iii); and (3) The comorbidity has caused significant functional ability decline in the individual such that, even in the absence of the admitting condition, the individual would require intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities and which cannot be appropriately performed in another setting, such as inpatient hospital, skilled nursing

facility, home health, or outpatient setting.

The following explanation provides guidance regarding classifying the proposed "arthritis-related" conditions as comorbidities which may be counted as complying with proposed § 412.23(b)(2)(i). If the comorbidity is active, polyarticular rheumatoid arthritis, psoriatic arthritis, seronegative arthropathies, or systemic vasculidities with joint replacement, the patient must have undergone an appropriate, aggressive, and sustained course of outpatient therapy immediately preceding the inpatient rehabilitation or have experienced a systemic disease activation immediately before admission in order for the admission to be included in cases complying with proposed § 412.23(b)(2)(i). If the comorbidity is severe or advanced osteoarthritis involving three or more joints, the patient must have undergone an appropriate, aggressive, and sustained course of outpatient therapy immediately preceding the inpatient rehabilitation in order for the admission to be included in cases complying with proposed § 412.23(b)(2)(i).

The following provides clinical examples of diagnoses which indicate when a comorbidity would and would not be considered in determining compliance with the proposed 65 percent rule. These examples are for illustrative purposes only and are not meant to be the only scenarios where comorbidities would or would not be considered in determining compliance with the proposed 65 percent rule. Furthermore, these examples are not intended to represent, define, or establish clinical criteria for benefit coverage determinations.

Examples of Clinical Scenarios That Are Likely To Be Included Under This Policy

(1) A patient who has severe arthritis in both shoulders and in his right knee has his left hip replaced with a non-cemented total hip prosthesis. Although before his joint replacement, he received an aggressive and sustained course of outpatient physical and occupational therapy, at the time of discharge from the acute care hospital, he still has considerable atrophy and weakness in his right quadriceps and hamstring muscles such that he is unable to support his entire weight on his right lower limb. He also has very restricted forward flexion in his right shoulder so that he is limited to 15 degrees of forward flexion. He has severe pain with weight-bearing through his upper limbs in both shoulders. Since after surgery, he can only have partial weight-bearing on his left lower limb, he requires

inpatient rehabilitation for daily occupational and physical therapy sessions to strengthen his right lower limb to bear his entire weight and to improve the function of both shoulders as well as therapy for his joint replacement.

(2) A patient undergoes emergency coronary artery bypass graft surgery for sudden onset of ischemic chest pain (unstable angina) unresponsive to medical management. During the operation she suffers a stroke and wakes up after surgery unable to speak, swallow, or move her right arm and leg. Over the next several days, she regains some partial movements in her leg and arm with minimal speech return. At the time of discharge, she still has significant weakness of the right arm and leg such that she is unable to walk without a walker and therapist by her side and she is unable to make coordinated movements with her right arm to feed and dress herself. She also cannot swallow liquids and solid food without choking spells. She, therefore, requires inpatient rehabilitation of at least 3 hours daily of physical therapy to strengthen her leg and arm, occupational therapy to improve right arm and hand coordination for activities of daily living (that is, eating, dressing, transfer, and bathing), and speech therapy to learn how to swallow her meals without choking.

Examples of Clinical Scenarios That Would Not Be Included Under This Policy

(1) A patient with a motor polyneuropathy who wears an ankle foot orthosis on the right lower limb elects to undergo a knee replacement due to severe osteoarthritis of the knee. Although the rehabilitation of the knee replacement may be complicated by the polyneuropathy, this patient would not be counted as satisfying the proposed change in § 412.23(b)(2)(i) because the comorbidity does not, by itself, require intensive inpatient rehabilitation.

(2) A patient had a stroke 5 years ago with residual weakness and lack of motor control in the left lower leg and that requires the use of a walking cane. She is involved in a car accident and undergoes surgery for a broken bone in her right arm (humerus) and a broken bone in her right ankle. At the time of discharge 2 days later, her dominant arm (right) is immobilized so she still has difficulty feeding herself and transferring from bed to chair. Also, she must learn to use a rolling walker because she cannot bear weight on her right leg and she can't reach the handle on her cane with her immobilized right arm. Although the rehabilitation of the

right arm and right foot fracture may be complicated by the stroke, this patient would not be counted as satisfying the proposed change in § 412.23(b)(2)(i) because the comorbidity does not, by itself, require intensive inpatient rehabilitation. She has no caregiver (family or friend) support person at home so she is transferred to a skilled nursing facility where, over the next 5 days, she receives a daily physical therapy session to learn how to ambulate with a rolling walker and she receives a daily occupational therapy session to learn how to feed herself with her non-dominant left hand. She is then discharged home for follow-up with Outpatient Rehabilitation Therapy.

