DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1262–F]

RIN 0938–AM71

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

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

ACTION: Final rule.

SUMMARY: This final rule responds to public comments on the September 9, 2003 proposed rule, and revises the classification criterion, commonly known as the ''75 percent rule,'' used to classify a hospital as an inpatient rehabilitation facility (IRF). This final rule also modifies and expands the medical conditions listed in the regulatory requirements as well as temporarily lowers the percentage of patients required to fall within one of the specified list of medical conditions.

DATES: *Effective Date:* These regulations are effective for cost reporting periods beginning on or after July 1, 2004.

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I. Conditions 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 standardized payment 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 extraordinarily high costs).

The regulations implementing the IRF PPS provisions are presently in 42 CFR part 412, subpart P. Regulations governing the requirements for exclusion from the inpatient prospective payment system (IPPS) and the classification of hospitals as IRFs are

located in 42 CFR part 412, subpart B. Specifically, § 412.23(b)(2) specifies one of the criteria Medicare uses for classifying a hospital or unit of a hospital as an IRF, commonly known as the ''75 percent rule.'' This regulation provides that during its most recent 12-month cost reporting period, 75 percent of an IRF's total inpatient 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 Web site that contains useful information regarding the IRF PPS. The Web site 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). This final rule responded solely to the comments we received in response to our proposed policies, and promulgated the final regulations regarding the proposed update to the IRF PPS for FY 2004.

In the May 16, 2003 proposed rule, we had also 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 the 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 our 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 (FIs), who are charged with enforcing the 75 percent rule.
- Our 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). However, in the September 9, 2003 proposed rule, we proposed to amend the requirements in § 412.23(b)(2), as discussed in section II of that proposed rule (68 FR 53269).

2. Classification as an IRF Under the 75 Percent Rule

As stated in the August 7, 2001 final rule that implemented the IRF PPS, we did not change the survey and certification procedures for classification as an IRF. Under the current regulations, a hospital or unit of a hospital, must first be deemed excluded from the diagnosis-related group (DRG)-based inpatient prospective payment system (IPPS) to be paid under the IRF PPS, and also 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 requirements, must be in compliance with all of the criteria specified in § 412.23(b) in order 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), which subsequently became the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and other accrediting organizations 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). Similarly, the 75 percent rule was established as a criterion for identifying 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 reflected 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). In section II.A.2 of that final rule (49 FR 240), 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 an IRF (49 FR 239 through 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 former § 405.471 that addressed the 75 percent rule as provisions under a new § 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 IPPS if, in addition to meeting other requirements, it submitted a written certification that it would be in compliance with the 75 percent rule during its first cost reporting period. 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 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 received 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 receiving comments requesting that we either 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); further, since we believed the existing regulation was appropriate, 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, and that some IRFs were not being reviewed at all for compliance. 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 lose its classification as an IRF inappropriately. Therefore, on June 7, 2002, we suspended enforcement of the regulatory requirements at § 412.23(b)(2) until we conducted a careful examination of this area and determined whether the regulation, or the operating procedures used to verify compliance with it, should be changed.

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. As stated in the May 16, 2003 proposed rule (68 FR 26791), 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 used were from the time period of January to August of 2002. We estimated that the percent of facilities with at least 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 the IRF–PAI or the claim whether the patient had a medical need for ''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 of the information necessary to classify a case under one 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 we did not propose changes to § 412.23(b)(2) in the May 16, 2003 proposed rule, we did express an expectation 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 or reduce the number of admissions that may result in a reduction of the facility's revenues or both.

The existing regulation reflects 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 (SNF), 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 that have 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 § 412.23(b)(2), the regulation that set forth the 75 percent rule. 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 our Regional Offices, the FIs, and 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) effective with cost reporting periods that start on or after October 1, 2003, we decided to revisit this issue due to the extensive public comments received. Further, as stated in the September 9, 2003 proposed rule, we have now proposed to amend the contents of § 412.23(b)(2) itself. Therefore, we have decided not to use cost reporting periods beginning on or after October 1, 2003 as the timeframe for renewed enforcement, as we had planned in the May 16, 2003 proposed rule. Instead, enforcement of the criteria contained in § 412.23(b)(2) (as revised in accordance with the September 9, 2003 proposed rule and this final rule) will commence with cost reporting periods that start on or after the effective date specified in this final rule. Thus, the provisions in this final rule are effective for cost reporting periods beginning on or after July 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 under the IPPS. We believed it was 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 believed it was 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, SNFs, and outpatient settings.

E. Summary of the September 9, 2003 Proposed Rule

In the September 9, 2003 proposed rule (68 FR 53270), we proposed a new § 412.23(b)(2)(i) that proposed a temporary revision to the compliance threshold commonly known as the ''75 percent rule.'' As discussed in that proposed rule, we proposed that, for cost reporting periods beginning on or after January 1, 2004 and before January 1, 2007, the hospital must serve an inpatient population of whom at least 65 percent required intensive

rehabilitative services for treatment of one or more of the conditions specified at § 412.23(b)(2)(iii). Further, we proposed (68 FR 53272) that 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 § 412.23(b)(2)(iii) of the September 9, 2003 proposed rule;
- The patient has a comorbidity that falls in one of the conditions specified at paragraph (b)(2)(iii) of the September 9, 2003 proposed rule; 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.

In addition, we proposed a new § 412.23(b)(2)(ii). As discussed in the September 9, 2003 proposed rule (68 FR 53273), this proposed provision would specify, for cost reporting periods beginning on or after January 1, 2007, that to be classified as an IRF, the facility must serve 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).

We also proposed a new § 412.23(b)(2)(iii), which included the list of medical conditions to be used in connection with the preceding criteria. As discussed in the September 9, 2003 proposed rule (68 FR 53271), this list would retain the existing conditions except for polyarthritis, which we proposed 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 vasculidities 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 is no longer considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

Finally, we proposed to amend § 412.23(b)(2), § 412.30(c), and § 412.30(d)(2)(ii) (68 FR 53274), to revise the time period used to determine compliance with the 65 percent rule set forth in proposed § 412.23(b)(2)(i).

F. Summary of Public Comments Received on the September 9, 2003 Proposed Rule

The September 9, 2003 proposed rule provided for a 60-day comment period ending November 3, 2003. We received approximately 9,800 timely items of correspondence containing multiple comments on the September 9, 2003 proposed rule. Major issues addressed by commenters included:

- Reducing the percentage requirement from 75 to 65.
- Deleting the term ''polyarthritis'' from the list of 10 qualifying conditions and replacing it with three groups of conditions that will more precisely identify the types of arthritis-related ailments appropriate for care in a rehabilitation facility.
- Continuing to use the IRF's total patient population to determine compliance with the proposed 65 percent rule, but establishing an administrative presumption that if the facility's Medicare population is representative of the total patient population, and that we would presume that the 65 percent rule was met if an IRF's Medicare patient population met the 65 percent compliance threshold.
- Counting toward the proposed 65 percent, not only those patients whose principal diagnosis falls into the 12 conditions, but also those who have a secondary medical condition or comorbidity that meets one of the 12 conditions. The secondary condition would have to complicate the rehabilitation process substantially and also require inpatient rehabilitative care.
- Changing the period of time to review patient data to determine compliance with the proposed 65 percent rule from the most recent 12-month cost reporting period to the most recent, appropriate 12-month time period.
- Using certain assumptions to estimate the impact of the September 2003 proposed rule on IRFs and the Medicare program.

Summaries of the public comments received and our responses to those comments are set forth below under the appropriate subject heading. More detailed background information for each issue can be found in the September 2003 proposed rule.