2. Proposed Alternative Methodology

As stated in the May 16, 2003 proposed rule (68 FR 26794), our analysis indicated the largest group of patients treated in IRFs that was not considered as matching one of the 10 conditions in the existing 75 percent rule is patients with major joint replacements, specifically knee and hip replacements. Thus, as an alternative to the proposed methodology above, we are also proposing an approach that would only apply to patients admitted to an IRF after hip or knee replacements. Under this alternative approach, only admissions to an IRF that are post-operative hip or knee joint replacements cases would be considered to count towards meeting the proposed 65 percent rule if the case also had a comorbidity that matches one or more of the 12 proposed conditions in proposed § 412.23(b)(2)(iii). Specifically, under this method we would count a case as meeting the proposed 65 percent rule if the patient matched all of the following criteria:

- Was postoperative following one or more hip or knee joint replacements that immediately preceded the transfer to an IRF.
- Had a condition at time of admission to an IRF that was complicated by an active comorbidity specified in proposed § 412.23(b)(2)(iii).
- Had an active comorbidity that resulted in a decline in the patient's function beyond the decline generally observed for other patients in that impairment category.
- Had an active comorbidity that substantially complicated the patient's rehabilitation to the point that it would improve only with the intensive, multidisciplinary rehabilitation treatment that is unique to inpatient rehabilitation facilities and that could not be performed in another setting (for example, skilled nursing facility,

inpatient hospital, home health, or outpatient).

D. Ongoing Assessment of Implementing the Proposed Policies and Potential Scheduled Phase-Out of the Proposed Policies

In proposing these changes to the criteria for classifying hospitals as IRFs, our intent is to clarify the conditions typically requiring intensive inpatient rehabilitation therapy under the IRF PPS. These proposals do not represent an expansion of existing coverage criteria, but provide clear, clinically meaningful guidance on the conditions that are most appropriately treated in IRFs as distinguished from care furnished in other settings.

The policy changes proposed in this rule represent one of the next steps in an ongoing process since the May 16, 2003 proposed rule and the May 19, 2003 Town Hall meeting to identify potential policy changes to enhance the effectiveness of the IRF PPS. We are aware of the intricacies of implementing these changes to the IRF compliance criteria, both in terms of the time needed for providers to make any necessary adjustments to their operations and in the risk of unanticipated changes impacting providers, beneficiaries, and the Medicare program.

Comments received on the proposed change to the compliance percentage and on the proposed clinical criteria to determine compliance will be an important step in our planned ongoing assessment of the effect these proposed changes may have on—

- The IRF industry; and
- The Medicare beneficiaries who require rehabilitative care.

The final rule will reflect all relevant comments received and relevant data obtained through the comment period that may result in us adopting the proposed policies or adopting alternative policies.

As part of the next step in our ongoing assessment, during the 3-year period after the final rule is effective, we intend to closely review both claims and patient assessment data to examine trends in admissions and overall utilization in IRFs. These analyses will allow us to monitor and evaluate the effect the policies adopted in the final rule had on utilization and beneficiary access. Specifically, we will use these data to determine the effectiveness that the adopted final policies had in achieving the objectives stated in this proposed rule, and we will assess the need for any future policy development related to provider compliance. Also, we will review whether the adopted

final policies (including considering comorbidities in determining compliance if we adopt that policy) have led to significant shifts in the site of treatment of beneficiaries with particular conditions, and whether the adopted final policies have led to inadvertent and substantial expansions in either the number of IRFs or in aggregate utilization and expenditures.

In addition, we are encouraging rehabilitation professionals, the rehabilitation industry, researchers, academia, and other relevant sources to consider the 3-year period after the effective date of the final rule as an opportunity to conduct literature reviews, clinical studies, and other objective analyses so that we may be better informed about the situations in which patients require the intensive inpatient rehabilitation treatment available in an IRF compared to other settings. Furthermore, during this 3-year period, we plan to seek information and obtain data from rehabilitation experts, the rehabilitation industry, researchers, academia, and other relevant sources. The data we plan to obtain include clinical data, data from clinical outcomes analyses, and data from well-designed analytical studies specific to rehabilitative care. We believe that significant, objective data obtained from these sources would be informative as we deliberate whether changes to the clinical criteria and/or to the compliance percentage adopted in the final rule are justified.

However, no later than 3 years after the effective date of our final rule, in the absence of any significant, objective data as described above, we are proposing to change the classification criteria under proposed § 412.23(b)(2)(ii) as follows: In place of the proposed 65 percent compliance threshold discussed in section II.A., we would determine compliance by verifying that 75 percent of all inpatients have one of the 12 proposed conditions listed in proposed § 412.23(b)(2)(iii), and we would phase-out the use of the proposed comorbidity compliance policy discussed in section II.C. If, as we anticipate, the effective date of the final rule will apply to cost reporting periods that begin on or after January 1, 2004, this proposed change to the classification criteria, as noted below, would be effective for cost reporting periods beginning on or after January 1, 2007. Accordingly, the proposed changes specified in proposed § 412.23(b)(2)(ii) would occur automatically for cost reporting periods beginning on or after January 1, 2007 unless before that date we propose new criteria to determine compliance or validate the criteria as adopted in our

final rule for identifying an IRF based on the data that CMS has obtained over the preceding 3 years including data from rehabilitation experts, the rehabilitation industry, researchers, academia, or other relevant sources.

As a future step in our ongoing assessment, we plan every 3 years after the initial 3 year assessment described above, to obtain objective updated clinical data from relevant sources and, if appropriate and justified, we may propose changes to the clinical criteria and/or the compliance percentage based on that updated data.

E. Proposed Change to the Time Period To Determine Compliance

Except for new IRFs, § 412.23(b)(2) for freestanding IRFs and § 412.30 for IRF converted/expanded units would require the use of the most recent 12-month cost reporting period to determine if the IRF was compliant with existing § 412.23(b)(2). In addition, existing § 412.23(i) and § 412.25(f) state that the classification of a hospital or unit, respectively, is effective for the hospital's or unit's entire cost reporting period and that any changes in the classification of a hospital or unit are made only at the start of a cost reporting period. We believe that the application of both of these regulations has resulted in much confusion as to the data used to determine compliance with existing § 412.23(b)(2). For example, if an IRF's cost reporting period begins January 1, 2005 and ends December 31, 2005, this period would represent the most recent 12-month cost reporting period used to determine if the classification of the IRF is correct for the next cost reporting period that begins on January 1, 2006 in accordance with existing § 412.23(b)(2) and § 412.23(i) or § 412.25(f). However, the process of reviewing the data, making a determination of compliance with existing § 412.23(b)(2), and notifying the IRF of its non-compliance (and de-certification as an IRF) may take at least 3 to 4 months. Therefore, in order to make a determination of compliance and implement any changes before the start of the January 1, 2006 cost reporting period, data for only the first 8 to 9 months from the most recent 12-month cost reporting period would be available.

In order to have the proposed regulation more precisely reflect the necessary operational procedures of our FIs, we are proposing to change § 412.23(b)(2), § 412.30(c), and § 412.30(d)(2)(ii) to specify that data from the most recent, consecutive, and appropriate 12-month period of time be used to determine compliance with the proposed policies set forth in this

proposed rule. Accordingly, using the example above, the last 3 to 4 months of data from the cost reporting period ending December 31, 2004, and the first 8 to 9 months of data from the cost reporting period ending December 31, 2005, could be used (for a total of 12-months of data from the most recent, consecutive, and appropriate period of time) to determine compliance with the proposed policies set forth in this proposed rule. These time periods may be different depending on the workload of the FIs and CMS Regional Offices. We believe that this change will give FIs and CMS Regional Offices the flexibility to make a determination and give the IRF sufficient time to adjust to any Medicare de-certification action. We are not proposing to make a similar change to the regulatory policies for new freestanding IRFs or new IRF units, because they can provide written certification for the first full 12-month cost reporting period after Medicare certification that they intend to meet the requirements of proposed § 412.23(b)(2).

The intent of this proposed change is to ensure that the patient data used to determine compliance with the requirements of proposed § 412.23(b)(2) are from the most recent, consecutive, and appropriate 12-month period of time. However, we recognize that 12 months of patient data for the initial cost reporting periods affected by these proposed changes will be from a period that is before the effective date of the final rule. Therefore, it will be necessary to institute a transition period for those cost reporting periods where the most recent 12-month period of time includes admissions that occur before the effective date of the final rule. Accordingly, to ensure that admissions that occur before the effective date of the final rule are not counted in an IRF's compliance percentage, the FIs and affected IRFs will be given the specific procedures regarding what time period the FIs will use to verify compliance during the transition from the existing requirements at § 412.23(b)(2) to the proposed changes specified in proposed § 412.23(b)(2).

F. General FI Operational Instructions

We will take the necessary action to ensure that the proposed compliance policies are consistently enforced on IRFs across all FIs. We will issue instructions to the FIs and provide guidance to the clinical/medical FI personnel responsible for performing the compliance reviews to ensure that they use a method that consistently counts only cases with a diagnosis that both serves as the basis for the intensive rehabilitation services that the IRF

would furnish, and meets one of the medical conditions specified in proposed § 412.23(b)(2)(iii). In addition, as discussed in section II.A, we plan to instruct the FIs in the use of a presumptive eligibility test for verifying compliance with proposed § 412.23(b)(2)(i) that includes only Medicare cases determined to be "reasonable and necessary."