II. Lowering the Compliance Threshold

In the September 9, 2003 proposed rule (65 FR 53270), we proposed 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 in 2004 (proposed § 412.23(b)(2)(i)). Therefore, we also proposed to allow the percentage of cases that met the proposed medical conditions to be lowered to 65 percent, which we believe identify patients who typically can benefit from the type of intensive inpatient rehabilitation services provided by IRFs. In addition, our proposal would allow IRFs to care for some atypical patients who require intensive inpatient rehabilitation and still maintain their status as an IRF. We further indicated that lowering the percentage of cases to 65 percent would be a preventive measure to mitigate any unintended effects on access to care. As part of our ongoing analysis (68 FR 53273), we stated that 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 listed in proposed § 412.23(b)(2)(iii). We welcomed the development and presentation of objective evidence that shows the type of patients most appropriately treated in

the IRF setting compared to other settings.

Comment: Commenters stated that the Medicare Payment Advisory Commission (MedPAC) recommended that we lower the compliance threshold to 50 percent for at least 1 year. According to the commenters, MedPAC recommended that during the period of this lower compliance threshold, we obtain the recommendations of an expert panel of clinicians regarding which medical conditions should be specified for this purpose in the regulation. The commenters also stated MedPAC's intention that we count, as meeting the 50 percent threshold, those diagnoses that the industry has historically interpreted as meeting the medical condition ''polyarthritis''.

Response: The commenters are referring to MedPAC's recommendations that were made in response to our May 16, 2003 proposed rule, rather than our September 9, 2003 proposed rule. In MedPAC's comments to our September 9, 2003 proposed rule, MedPAC characterized our proposal to lower the compliance threshold to 65 percent as ''a positive step,'' and did not recommend setting the compliance threshold lower than 65 percent. MedPAC recognized that, as discussed more fully elsewhere in this preamble, we examined information gathered from experts in the rehabilitation field regarding the medical conditions specified in § 412.23(b)(2)(iii). MedPAC recommended that we continue this information gathering, including convening an expert panel of clinicians, and report to the public the suggestions of these rehabilitation clinicians. We will evaluate the feasibility of convening the panel of clinicians.

Comment: Some commenters stated that Medicare will not pay for the services an IRF furnishes to any patient who does not have a medical condition specified in § 412.23(b)(2)(iii).

Response: Medicare will pay for the services an IRF furnishes to patients who have a medical need for intensive inpatient rehabilitation services, but do not have one of the medical conditions specified in § 412.23(b)(2)(iii). Each patient is evaluated individually for coverage, whether they have a condition specified in § 412.23(b)(2)(iii) or not. However, a facility is recognized as an IRF and is paid under the IRF PPS (rather than under the payment system that applies to acute care hospitals), if the facility's admissions (from any payer source, not just Medicare patients) meets the compliance threshold of revised § 412.23(b)(2)(i) and (b)(2)(ii) and conditions listed in revised § 412.23(b)(2)(iii), and if the IRF also meets the other applicable classification criteria.

Comment: Some commenters stated that enforcement of § 412.23(b)(2) would result in IRFs closing.

Response: We do not believe that an IRF's compliance with revised § 412.23(b)(2) would necessarily result in it closing. We believe that there are a variety of techniques an IRF can use to mitigate any potential or possible adverse effects it may experience due to our enforcement of § 412.23(b)(2). For example, we believe an IRF can alter its admission procedures, and that would result in the IRF managing its case-mix so that its patient population during its most recent, consecutive, and appropriate 12-month time period (as defined by us or the FI) is in compliance with revised § 412.23(b)(2). In addition, an IRF may chose to comply with the amended regulation by reducing its available patient capacity. Reduction of available patient capacity would have the effect of altering the percentage of the Medicare and total patient population that would have to meet the amended regulation. We believe that decreasing the percentage of the IRF's total patient population that must comply with the medical conditions specified in revised § 412.23(b)(2)(iii), gives the IRF sufficient flexibility to achieve compliance with the regulation.

In addition, it is worth noting that the failure of an IRF to comply with revised § 412.23(b)(2) does not preclude it from participating in the Medicare program altogether. A facility that fails to comply with the revised regulation could still participate in the Medicare program as an acute care hospital or unit and be paid under the IPPS.

Comment: Facilities have stated that IPPS payment for the services they furnish would not be sufficient to meet their revenue needs due to the higher operating expenses of being an IRF.

Response: If the IRF has not met the compliance threshold criterion and, thus, did not qualify to be classified as an IRF, then it has not treated a sufficient percentage of patients with the types of medical conditions we believe require the intense inpatient rehabilitation services that are suitable for payment under the IRF PPS. Not being classified as an IRF means that the facility is an acute care free standing hospital or unit, if it meets the criteria for being classified as an acute care facility, and has the operating expenses of an acute care free standing hospital or unit. The services that are being furnished by these facilities are acute care services. The only appropriate payment for acute care services is payment under the IPPS. In addition, if the facility is no longer classified as an IRF, the facility is no longer constrained to provide all patients with the range and intensity of services required of IRFs. Therefore, facilities that were formerly IRFs may be able to reduce their operating expenses by furnishing only an acute care hospital or unit level of services.

Comment: Commenters believe that other medical conditions, not specified in revised § 412.23(b)(2)(iii), that qualify for rehabilitation treatment, including the replacement of a single joint, debility, pulmonary conditions necessitating rehabilitation, cardiac conditions requiring rehabilitation, other circulatory disorders that impair mobility, multi-organ failure (shock/sepsis) that impairs mobility, cancer that requires a patient to receive rehabilitation, and pain, should be counted as part of the percentage of the patient population used to classify a facility as an IRF. Commenters believe that the IRF treatment furnished to patients with these medical conditions leads to faster improvement and fewer medical complications. This results in less cost to Medicare in comparison to these patients receiving rehabilitation services in a different inpatient setting or mode of rehabilitation. Many commenters believe non-IRF rehabilitation programs are not as appropriate for treating the rehabilitation needs of a patient with one or more of these other medical conditions, because in other rehabilitation programs the patient receives less therapy and nursing care. Also, when furnishing outpatient rehabilitation services, it is not possible to furnish intravenous medications concurrently as in an IRF.

Response: As stated more fully in the September 9, 2003 proposed rule (68 FR 53268) and in the September 1, 1983 interim final rule (48 FR 39752), eight of the medical conditions originally specified in § 412.23(b)(2) are based on a document that was the result of a project regarding admission criteria for IRFs, as well as input from the National Association of Rehabilitation Facilities and the American Hospital Association. In addition, Agency physicians, who were knowledgeable about rehabilitation treatment, contributed to the effort to determine what medical conditions should originally be listed in existing § 412.23(b)(2). As a result of comments received in response to the September 1, 1983 interim final rule, the final rule that we published on January 3, 1984 (49 FR 234) modified the original list of medical conditions, by adopting commenters'

recommendations to add two other medical conditions to the list.

Although we have searched the medical literature and received information from experts in private insurance, academic physicians, and others knowledgeable in the field of rehabilitation, we have not seen any studies indicating that medical conditions not now listed in existing § 412.23(b)(2) require the type of intensive rehabilitation treatment that IRFs can uniquely deliver. Although the conditions listed by commenters have been treated in IRFs, we do not believe that they are the type of conditions that typically require intensive rehabilitation. Therefore, we believe it would be inappropriate to use these cases as the basis for the classification criteria used to identify IRFs. None of the literature cited in the comments or the additional literature we have reviewed to date have provided evidence that the list of conditions should be expanded. As described in the September 9, 2003 proposed rule, we proposed to clarify the condition formerly described as ''polyarthritis.'' The proposed clarification of polyarthritis was favorably received by academic reviewers, though many commenters who preferred to interpret the prior term very broadly commented negatively on the clarification.