G. Conclusion

We believe that the changes we are proposing to § 412.23(b)(2) will help ensure the following:

- The incentives are appropriate for IRFs to admit patients that need and would benefit the most from intensive inpatient rehabilitation.
- The preservation of access to intensive inpatient rehabilitation services.
- IRFs provide distinct services and continue to be compensated with payment rates appropriate for their type of facility.
- The most prudent use of Medicare funds.
- More consistent implementation and enforcement by specifying more clearly what conditions are included in proposed § 412.23(b)(2).

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Introduction

In this proposed rule, we are proposing changes to the 75 percent rule for IRFs. Specifically, we are proposing that 65 percent of all patients treated in an IRF meet one of the proposed specified conditions, as discussed earlier in this preamble. We are also proposing to count comorbidities under certain conditions, as specified in this

preamble, towards meeting the proposed 65 percent rule.

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA), (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

B. Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more).

In this proposed rule, we are proposing changes to the 75 percent rule as described above. We estimate the savings to the Medicare program would be greater than \$100 million. Therefore, this proposed rule would be considered a major rule.

C. Regulatory Flexibility Act (RFA) and Impact on Small Hospitals

The RFA requires agencies to analyze the economic impact of our regulations on small entities. If we determine that the regulation will impose a significant burden on a substantial number of small entities, we must examine options for reducing the burden. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and governmental agencies. Most hospitals are considered small entities, either by nonprofit status or by having receipts of \$6 million to \$29 million in any 1 year. (For details, see the Small Business Administration's regulation, at 65 FR 69432, that set forth size standards for health care industries.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs. Therefore, we assume that all IRFs are considered small entities for the purpose of the analysis that follows. Medicare fiscal intermediaries and carriers are not considered to be small entities. Individuals and States are not included in the definition of a small entity. Accordingly, we have determined that this proposed rule would have a significant impact on a substantial number of small entities.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that will have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area (MSA) and has fewer than 100 beds. This proposed rule would have a significant impact on the operations of small rural hospitals.

D. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of at least \$110 million. This proposed rule would not have a substantial effect on the governments mentioned, or on private sector costs.

E. Executive Order 13132

We examined this proposed rule in accordance with Executive Order 13132 and determined that it would not have a substantial impact on the rights, roles, or responsibilities of State, local, or tribal governments.

F. Overall Impact

For the reasons stated above, we have prepared an analysis under the RFA and section 1102(b) of the Act because we have determined that this proposed rule is a major rule and the proposed policies set forth in this proposed rule would have a significant impact on all IRFs (small entities and small rural hospitals).

G. Anticipated Effects of the Proposed Rule

One of the primary purposes of the regulatory impact analysis is to understand the effects policies would have on facilities. As we analyze the impacts of our proposed policies, we assess the extent to which these policies may unduly harm facilities. If there is evidence that we are unduly harming facilities, we make attempts to mitigate these effects, while ensuring that the proposed policies are fair and achieve the intended policy objectives. The intent of the policy objective of proposed § 412.23(b)(2) and of other policy criteria for IRFs is to ensure the distinctiveness of facilities providing intensive rehabilitative services in an inpatient setting. The distinctiveness of these facilities is what justifies paying them under a separate payment system

as opposed to under another payment system, such as the acute care IPPS, which may not adequately compensate these facilities for the intensive rehabilitative services they are to provide. We believe it is crucial to ensure that IRFs are indeed providing intensive rehabilitation so that we pay for these services appropriately under the IRF PPS. In addition, we believe it is imperative to identify conditions that would “typically require intensive inpatient rehabilitation” in IRFs because rehabilitation in general can be delivered in a variety of settings such as acute care hospitals, skilled nursing facilities, outpatient or home health.

This policy objective is not new. However, the manner in which the existing regulations have been implemented and enforced may not have enabled CMS to accomplish these objectives to the extent we hoped. The policies set forth in this proposed rule are intended to accomplish these same policy objectives, clarify interpretational issues that have led to inconsistent implementation, and improve the extent to which IRFs can admit patients that would need and benefit from intensive inpatient rehabilitative services. Therefore, although the impacts of the proposed policy changes shown below illustrate that IRFs may experience reduced Medicare payments from these proposed policies, we believe the impacts would show a greater reduction in Medicare payments to IRFs if the existing policies were more effectively enforced.

We discuss below the Medicare impact of this proposed rule on IRFs. We used the following data and assumptions to estimate the impacts of the proposed policies set forth in this preamble.

- As stated in section I.D. of this proposed rule, we used patient assessment data from January to August 2002 to estimate compliance with the 75 percent rule in the May 16, 2003 proposed rule. We are using the same patient assessment data to construct the impact analysis set forth in this proposed rule.

- We used data described in the report titled Case Mix Certification Rule for Inpatient Rehabilitation Facilities”, published in May 2003, developed by the Rand Corporation. This report states, on page XIV, that 70 percent of all cases treated in IRFs are those of Medicare beneficiaries.

- In addition to Medicare patients, this proposed rule may have an effect on the 30 percent, or approximately 200,000, of the cases in IRFs that are non-Medicare. While there are numerous approaches a facility might

take, and it is impossible to predict either the specific course of treatment or the financial impact, the facility could change both its Medicare and non-Medicare case mix in order to remain an IRF.

- We used regression results from page 25 of the Rand report to estimate that the percentage of total cases that meet the specified conditions for each IRF will be approximately 5 percent more than the percentage of Medicare cases that meet the specified conditions. However, other than an estimate of the size of the non-Medicare population in this proposed rule may affect, CMS does not have enough information to quantitatively estimate the impact to non-Medicare IRF cases, and encourages comments on this issue.

- 10 percent of the cases that did not meet the proposed criteria would meet the proposed criteria due to more accurate coding and removing the moratorium of the classification rule.

- 10 percent of the cases that did not meet the proposed criteria with the limited Medicare administrative data used in our analysis would meet the proposed criteria using more extensive medical record data.

- The diagnosis listed in Appendix A in the “Case Mix Certification Rule for Inpatient Rehabilitation Facilities” report, published in May 2003, developed by Rand identified cases that would meet the 75 percent rule. The report showed that a large number of cases with possible arthritis-related joint replacements did not meet the 75 percent rule. We believe that the proposed changes to the conditions related to arthritis in this proposed rule may increase the number of these cases that would count towards meeting the proposed 75 percent rule over those cases shown in the RAND report. However, it is difficult to determine the exact number of joint replacement cases that would meet the proposed criteria without extensive medical record data. Therefore, to estimate the impacts on the various classifications of IRFs shown in Chart 1, we chose the assumption that 35 percent of the joint replacement cases would meet the proposed clinical criteria as set forth in this proposed rule.

- We assume that a percentage of Medicare cases being admitted under the current practices would not be admitted to an IRF under the proposed criteria. We believe that these cases would be admitted or treated in extended hospital inpatient stays, outpatient departments, or other post acute care settings. We estimated that it would be equally possible that the cases not admitted to IRFs may be treated in

inpatient hospitals, outpatient departments, or home health care settings. We found that approximately 80 percent of IRFs are units within a hospital complex and that approximately 60 percent of these hospital complexes include a skilled nursing facility. Accordingly, we estimated that skilled nursing facilities will have a higher possibility than other settings to absorb the cases not admitted to IRFs. Since long term care hospitals need to meet the average 25-day length of stay requirement and the average IRF length of stay is 14 Days, we estimated that long term care hospitals will absorb a smaller portion of the cases not admitted to IRFs.

Based on the above assumptions and the average payments for their respective settings, we have estimated that the average payment for these hospital inpatient, outpatient, and other post acute care settings to be approximately \$7,000 per case. Thus, for Medicare patients, the difference between the IRF standardized payment per case (\$12,525) and the estimated average per case amount for hospital inpatient, outpatient, and other post acute care settings (\$7,000) results in a net savings to the Medicare program of approximately \$5,525 per case.

Note that this result also depends on the assumption that all IRFs will continue to want to be classified as an IRF and admit those patients that will allow them to meet the proposed changes set forth in this proposed rule.

1. Impact Summary

Dependent on the range of assumptions related to joint replacement cases described above, we project a proposed net savings to the Medicare program between \$42 million and \$161 million. Specifically, the estimated net savings would be \$161 million if we assume that 20 percent of joint replacement cases meet the proposed criteria, \$98 million if 35 percent of joint replacement cases meet the proposed criteria, and \$42 million if 60 percent of joint replacement cases meet the proposed criteria. This net savings to Medicare would be a net loss of Medicare payments to IRFs or facilities that contain both an IRF and an alternative treatment facility. Some alternative treatment facilities, however, would experience an increase in Medicare payments if they experience a net increase in cases.

2. Calculation of Impacts

To determine the estimated effects of implementing the policies in this proposed rule, we have developed Chart 1 to show the estimated impact on the

Medicare program among various classifications of IRFs. Chart 1 assumes the middle estimate that 35 percent of joint replacement cases meet the proposed criteria. The columns in Chart 1—Projected Impact of the Proposed Changes to the 75 percent Rule on the Medicare Program are defined as follows:

- The first column, Facility Classification, identifies the type of facility. Where data were not available to classify an IRF into a category, the IRF was identified as “missing” in the first column.
- The second column identifies the number of facilities for each classification type.
- The third column lists the estimated number of Medicare cases admitted to IRFs under the existing policies. We estimated the number of Medicare cases from 8 months worth of post-IRF PPS data (the available data at the time the analysis was done) to represent an annual number of Medicare cases.
- The fourth column, Ratio of Medicare Cases Not Admitted, represents an estimate of the percentage of Medicare cases that would no longer be treated in an IRF due to the proposed policies set forth in this proposed rule.
- The fifth column represents the Ratio of All Setting Cost/Savings to IRF

Medicare Payments. To estimate this amount we divide the All Setting Cost/Saving in Millions in column six by the Current IRF Medicare Payments in Millions in column eight.