On pages 53270–53271 of the September 9, 2003 proposed rule, we encouraged providers and any other interested parties to develop and present objective data or evidence from well-designed research studies that would support a change in the policies stipulated in the proposed rule. We still welcome such data or evidence. In addition, we will continue to monitor the literature for studies that support setting a compliance threshold standard less than compliance threshold standards as specified in revised § 412.23(b)(2)(i) and (b)(2)(ii). While our administrative data show that IRFs are treating many patients with medical conditions that do not match the existing list of medical conditions specified in revised § 412.23(b)(2)(iii), an IRF is not necessarily the most appropriate treatment modality for patients with those medical conditions to receive rehabilitation services. Although we believe that 75 percent is still an appropriate threshold to use as the classification criterion, we are lowering the threshold for a period of 3 years to give IRFs additional flexibility to more easily adjust their case-mix so that they can comply with the amended regulation.

We have not encountered data indicating that patients who require some form of rehabilitation for a non-listed medical condition improve faster or have fewer medical complications when treated in an IRF, as opposed to some other treatment setting or program. Thus, we regard comments that state such a perspective as anecdotal in nature. Also, we have not seen objective and comprehensive data to support the commenters' assertions that patients who enter a non-IRF rehabilitation program for medical conditions other than those specified in revised § 412.23(b)(2)(iii) do not receive an amount of therapy, nursing care, or intravenous medications commensurate with their rehabilitation or recuperative needs, as determined by the staff of that treatment setting or program.

While it is true that the state of rehabilitation has changed over the past 20 years since the original medical conditions listed at existing § 412.23(b)(2) were determined, a modification in rehabilitation practices is not, in itself, a determinant that the IRF setting is the most appropriate setting for treating a specific medical condition. Historically, the last 20 years have seen changes in other types of treatment techniques, leading to treatment being shifted from the inpatient setting to other treatment settings. For example, surgical procedures that were formerly performed in the inpatient setting are now performed safely, efficiently, and effectively in another treatment setting.

Comment: Many commenters recommended that we establish a panel of experts to advise CMS on issues relating to the ''75 percent'' rule.

Response: Although we did not establish a panel of experts, we received written or transcribed oral opinions from a range of experts. We received information from two industry representatives, one chief executive from a distinguished rehabilitation hospital and another executive responsible for a chain of rehabilitation hospitals; four academic physicians with expert knowledge of the field of rehabilitation, including a physician responsible for reviewing and funding rehabilitation research and another who is a leader in academic research in rehabilitation; two physicians from private insurance knowledgeable about rehabilitation; and three physicians knowledgeable about rehabilitation who review Medicare claims. These experts commented on the policies in the proposed rule and the broader issues.

Most of the individuals did not believe that lowering the compliance percentage from 75 percent to 65 percent (as proposed) would change the nature of IRF's focus on delivering intensive rehabilitations services nor diminish the distinction between IRFs and acute care hospitals. However, some individuals were concerned that lowering the percentage may diminish the distinction between IRFs and other types of facilities especially skilled nursing facilities.

Three of the four academic physicians, both of the physicians from private insurance, and two of the physicians reviewing Medicare claims concurred with the proposed definitions to replace polyarthritis. One of the Medicare physicians believed that the definition of osteoarthritis was too broad thus, allowing more patients than appropriate to be counted.

One academic physician did not agree with the proposed osteoarthritis definition because ''it offers no relief to the field from the impact of not allowing coverage [sic] for joint replacement patients''. The two rehabilitation hospital executives also did not agree with the definition, one, because the proposed definition excludes joint replacement patients, and the other, because the proposed definition represents only 2 percent of all IRF admissions. One of the rehabilitation hospital executives maintained that ''a course of outpatient therapy will not increase functioning of patients with osteoarthritis. Joints with no cartilage have bone on bone, which is causing pain that brings the patient in for surgery. No amount of therapy will improve this.''

Although we obtained input from various sources regarding which medical conditions should be included in revised § 412.23(b)(2)(iii), we continue to welcome additional input (clinical or otherwise) that would help us determine the best method to use to classify a facility as an IRF.

Comment: Several commenters believe that the methodology used to determine the RICs was more rigorous than the methodology used to determine the medical conditions listed in revised § 412.23(b)(2)(iii). Numerous commenters believe the medical conditions associated with either all of the RICs or 20 of the RICs should be the medical conditions listed in revised § 412.23(b)(2)(iii), or should be used in lieu of these medical conditions as criteria to classify a facility as an IRF. The commenters believe that the medical conditions listed in revised § 412.23(b)(2)(iii) are inconsistent with the IRF PPS, because these are not the same medical conditions that are associated with the rehabilitation services paid for under the IRF PPS.

Response: As stated elsewhere in this preamble, the original medical

conditions listed in § 412.23(b)(2) were the result of a project regarding IRF admission criteria, input from two health associations, as well as input from our staff physicians who are knowledgeable about medical conditions requiring rehabilitation. In addition, input from commenters was used to expand the original list.

The process used to develop the list of medical conditions in § 412.23(b)(2)(iii) was different from the process used to develop the RICs. The process used to develop the RICs depended upon just describing every patient being treated in an IRF, without examining if it was appropriate for the patient to be treated in that setting. We have no data to support the belief that the process used to develop the RICs resulted in the RICs being superior to the medical conditions in revised § 412.23(b)(2)(iii) as criteria to classify a facility as an IRF. Rather, we believe the process used to develop the list of medical conditions specified in revised § 412.23(b)(2)(iii) was valid and resulted in the correct list of medical conditions. The process we relied on to develop and revise the conditions listed in revised § 412.23(b)(2)(iii), as well as the other proposed policies in the proposed rule, included soliciting the views of various individuals knowledgeable in inpatient rehabilitation. However, we still encourage additional expert input (for example, clinical research studies) to help determine what cases are appropriate to the IRF setting for classification purposes.

In a basic way, the processes used to develop the RICs and the medical conditions used to classify a facility as an IRF have some similarities, because both processes analyzed the admission data regarding the types of medical conditions that were being treated in IRFs. We used a data file consisting of information on all patients treated in an IRF in order to develop the RICs. However, when the RICs were being developed, the methodology used was designed solely to develop payment rates. If the RICs had also been developed as a means to classify a facility as an IRF, then we would have attempted to modify the process significantly to allow the payment categories to accomplish that additional task. Thus, we disagree that the RICs should form the basis of the classification criteria.

Medical reviews of admissions to IRFs showed that Medicare often made payments to IRFs for non-intensive rehabilitation cases that exceeded the percentage allowed in the existing regulation. Consequently, Medicare payment for a patient's treatment in an IRF did not necessarily mean that the patient actually required intensive inpatient rehabilitation. The inevitable effect of this occurrence is that despite the fact that we used the best available data to develop the RICs, the RICs may capture patient cases that require less than intensive inpatient rehabilitation services.