- The sixth column, All Setting Cost/Saving in Millions, indicates the savings impact to the Medicare program. To estimate the savings, we consider that some Medicare cases would possibly be treated in other settings and those settings would be paid accordingly. The following steps illustrate how we estimate this amount.

- Step 1—First we estimate the number of Medicare cases that may not be admitted to IRFs by multiplying the percentage in column four, Ratio of Medicare Cases Not Admitted, by the Total Medicare Cases reflected in column three.

- Step 2—We then take the number of cases calculated in the Step 1 and multiply these cases by \$12,525 (the standardized FY 2004 payment amount) to determine the estimated Medicare impact to IRFs.

- Step 3—Then we estimate the amount of Medicare payments that these cases may generate in other settings. Specifically, we multiply \$7,000 by the number of Medicare cases estimate in the Step 1 (the number of Medicare cases that may not be admitted to IRFs).

- Step 4—Then we subtract the total amount calculated in Step 3 by the total amount calculated in Step 2 in order to estimate the total savings to the Medicare program.

- The seventh column, IRF Medicare Payment Impact in Millions, shows the estimated Medicare impact specific to IRFs. We calculate this estimate by multiplying the percentage of Medicare cases that will not be admitted shown in column four by the Total Medicare Cases shown in Column three and determine the number of Medicare cases that will not be admitted to IRFs. We then take the total number of Medicare cases that will not be admitted to IRFs and multiply it by \$12,525 to estimate column seven, IRF Medicare Payment Impact in Millions.

- The eighth column, Current IRF Medicare Payments in Millions, is the number of Medicare cases reflected in column three multiplied by \$12,525.

- The ninth column, Projected IRF Medicare Payments in Millions, reflects the estimate of the total Medicare payments IRFs may receive as a result of the policies set forth in this proposed rule. This amount is calculated by subtracting the estimate of the IRF Medicare Payment Impact in Millions (column seven) from the estimate of the Current IRF Medicare Payments in Millions (column eight).

CHART 1.—PROJECTED IMPACT OF THE PROPOSED CHANGES TO THE 75 PERCENT RULE ON THE MEDICARE PROGRAM

Facility classification	Total number of IRF	Total Medicare cases	Ratio of Medicare cases not admitted	Ratio of all setting cost/saving to IRF Medicare payments	In millions			
					All setting cost/saving	IRF Medicare payment impact	Current IRF Medicare payments	Projected IRF Medicare payments
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8	Column 9
Total	1,170	459,682	4%	–2%	–98	–223	5,758	5,534
Census:								
1: New England	38	20,133	6%	–3%	–7	–16	252	236
2: Middle Atlantic	170	87,639	7%	–3%	–35	–80	1,098	1,018
3: South Atlantic	143	75,808	2%	–1%	–10	–23	949	926
4: East North Central	220	74,361	3%	–1%	–13	–29	931	903
5: East South Central	66	35,764	3%	–1%	–6	–13	448	435
6: West North Central	99	26,672	2%	–1%	–2	–6	334	328
7: West South Central	235	87,206	4%	–2%	–17	–39	1,092	1,054
8: Mountain	78	24,522	5%	–2%	–7	–17	307	290
9: Pacific	121	27,577	0%	–0%	0	–1	345	344
Free Standing/Unit Facility:								
Free	214	165,593	5%	–2%	–49	–111	2,074	1,963
Unit	956	294,089	3%	–1%	–50	–113	3,683	3,571
Teaching Status:								
Missing	180	37,039	3%	–2%	–7	–16	464	448
Non-teaching	845	344,216	4%	–2%	–70	–158	4,311	4,154
Teaching	145	78,427	5%	–2%	–22	–50	982	933
DSH:								
<0.05	226	80,921	5%	–2%	–23	–51	1,014	962
>=0.2	145	45,549	2%	–1%	–4	–9	571	562
0.05–0.1	339	161,550	5%	–2%	–41	–92	2,023	1,932
0.1–0.2	313	143,173	3%	–1%	–26	–60	1,793	1,734
Missing	147	28,489	3%	–1%	–5	–12	357	345
Facility Control:								
Government	135	38,942	2%	–1%	–4	–9	488	478
Missing	76	10,264	4%	–2%	–2	–5	129	123
Proprietary	259	140,311	5%	–2%	–40	–90	1,757	1,667
Voluntary	700	270,165	3%	–2%	–52	–118	3,384	3,266

CHART 1.—PROJECTED IMPACT OF THE PROPOSED CHANGES TO THE 75 PERCENT RULE ON THE MEDICARE PROGRAM—
Continued

Facility classification Column 1	Total number of IRF Column 2	Total Medi- care cases Column 3	Ratio of Medicare cases not admitted Column 4	Ratio of all set- ting cost/saving to IRF Medicare payments Column 5	In millions			
					All setting cost/saving Column 6	IRF Medi- care pay- ment impact Column 7	Current IRF Medicare payments Column 8	Projected IRF Medi- care pay- ments Column 9
Urban/Rural:								
Large Urban	493	209,489	4%	-2%	-48	-109	2,624	2,515
Missing	103	18,881	4%	-2%	-4	-10	236	227
Other Urban	404	188,494	4%	-2%	-42	-95	2,361	2,266
Rural	170	42,818	2%	-1%	-4	-9	536	527
Size:								
Large	201	172,951	5%	-2%	-43	-99	2,166	2,068
Medium	502	198,451	4%	-2%	-41	-93	2,486	2,393
Missing	158	31,400	3%	-1%	-5	-12	393	381
Small	309	56,880	3%	-1%	-9	-20	712	693
Size by Free Standing/Unit Facility:								
Free:								
Large	74	91,409	6%	-2%	-28	-64	1,145	1,081
Medium	71	53,640	6%	-3%	-17	-38	672	633
Missing	38	10,817	4%	-2%	-3	-6	135	130
Small	31	9,727	2%	-1%	-1	-2	122	120
Unit:								
Large	127	81,542	3%	-1%	-15	-34	1,021	987
Medium	431	144,811	3%	-1%	-24	-54	1,814	1,759
Missing	120	20,583	2%	-1%	-3	-6	258	252
Small	278	47,153	3%	-1%	-8	-18	591	573

Chart 1 breaks down the Medicare impacts into many categories that should serve to inform the public and interested parties of the different types of impacts of the changes in this proposed rule. As column seven in Chart 1 shows, IRFs are expected to experience a reduction in Medicare payments from the proposed rule of approximately \$223 million, with a net savings to Medicare of approximately \$98 million for all Medicare providers. Applying the different assumptions regarding qualifying joint replacement cases yields a Medicare impact range of \$42 million (60 percent qualifying) to \$161 million (20 percent qualifying).

For the purposes of the RFA analysis, the next few paragraphs discuss IRF impacts in more detail, and regulatory alternatives considered by CMS to explore the impact of different options on IRFs. There are distributional impacts among various IRFs due to existing levels of compliance. The expected Medicare savings is due to the percentage of patients admitted to IRFs that fall outside the identified conditions in relation to what IRFs would be paid in FY 2004 for all Medicare discharges assuming status quo (varying levels of compliance to the existing 75 percent rule). As we previously stated in this proposed rule, although the impacts of the proposed policy changes illustrate IRFs may experience a reduction in payments, we believe the impacts would show a greater reduction in payments to IRFs if

the existing policies were more effectively enforced. Further, we believe this reduction in Medicare payments is appropriate given the existing policy objectives described above.

Because this rule is likely to have a significant impact on all IRFs based on the RFA guidelines, we will discuss the alternative changes to the 75 percent rule that we considered.

One option (Option A) would have been to consider all cases in rehabilitation impairment categories (RICs) 1–19 and 21 as cases that could be counted towards the 75 percent rule. This would leave only miscellaneous cases (RIC 20) as cases that would not be considered to satisfy the requirements in proposed § 412.23(b)(2). The result would have been that all existing IRFs would not only meet the standard, but that they would have almost no restrictions on the type of cases that they would admit. The intent of the policy specified in proposed § 412.23(b)(2) is to ensure that IRFs are unique compared to other hospitals in that they provide intensive rehabilitative services in an inpatient setting. The uniqueness of these facilities justifies paying them under a separate payment system rather than paying them with the same payment system for acute care inpatient PPS. Thus, we believe it is crucial to Medicare to maintain criteria ensuring that only facilities providing intensive rehabilitation are identified as IRFs. In addition, we believe that it is imperative

to identify conditions that would typically require intensive inpatient rehabilitation in IRFs because rehabilitation, in general, can be delivered in a variety of other settings.

We have estimated that the average occupancy rate of all IRFs is approximately 70 percent. If we were to implement option A, we believe that IRFs with available capacity would increase their occupancy rate because, as stated above, IRFs would have almost no restrictions on the type of cases that they would admit. The following estimated effects of implementing option A on the Medicare program assumes that IRFs would increase their Medicare cases using the present ratio of 70 percent Medicare beneficiaries to total patients. Thus, we estimate that in the first year of implementing option A it would cause an increase in IRF Medicare payments, and would cost the Medicare program, an additional \$2.7 billion dollars if occupancy increased to 100 percent, \$1.9 billion if occupancy increased to 90 percent, and \$1.2 billion if occupancy increased to 80 percent. This range of additional costs to the Medicare program represents up to 50 percent more than the current total IRF Medicare expenditures.