In general, under the IRF PPS, the RIC serves to identify the medical condition that caused the patient to be admitted to an IRF. If the case had been reviewed against the coverage criteria, an individual patient may have required intensive rehabilitation treatment, but not all patients with that condition would require intensive inpatient rehabilitation services. The RICs alone may not identify the most appropriate setting for furnishing those rehabilitation services. Thus, the RICs simply group those cases that were being treated in IRFs before the implementation of the IRF PPS, using labels to identify these medical conditions and associated payment rates with these labels. However, the RICs do not serve to identify medical conditions that are likely to be most appropriately treated in an IRF, or that require intensive inpatient rehabilitation services, because their primary function is to determine payment rates. Since the goal of the methodology used to develop the RICs was to include medical conditions both listed and not listed in revised § 412.23(b)(2)(iii), the RICs are not appropriate for use as an IRF classification criterion. In addition, because they serve solely a payment function, the RICs are no more than a formalized system to group and label medical conditions in order to facilitate appropriate payment for the services furnished to treat these medical conditions. Development of a formalized grouping and labeling methodology that associates medical conditions with a payment rate is not the same as using a payment system to identify the IRF as the most appropriate setting or rehabilitation program to treat these medical conditions. As we refine the payment system, we expect the definitions of the RICs and CMGs to change based upon updated claims and cost information, but the changes in the conditions that we may propose in the future to define an IRF under revised § 412.23(b)(2)(iii) will be based upon research.

The RIC medical conditions that are not included in revised § 412.23(b)(2)(iii) are the same medical conditions that were not included in the classification criteria before the creation of the IRF PPS. Because we continue to pay IRFs for treatment of some patients with these RICs does not mean that some of these patients could not be treated in other patient care settings.

We believe it is not necessary for an IRF to treat only those medical conditions listed in revised § 412.23(b)(2)(iii) for the IRF to be distinguished as an inpatient hospital setting that is primarily engaged in furnishing intensive inpatient rehabilitation services. Patients have a variety of medical conditions that require rehabilitation treatment, and that rehabilitation treatment may be furnished by a variety of rehabilitation programs. However, merely because an IRF is one of the settings that is available to furnish rehabilitation does not mean it is the most appropriate setting to treat a medical condition not listed in revised § 412.23(b)(2)(iii). As a prudent purchaser of health care services, we must try to ensure that the rehabilitation setting or program closely matches the level of rehabilitation services furnished by a particular provider. Requiring an IRF to treat a patient population that has a high concentration of the conditions listed in revised § 412.23(b)(2)(iii) is one of the means we have chosen to ensure that the treatment setting is appropriately classified to justify our payment of the level of services furnished.

Comment: Many commenters stated that not including in revised § 412.23(b)(2)(iii) cardiac, pulmonary, cancer, debility, single joint replacement, and other medical conditions that they believe should be treated in an IRF will result in a longer acute care hospital length-of-stay (LOS) for a patient with one or more of these medical conditions, thereby increasing Medicare's costs.

Response: Our data demonstrate that most of the patients with the medical conditions identified by the commenters are not predominantly treated in IRFs. In addition, patients with the conditions listed above have always had, and will continue to have, a range of rehabilitation programs available to them that can furnish treatment commensurate to these patients' need for rehabilitation. The argument that sending patients to IRFs is appropriate because it shortens patients' acute hospital LOS is not a compelling one. Patients should be admitted to IRFs because that site of care is uniquely equipped to meet patients' needs.

Comment: Commenters believed if an IRF's Medicare population met the compliance threshold, we should use the result to administratively presume that the facility's total patient population met the compliance threshold. However, if an IRF's

Medicare population did not meet the compliance threshold, they wanted us to specifically use the IRF's total patient population to calculate if the compliance threshold had been met.

Response: In general, we agree with the commenters because our analysis indicates that an IRF's Medicare patient population is highly predictive of whether an IRF's total patient population meets the compliance threshold. In addition, our analysis, as stated on page XIV of the Rand report entitled ''Case Mix Certification Rule for Inpatient Rehabilitation Facilities,'' indicates that, on average, 70 percent of all cases treated in IRFs are Medicare beneficiaries. Based upon both of these findings, we will issue instructions to the FIs regarding the application of the administrative presumption test to determine if the compliance threshold was met. Specifically, we will instruct the FIs that if, in most cases, an IRF's Medicare population met the compliance threshold, the FI should administratively presume that the facility's total patient population met the compliance threshold. If an IRF's Medicare population did not meet the compliance threshold, we will instruct the FI to specifically calculate if the IRF's total patient population met the compliance threshold.

As stated in the September 9, 2003 proposed rule (68 FR 53271), ''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.'' There may be situations when an IRF's Medicare population is only a small portion of the IRF's total patient population. Thus, if an IRF's Medicare population does not represent at least a majority of the IRF's total population, we believe that it is not appropriate for the FI to use the administrative presumption discussed above to verify if the compliance threshold was met. Accordingly, we will instruct the FIs that if an IRF's Medicare population does not represent at least a majority of the facility's total patient population, the FI is to verify if the compliance threshold was met using only the facility's total patient population. In addition, the FIs will always have the discretion to analyze a facility's total patient population even if its Medicare patient population met the compliance threshold.

III. Using a Comorbidity To Verify Compliance

In the September 9, 2003 proposed rule, we proposed to consider using comorbidities to verify compliance (proposed § 412.23(b)(2)(i)). In § 412.602, we defined a comorbidity as a specific patient condition that is secondary to the patient's principal diagnosis that is the primary reason for the inpatient rehabilitation stay.

A. Proposed Methodology

In the proposed rule, we proposed that a hospital could be considered to be providing intensive rehabilitation services even if it did not admit the patient for a condition that is specified in revised § 412.23(b)(2)(iii) as long as specific conditions were met. We proposed that such a hospital could still satisfy the 65 percentage as long as all of the following criteria were met:

- The patient is admitted for rehabilitation for a condition that is not one of the conditions listed in proposed § 412.23(b)(2)(iii).
- The patient also has a comorbidity that falls in one of the conditions listed in proposed § 412.23(b)(2)(iii).
- 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 the inpatient hospital, SNF, home health, or outpatient setting (68 FR 53272).

B. Proposed Alternative Methodology

We also proposed an alternative, in which a case that has a comorbidity that matches one of the conditions in proposed § 412.23(b)(2)(iii) could be included in the proposed percentage only if the patient is admitted to an IRF for postoperative care immediately following a hip or knee replacement (68 FR 53273).

Under this alterative method, we would count a case as included in the proposed percentage that 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 in 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, SNF, inpatient hospital, home health, or outpatient).

Many commenters addressed the two alternative methods pertaining to the use of specific comorbidities that could result in a patient being counted as a case satisfying one of the conditions in § 412.23(b)(2).

Comment: One commenter stated that the two proposed alternative methodologies fail to increase the number of cases falling within the compliance threshold. The commenter objected that the comorbidity itself would require intensive rehabilitation. They claimed that CMS failed to grasp that the initial condition and the co-condition interrelate to reduce function. They believe that CMS' policy should be to count the condition if a comorbidity condition adversely affects the patient's overall function such that the patient requires intensive rehabilitation services.

Response: Not all reductions in a patient's function are appropriate for treatment with intensive rehabilitation. In addition, not all patients and conditions that require rehabilitation treatment require the type of intensive inpatient rehabilitation treatment provided in an IRF. Many conditions affect a patient's overall function but are not appropriately treated in a rehabilitation hospital. For example, iron deficiency anemia is appropriately treated with medications such as iron or erythropoietin or a packed red blood cell transfusion rather than rehabilitation. Almost all diseases affect patients' function, but intensive inpatient rehabilitation is only appropriate for certain conditions. We believe that the conditions identified in revised § 412.23(b)(2)(iii) are typically, though not always, appropriately treated with intensive inpatient rehabilitation. Moreover, there are atypical individual patient cases that fall outside of revised § 412.23(b)(2)(iii) but may nonetheless receive intensive rehabilitation therapy services.

Comment: One commenter points out an inconsistency in the definition of osteoarthritis as an admitting condition (65 FR 53270) and osteoarthritis as a comorbidity (68 FR 53272). It was pointed out that we specified three circumstances when osteoarthritis was defined as a medical condition under revised § 412.23(b)(2)(iii), but we only specified two circumstances when osteoarthritis was a comorbid condition that may be counted as complying with revised § 412.23(b)(2)(i).

Response: This inconsistency was not intentional. The criteria for both should be the same, as follows: The patient has— (1) severe or advanced osteoarthritis in at least three, but now, based on a response to another comment, two major joints, including elbows, shoulders, hips, or knees (but not including any replaced joints); (2) by joint deformity, substantial loss of range of motion, atrophy of surrounding muscles, and significant function impairment of ambulation and other activities of daily living, which has not improved after an appropriate, aggressive, and sustained course of outpatient therapy or in a therapy program in another less intensive rehabilitation setting immediately preceding the inpatient rehabilitation admission; and (3) the potential to improve with more intensive rehabilitation.

Comment: Some commenters requested that we provide a list of specific ICD–9–CM codes that qualify as comorbidities and ensure the definitions of the admitting conditions conform with the definitions of the comorbidities.

Response: We will be providing guidance to our FIs on how to identify patients who fall into the conditions specified in the revised § 412.23(b)(2)(iii). Diagnosis will only be one aspect of the FI's determination, so we believe it is not appropriate, at this time, to supply a list of ICD–9-CM codes. The FI may also review information to assess (1) the medical necessity of rehabilitation in an inpatient setting: (2) the severity of the specific condition(s); (3) the patient's function; and (4) the capacity of the patient to participate in intensive rehabilitation and benefit from it.

Comment: Commenters disagreed with our assertion that adding cardiac, cancer, pulmonary, and pain as conditions would result in virtually all Medicare patients qualifying for inpatient rehabilitation. They argued that these cases currently comprise almost 10 percent of cases treated in rehabilitation hospitals. They also claim that InterQual, a private entity that develops utilization management clinical guidelines, has screening criteria that would identify these patients as requiring intensive rehabilitation.

Response: Almost all patients admitted to acute inpatient hospitals have one of these four conditions. The comments assert that only 10 percent fall into this category now, but almost 11 percent of cases admitted to IRF or acute care in 2002 fall into cardiac, pulmonary and pain impairment categories, with additional cases in the miscellaneous impairment category, which amounts to over 12 percent in total. We believe that the 75 percent rule has constrained the admission of these patients. If they were added to the list of patients in revised § 412.23(b)(2)(iii), the numbers would increase considerably. We have seen no literature indicating that these patients typically require the intensive inpatient rehabilitation appropriately provided in an IRF. We attempted to review the InterQual criteria, but they are proprietary and not available for our review. We are aware of other similar proprietary utilization management clinical guidelines as well, but such proprietary information has not been submitted for consideration and is not available for review by CMS. If we were to modify our policy based on these proprietary clinical guidelines, we believe that we should review guidelines from various sources, not just the one cited by the commenter. If there is, in fact, a small subset of high-risk cardiac patients who require intensive inpatient rehabilitation services, then these patients could be included as part of the cases that do not need to be in the list of conditions specified in revised § 412.23(b)(2)(iii), because this section only applies to a portion of the hospital's admissions.

Comment: One commenter urged us not to consider comorbidities in determining whether a patient could be counted as meeting one of the conditions in revised § 412.23(b)(2)(iii).

Response: Although the commenter seemed to believe that recognition of comorbidities was undesirable many other commenters did not agree. The commenter did not provide a clear explanation of why the comorbidities should not be considered. We were concerned that this commenter thought that the patient would be grouped into the impairment group of the comorbidity instead of being grouped into the impairment group that was the reason for admission. We still believe it is the medical condition that required the patient to be admitted to an IRF, that is, the principal diagnosis, that must be used to group the patient into a CMG. For example, if a patient is admitted for rehabilitation after pneumonia complicated by an ill-fitting below-knee prosthesis and a knee contracture the admission is grouped into the RIC specified by the pneumonia rather than the amputation RIC.

Comment: We proposed two methods for how we would calculate the compliance threshold with the use of certain comorbid conditions. Many commenters preferred the first proposed alternative in which a case with a principal diagnosis that did not match one of the proposed 12 conditions would be considered as meeting § 412.23(b)(2)(i) if all of the following criteria were 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.

Response: We will adopt the alternative that is specified above, instead of the alternative that limits counting the comorbidities for only joint replacement cases, except that now there are 13 medical conditions used to count as comorbidities as meeting the compliance threshold specified in revised § 412.23(b)(2)(i). As discussed in section IV of this final rule, this provision to count comorbidities as meeting the compliance threshold expires for cost reporting periods beginning on or after July 1, 2007. As mentioned previously, the vast majority of commenters preferred this method. We believe that this method of counting comorbidities is more comprehensive in recognizing the types of conditions requiring intensive inpatient rehabilitation.

IV. Ongoing Assessment of Implementing the Proposed Policies and Potential Scheduled Sunset Provision to 75 Percent

As stated previously, we originally wanted to publish this final rule so that it would be effective on January 1, 2004. Thus, in the September 9, 2003 proposed rule, we proposed that for cost reporting periods that start on or after January 1, 2004, and before January 1, 2007, the compliance threshold be lowered from 75 percent to 65 percent, but only for a 3-year period. If, during that time period, data from well-designed studies (or other compelling clinical evidence) indicate that the compliance threshold should remain at 65 percent, we would issue a proposed rule and final rule in sufficient time to maintain the compliance threshold below 75 percent.

Comment: Commenters requested that we set a permanent rather than temporary compliance threshold. In addition, commenters stated that the other provisions we proposed greatly reduced any benefit to providers or patients from the temporary lowering of the compliance threshold. Commenters requested that we permanently or temporarily lower the compliance threshold below 65 percent of the IRF's total patient population.

Response: We are concerned that permanently lowering the compliance threshold could have unforeseen and unintended consequences. Those consequences could include a substantial and unwarranted expansion of utilization, resulting in inappropriate additional Medicare expenditures. For example, we are concerned that permanently lowering the compliance threshold might cause beneficiaries who could have been treated appropriately in a less intensive setting to be treated instead in an IRF.

However, we recognize that IRFs may need some additional time to adjust to the amended regulations. In order to provide IRFs with additional time and flexibility to adjust their case-mix, and to take into consideration that this final rule is being published after January 1, 2004, we are modifying the proposed compliance threshold percentage and the ''sunset'' policy in the proposed rule that lowered the compliance threshold from 75 percent to 65 percent only during the time period from January 1, 2004, to December 31, 2006. Instead, for cost reporting periods beginning on or after July 1, 2004, the compliance threshold will be as follows:

- For cost reporting periods beginning on or after July 1, 2004, and before July 1, 2005, the compliance threshold will be 50 percent of the IRF's total patient population.
- For cost reporting periods beginning on or after July 1, 2005, and before July 1, 2006, the compliance threshold will be 60 percent of the IRF's total patient population.
- For cost reporting periods beginning on or after July 1, 2006 and before July 1, 2007, the compliance threshold will be 65 percent of the IRF's total patient population.
- For cost reporting periods beginning on or after July 1, 2007, the compliance threshold will be 75 percent of the IRF's total patient population. In addition, the provision to use a patient with a comorbidity as counting towards the referenced compliance threshold will expire for the cost reporting periods beginning on or after July 1, 2007.