A variant of option A is option B which would add joint replacements, cardiac, pulmonary, pain, and cancer patients to the list of conditions, as discussed previously in this preamble in section II.A., which would also result in a significant impact on Medicare

expenditures and IRF Medicare payments. If we were to implement option B, using the same assumptions described in option A, we estimate it would have cost the Medicare program approximately \$940 million dollars in the first year.

Another option (Option C) would be to retain the compliance percentage requirement at 75 percent, rather than lowering it to 65 percent, but recognize the comorbidities as proposed in section II.C. of this proposed rule. This option is similar to enforcement of the current policy and, thus, would further reduce Medicare payments to all IRFs over the policies proposed in this rule. Specifically, total estimated savings to Medicare from all IRFs would be increased from the range of \$42 to \$161 million (under the proposed policies) to the range of \$154 to \$357 million if we proposed 75 percent.

Another option (Option D) that we considered, similar to option C, was to allow a comorbidity to count only for hip and joint replacement patients as discussed previously in section II.C. of this proposed rule. If the compliance requirement were to be held at 75 percent along with this policy, the estimated reduction in Medicare payments for IRFs and savings to Medicare would be approximately the same as in option C.

We believe that the proposed changes to the clinical criteria are adequate to make the distinction of the intensive inpatient rehabilitation provided in IRFs from rehabilitation services provided in other settings, unlike the first alternative described above. In addition, while the proposed changes to the clinical criteria and the reduction in the compliance percentage to 65 percent do have a significant impact on Medicare payments to IRFs (\$42 to \$161 million), they are not as significant as the impact of the other alternatives described above. It is also important to note, as previously mentioned in section V.G., that approximately 80 percent of IRFs are units within a hospital complex and that approximately 60 percent of these hospital complexes include a skilled nursing facility. Thus, a majority of hospital complexes (including rural hospitals) that maintain an IRF unit may experience an increase in Medicare payments from the proposed changes in this proposed rule in other settings within the complex.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget (OMB).

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV, part 412 as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

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

2. In § 412.23, paragraph (b)(2) is revised to read as follows:

§ 412.23 Excluded hospitals: Classifications.

* * * * *

(b) * * *

(2) Except in the case of a newly participating hospital seeking classification under this paragraph as a rehabilitation hospital for its first 12-month cost reporting period, as described in paragraph (b)(8) of this section, a hospital must show that during its most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), it served an inpatient population that meets the criteria under paragraph (b)(2)(i) or (b)(2)(ii) of this section.

(i) For cost reporting periods beginning on or after January 1, 2004 and before January 1, 2007, the hospital has served an inpatient population of whom at least 65 percent required intensive rehabilitative services for treatment of one or more of the conditions specified at paragraph (b)(2)(iii) of this section. A patient with a comorbidity, as defined at § 412.602, may be included in the inpatient population that counts towards the required 65 percent if—

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

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

(C) The comorbidity has caused significant functional ability decline in the individual such 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 which cannot be appropriately performed in another care setting covered under this title.

(ii) For cost reporting periods beginning on or after January 1, 2007, the hospital has served an inpatient population of whom at least 75 percent required intensive rehabilitative services for treatment of one or more of the conditions specified at paragraph (b)(2)(iii) of this section.

(iii) List of conditions.

(A) Stroke.

(B) Spinal cord injury.

(C) Congenital deformity.

(D) Amputation.

(E) Major multiple trauma.

(F) Fracture of femur (hip fracture).

(G) Brain injury.

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

(I) Burns.

(J) Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living, which 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 which result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(K) Systemic vasculidities with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living, which 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 which result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(L) Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving three or more major joints (elbow, shoulders, hips, or knees) with joint deformity and substantial loss of range of motion, atrophy, significant

functional impairment of ambulation and other activities of daily living, which 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 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.)

* * * * *

3. Section 412.30 is amended by—

A. Revising paragraph (c).

B. Revising paragraph (d)(2)(ii).

The revisions read as follows:

§ 412.30 Exclusion of new rehabilitation units and expansion of units already excluded.

* * * * *

(c) *Converted units.* A hospital unit is considered a converted unit if it does not qualify as a new unit under paragraph (a) of this section. A converted unit must have treated, for the hospital's most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), an inpatient population meeting the requirements of § 412.23(b)(2).

* * * * *

(d) * * *

(2) * * *

(ii) A hospital may increase the size of its excluded rehabilitation unit through the conversion of existing bed

capacity only if it shows that, for the hospital's most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), the beds have been used to treat an inpatient population meeting the requirements of § 412.23(b)(2).

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: July 16, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: July 22, 2003.

Tommy G. Thompson,

Secretary.

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