Thus, we are implementing a 3-year period, as proposed in the proposed rule, to analyze claims and patient assessment data to evaluate if and how the lowering of the compliance threshold, as well as the other policies stipulated in this final rule, affected admission trends and overall IRF utilization. We will use that analysis to determine if we should continue to use a compliance threshold that is lower than 75 percent, as well as continue to use the comorbidity methodology specified elsewhere in this preamble, as criteria to classify a facility as an IRF. If our analysis indicates that the compliance threshold should be set lower than 75 percent, we would publish a proposed rule to lower the compliance threshold based on our analysis.

In addition, we may analyze other potential policy alternatives during this 3-year review period. For example, we received comments suggesting a new policy whereby an IRF may use its idle bed capacity to provide care to patients requiring lower levels of intensive rehabilitative services. To explore this, we would analyze the feasibility of developing a distinct payment rate commensurate with these services. As discussed previously, we also received comments suggesting that CMS incorporate additional conditions under this regulation (for example, cardiac rehabilitation and cancer). We expect to continue to evaluate the available research and medical literature to determine the appropriateness of adding new conditions. Finally, we may explore additional or alternative methods to classify a hospital as an IRF. For example, consistent with several comments that we received, we may evaluate the use of existing or revised criteria that the Commission on Accreditation of Rehabilitation Facilities, and/or the Joint Commission on Accreditation of Healthcare Organizations uses to accredit a hospital as a specialty rehabilitation hospital or unit.

We realize that, for various reasons such as diagnosis coding, there are limitations to the policy conclusions that can be drawn from claim and patient assessment data analysis. Therefore, we will also consider using the results of well-designed analytical studies specific to rehabilitative care to help guide our policy decisions. We believe that this approach benefits the rehabilitation industry, because it affords the industry the opportunity to provide us with compelling clinical evidence to maintain the policies in this final rule, or that supports changes that the industry may want us to consider proposing to these policies. Thus, we are encouraging interested parties to conduct scientifically sound research demonstrating that additional diagnoses are most appropriately treated in the IRF setting. This research should show which patients experienced better medical/health outcomes by receiving rehabilitation services in IRFs, as opposed to other settings (for example, SNFs, the outpatient setting, or home health.) We also encourage research supporting the continued use of comorbidities in determining compliance with the IRF threshold.

In accordance with the above comment and response, we are adopting the policy that for cost reporting periods that begin on or after July 1, 2004, the compliance threshold will be: (a) 50 percent of the IRF's total patient population for cost reporting periods that begin on or after July 1, 2004, and before July 1, 2005; (b) 60 percent of the IRF's total patient population for cost reporting periods that begin on or after July 1, 2005, and before July 1, 2006; (c) 65 percent of the IRF's total patient population for cost reporting periods that begin on or after July 1, 2006, and before July 1, 2007; and (d) 75 percent of the IRF's total patient population for cost reporting periods that begin on or after July 1, 2007.

V. New Medical Conditions

In the September 9, 2003 proposed rule, we proposed to remove the term ''polyarthritis'' from the list of 10 conditions and substitute instead 3 more clearly defined arthritis-related conditions (as described in section I.E. of this preamble). We also proposed to adopt in proposed § 412.23(b)(2)(iii) the other conditions currently listed in § 412.23(b)(2) because we believed that these other conditions are the most appropriate conditions for treatment in an IRF.

Comment: Several commenters recommended that CMS convene an ''expert panel'' under the auspices of the Institute of Medicine (or other body) or support research to evaluate the appropriateness of adding other conditions under this policy.

Response: We considered these recommendations very carefully with a view towards establishing a process to ensure that our policy remains consistent with current trends in medical practice.

We have searched the medical literature and received information from experts in private insurance, academic physicians, and others knowledgeable in the field of rehabilitation to support development of the September 9, 2003 proposed rule. However, studies supporting the inclusion of additional medical conditions have not been

found. Although the conditions listed by commenters (for example, joint replacements, cardiac and pulmonary rehab, pain) have been treated in IRFs, the available medical/scientific evidence does not support that they are conditions that typically require intensive inpatient rehabilitation or cannot be treated just as effectively in alternative care settings (such as skilled nursing facilities, home health, or outpatient rehabilitation). As a result, CMS has not used these conditions as a basis for the criteria used to identify IRFs in this final rule.

There are only a few studies that evaluate the effectiveness of inpatient treatment in a rehabilitation hospital (or units—both referred to as IRFs) compared to other settings. A few studies have shown that patients with hip fractures actually do no better in IRFs than in skilled nursing facilities (SNFs). On the other hand, one study showed stroke patients did better in IRFs than in SNFs.

We believe a focused research program offers the best approach to generate the data needed for continued assessment of the efficacy of rehabilitation services in various settings. In particular, the two questions most in need of objective, outcomes-oriented answers with respect to IRFs are: (1) How better to identify those patients who are most appropriate for intensive medical rehabilitation resources provided in the IRF setting as opposed to alternative care settings (such as acute hospital, skilled nursing facilities, home health rehabilitation, or outpatient rehabilitation)? and (2) what conditions, in addition to those in § 412.23(b), are frequently cited as typically requiring the intensive rehabilitation treatment available in IRFs but not in alternative care settings? Because of the relative absence of appropriate evidence-based outcomes-oriented clinical research studies in the peer-reviewed medical literature, CMS maintains an interest in encouraging this type of research and understanding the optimal approaches to answering the questions articulated above. We are concerned that simply convening a group of medical rehabilitation experts in the form of a consensus panel would only reflect ''expert opinions'' of the individuals involved without the benefit of advancing the more rigorous scientific studies needed in this area.

To assist in facilitating better understanding in this area, we expect to convene a research panel early in the transition period to review the current medical literature and identify optimal approaches to conducting studies in this area. This panel would have two primary purposes. First, based on the evidence currently available, it will consider which are the most appropriate clinical conditions for care in IRFs. Second, it will formulate a research agenda to assist in developing scientific studies to examine this question. We believe this approach will enhance the understanding of care in this important setting and provide the potential to inform future policy changes under Medicare. This panel will provide an opportunity for public input.

We anticipate that the panel will discuss available (or soon to be available) evidence to support some of the conditions identified by commenters to the September 9, 2003 proposed rule, the availability of data sources to support research, and the appropriate research design for studies in this area. This group would also explore available options to direct clinical research studies and identify the most optimal approach to establishing a research program that would provide meaningful and useful answers to the questions posed above. This group could also draw on the knowledge and experience of the clinical researchers with demonstrated expertise in the field of rehabilitation with published findings in the peer-reviewed medical literature. While CMS may not directly sponsor research or clinical trials in this area, we believe this type of discussion will help focus the medical research community on this important public policy area and aid us in our continued review of medical trends in rehabilitation.

We will also determine the feasibility of periodically holding these types of meetings to identify the latest research findings in this area and potential for future studies to inform this policy area. This will assist CMS in its ongoing monitoring of the policy, and the need for future changes in policy to conform to appropriate trends in medical practice. CMS will also periodically solicit comments from the public for data and studies through its annual rulemaking process associated with the IRF PPS, and discuss the need for changes with experts in commercial insurance, the health care industry, and academic researchers.

Comment: Many commenters asserted that the proposed changes to ''polyarthritis'' will limit the patients counted as meeting revised § 412.23(b)(2)(iii). Some commenters stated that for years, FIs have made the determination that an IRF admission following a lower joint replacement due to arthritis is counted as meeting the term polyarthritis in current § 412.23(b)(2).

Response: We do not agree with the assertions that we have changed the circumstances under which these cases can be considered as cases that meet the medical condition polyarthritis. We believe the confusion regarding the circumstances in which such cases can be counted as a case that meets current § 412.23(b)(2) can be attributed to a variety of causes, such as inadequate communication, misinterpretation by providers of current criteria, and insufficient monitoring. In addition, confusion regarding polyarthritis, which is acknowledged by many clinicians not to represent any clearly defined clinical condition because it can be defined differently by clinicians, has been compounded by insufficient and inconsistent procedures being used to verify compliance with current § 412.23(b)(2). For example, some FIs were using statistical sampling methods to obtain pertinent patient record data, and then analyzing that data in order to determine which cases met the provisions of current § 412.23(b)(2). However, many other FIs were simply allowing the IRF to self-attest that it was in compliance with the provisions of current § 412.23(b)(2), and not independently verifying that the IRF was actually complying with these requirements.

In order to clarify the meanings of the medical conditions specified in current § 412.23(b)(2), as discussed more fully in the preamble, we are amending § 412.23(b)(2) by removing the medical condition ''Polyarthritis, including rheumatoid arthritis'' and now substituting four groups of arthritis conditions.

Comment: We received many comments related to the medical management and monitoring of patients undergoing rehabilitation. Commenters believe that patients with medical conditions not specified in proposed § 412.23(b)(2)(iii) who do not receive rehabilitation services in an IRF would be denied the level of medical management and monitoring that they need. For example, commenters believe patients who receive rehabilitation for single joint replacement in an IRF also have other serious medical conditions that are best medically managed in an IRF. Commenters believe that for patients undergoing rehabilitation, the medical management received in an IRF results in faster and enhanced improvement by the patient. They also believe that patients denied the option of being treated in an IRF will be discharged home, where they will not be adequately cared for or medically monitored, leading to these patients being more frequently re-hospitalized in

acute care hospitals. In addition, commenters believe that compared to other rehabilitation programs, IRFs provide the best education to patients in adapting to lifestyle changes caused by impairment and/or the use of adaptive devices.

Response: An IRF is an inpatient hospital setting designed to provide the specialized, intensive, interdisciplinary level of care that certain types of patients need. For example, a stroke patient is much more likely to require physical and occupational therapy and speech and language pathology services that are well coordinated for their medical problems, but not all stroke patients require this level of care. Conversely, there may be a patient, for example, with a cardiac problem who also might require the specialized and intensive multidisciplinary rehabilitation services an IRF furnishes, and this patient could also be admitted to an IRF. However, patients who require medical management but not intensive, interdisciplinary rehabilitation can be cared for in another setting. The fact that care in an IRF may be convenient for other patients who require more intensive medical management does not make it the most appropriate clinical treatment setting nor the most optimal use of intensive rehabilitation resources uniquely provided by IRFs. For example, a post cardiac transplant patient may need to be seen daily by cardiologists and surgeons for medical management, but the deconditioning and possible steroid myopathy do not generally require intensive multidisciplinary inpatient rehabilitation. Without supporting data or studies, we do not believe conditions such as transplants or other complex medical conditions should be added to the list of conditions that can be used to define an IRF. However, cases with such conditions may be considered part of the percentage of cases with conditions not included in revised § 412.23(b)(2)(iii).

Commenters provided no documentation or reference to the medical literature to support their assertion that patients denied the option of being treated in an IRF will be discharged home with worse outcomes. These patients have the option of obtaining rehabilitation services in a SNF setting where their physicians can provide close medical oversight and guidance.

Comment: One commenter stated that the polyarthritis definition has been commonly understood to include joint replacements, and that our proposed revisions represent a departure from this common understanding.

Response: We know of no CMS policy that states that joint replacements were ever recognized as polyarthritis. In addition, for at least the past 5 years, we have met often with industry representatives and have consistently expressed our position that joint replacements did not meet the polyarthritis condition used to classify IRFs. Although industry representatives have repeatedly urged us to change our interpretation, we believe the agency's guidance has been consistent and based on the best data available to us.

Comment: Some commenters oppose the requirement of prior therapy for osteoarthritis patients because it poses a burden on beneficiaries and would be difficult for providers to verify.

Response: Osteoarthritis is a chronic disease that develops over years, unlike rheumatoid arthritis, systemic lupus erythematosus, and related diseases that can exacerbate more rapidly. The rehabilitation prescriptions typically involve outpatient therapy several times a week for 4 weeks or more. (Recent reviews of this literature which support this include Hurley, M.V., Muscle Dysfunction and Effective Rehabilitation of Knee Osteoarthritis: What We Know and What We Need to Find Out, Arthritis and Rheumatism [Arthritis Care and Research], 49, 444–52, 2003 and Bischoff, H.A. and Roos, E.M., Effectiveness and safety of strengthening, aerobic, and coordination exercises for patients with osteoarthritis, Current Opinion in Rheumatology, 15: 141–144, 2003.)

Although we recognize that some very unusual cases may require the intensive, multidisciplinary services available at an IRF without prior outpatient treatment, we believe that patients should have participated in a course of appropriate, sustained, and aggressive outpatient treatment before the more intensive treatment in an inpatient setting is determined to be medically reasonable and necessary because of the chronic nature of osteoarthritis. We want to be able to count patients who are appropriate for an intensive, interdisciplinary rehabilitation inpatient treatment as cases that count towards one of the conditions in the revised § 412.23(b)(2)(iii). Thus, we believe the requirement for prior therapy is appropriate. The reduced percentage standard allows IRFs to have the option to treat more exceptional patients who do not meet this criterion of prior therapy; nevertheless, we believe that the requirement is consistent with the pathophysiology of osteoarthritis and with the literature on its appropriate treatment.

Comment: Some commenters indicated that a joint replaced by a prosthesis still has arthritis and should be counted as having osteoarthritis, citing a definition of arthritis: ''the pathology of osteoarthritis involves the whole joint including focal and progressive hyaline articular cartilage loss with concomitant changes in the bone underneath the cartilage, including development of marginal outgrowth, osteophytes, and increased thickness of the bony envelope (bony sclerosis). Soft tissue structures in and around the joint are also affected, including synovium, which may show modest inflammatory infiltrates, ligaments, which are also often lax; and bridging muscle, which becomes weak.'' (Felson, DT, Lawrence, RC, Dieppe, PA *et al,* Osteoarthritis: New Insights. Annals of Internal Medicine 133: 635–646, 2000.

Response: Surgery to implant a total joint replacement removes the hyaline cartilage, underlying bone, and joint synovium. ''Total hip arthroplasty is an operative procedure in which the diseased hip joint is resected and replaced with a synthetic acetabulum, femur, and polyethelene liner fixed to bone by cement or bone ingrowth.'' (Brandler, VA and Mullarkey, CF, Rehabilitation After Total Hip Replacement for Osteoarthritis., Physical Medicine and Rehabilitation: State of the Art Reviews, 16: 415–430, 2002) ''In total knee arthroplasty, both the femoral and tibia sides of the joint are replaced using either a long or short stem, most commonly fixated with cement.'' (Mullarkey, CF, and Brandler, VA, Rehabilitation After Total Knee Replacement for Osteoarthritis., Physical Medicine and Rehabilitation: State of the Art Reviews, 16: 431–443, 2002) Some of the ligaments may also be removed, but others may be retained. Osteoarthritis is ''degeneration of articular cartilage and reactive changes in surrounding bone and periarticular tissue.'' (Wise, C. Osteoarthritis, Scientific American Medicine, 2001 from WebMD 2003) However, the residual, secondary effects of osteoarthritis, for example, the effects on ligaments and muscles surrounding the joint, do not continue to define arthritis in the patient. This description of osteoarthritis is consistent with ICD–9–CM diagnosis coding. Furthermore, a patient's care differs considerably once a prosthetic has been placed as compared to care prior to the joint replacement, indicating the distinction between the two conditions.

For this reason, only joints without joint replacement will be counted as joints with arthritis.

Comment: Commenters recommended that we use two joints rather than three joints to determine if a case complies with the arthritis-related conditions.

Response: After considering the comments, we are aware of the ambiguity in the number of major joints needed to describe the extent of osteoarthritis that would typically require intensive rehabilitation treatment in an IRF. Although some of the experts agreed with the three-joint standard, conflicting opinions would suggest that this issue may need additional study. Until we have more information or clinical outcomes studies that provide data to address this issue, we will revise the standard for osteoarthritis and consider a patient who has two major, weight bearing joints (that is, shoulders, elbows, hips, and knees, but not including joints with a prosthesis) with severe osteoarthritis manifested by joint deformity, substantial loss of range of motion, atrophy of surrounding muscles, significant functional impairment of ambulation and other activities of daily living, as described in the proposed regulations, to count as one of the now 13 conditions that could be counted in revised § 412.23(b)(2)(iii). We believe using the two joint standard provides greater flexibility for the IRF to select patients who require intensive interdisciplinary inpatient rehabilitation. As we develop additional information to determine whether osteoarthritis of two or three joints better defines the type of osteoarthritis typically requiring intensive inpatient rehabilitation, we will, at this time, give IRFs the flexibility of using the lower standard of two joints. The regulatory language will be modified accordingly.

Comment: Commenters stated that we offer no explanation or reasoning for choosing DRGs 484, 485, and 486 to define ''major multiple trauma.'' Instead, commenters propose the use of the Injury Severity Score (ISS) with a score of 16 or higher.

Response: We chose these DRGs to define major multiple trauma because they are consistent with the use of the term in IPPS, and because we believe the acute care classification scheme is used by coders generally and is well understood. Thus, we do not believe this definition narrows the current concept. We are concerned that some fractures of multiple bones, especially tibia and fibula, radius and ulna, or multiple bones of ankle or wrist do not represent major trauma and do not require intensive inpatient rehabilitation and should not be counted towards the condition of major multiple trauma. We would be open to exploring the possibility of modifying the standard, but at present, we are concerned that the ISS may not be used nationwide in all acute care hospitals or be as available to many IRF staff as the DRG classification of the acute hospital admission.

Comment: One commenter believes that we lack concern for patient safety. They cite the CMS Nursing Home Compare data that only 30 percent of short stay SNF residents walk as well or better after discharge.

Response: The CMS Nursing Home Compare website presents quality measure data for SNFs showing the percentage of short stay, independent residents (residents who are expected to stay for a short period of time) who walked better on day 14 than on day 5 of their stay or who walked independently on day 5 and maintained that level on day 14. The measure is based on Minimum Data Set (MDS) assessments. The national average on this quality measure is 30 percent, as the commenter noted. It is important to the interpretation of these data to point out that the measure includes all residents admitted to the SNF under Medicare SNF PPS payment (except coma patients, ventilator-dependent patients, paraplegic or quadriplegic patients, and patients receiving hospice care). This includes a wide range of patients who are being admitted to the SNF for a wide variety of reasons, even including residents who may have been in nursing homes before a qualifying hospital stay and who are now being admitted to the SNF under Medicare SNF PPS after the acute hospital admission. A further qualifier is that the patient must have had an MDS assessment at both day 5 and day 14 of the stay to be represented in this measure. If a patient improved so much that he or she was discharged before day 14, then that patient would not be included in the data.

For the reasons discussed, we believe that the CMS Nursing Home Compare data do not reflect the efficacy of rehabilitative care in a SNF and are inappropriate to be compared with outcome data from IRFs. Thus, we do not believe that providing certain patients rehabilitation services in a SNF impairs the patient's safety.

Comment: Some comments suggested that some knee or hip joint replacement patients should be counted towards the conditions satisfying a revised § 412.23(b)(2)(iii) where the treatment is complicated because of certain special circumstances, such as patients with bilateral replacements, obese patients, and very elderly patients.

Response: Although we are still hampered by the lack of data on the relative efficacy of rehabilitation in different settings, we will recognize certain categories of hip and joint replacement patients as countable under revised § 412.23(b)(2)(iii). Although we still believe that additional studies are needed, we will add a condition to account for these special circumstances. The 13th condition will include patients who undergo knee and/or hip joint replacement during an acute hospitalization immediately preceding the IRF stay and also meet at least one of the following specific criteria:

- Underwent bilateral knee or hip joint replacement surgery during the acute hospitalization immediately preceding the IRF admission.
- Are extremely obese patients as measured by the patient's Body Mass Index (BMI) of at least 50, at the time of admission to the IRF.
- Are patients considered to be ''frail elderly,'' as determined by a patient's age of 85 or older, at the time of admission to the IRF.

Although the industry suggests a variety of patients to be added, these three groups of patients were mentioned most consistently. The patients with bilateral hip and/or knee joint replacements typically are more challenging to treat in a rehabilitation setting. These patients are likely to have weight bearing restrictions on both of their lower limbs, which explains why they are likely to require more intensive, specialized inpatient rehabilitation treatment.

We believe that the BMI, ratio of a patient's weight (in kilograms) to the height (in meters squared), is the standard that is widely recognized within the medical community as a measure of obesity. We will use the BMI to determine if the patient is extremely obese and, when receiving rehabilitation after a joint replacement, is much more likely to require more skilled therapy personnel and specialized equipment. Patients would be considered extremely obese if their BMI was at least 50 at the time of admission to the IRF.

The industry representatives also cited that some very elderly patients may require intensive inpatient multidisciplinary rehabilitative care. These patients are often characterized as the ''frail elderly.'' Again, although we anticipate better data in the future regarding the appropriateness of setting for inpatient rehabilitation for the frail elderly, at the present, we will allow very elderly patients, following replacement of a hip or knee (likely to

result from osteoarthritis) who require multidisciplinary rehabilitative care to be counted under revised § 412.23(b)(2)(iii). Patients would be considered frail, elderly, if at the time of admission to the IRF, the patient is age 85 or older.

We have revised our regulations at revised § 412.23(b)(2)(iii) to reflect this change in policy. All admitted patients must still meet coverage requirements for IRF care and be able to actively participate in 3 hours of multidisciplinary rehabilitation and have the physical and cognitive capacity to benefit from the rehabilitation treatment.

As noted in a previous comment, we have also decided to amend the proposed definition for osteoarthritis and consider a patient who has two major, weight-bearing joints (that is, shoulders, elbows, hips, and knees, but not counting any joint with a prosthesis) with severe osteoarthritis manifested by joint deformity, substantial loss of range of motion, atrophy of surrounding muscles, and significant function impairment of ambulation and other activities of daily living, as described in the proposed regulation, to now count as one of the 13 conditions that could be counted in the revised § 412.23(b)(2)(iii). The regulatory language will be modified accordingly.

VI. Time Period To Determine Compliance

Under our current regulations at § 412.23(b)(2), § 412.30(c), and § 412.30(d)(2)(ii), we require that data from ''the most recent 12-month cost reporting period'' be used to determine compliance with the existing 75 percent rule (68 FR 53274). In the September 9, 2003 proposed rule, we proposed to amend the above sections to specify that data from the most recent, consecutive, and appropriate 12-month period of time be used to determine compliance with the proposed 65 percent rule.

As stated in the proposed rule, the intent of the proposed provision was to ensure that a full 12-month period of time is used to determine compliance with the proposed compliance threshold. However, in the proposed rule we recognized that using 12 months of patient data for the initial cost reporting periods affected by these proposed changes would mean that some data would be from a period that is before the effective date of the final rule. Therefore, we stated that it would 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 occurring before the effective date of the final rule are not counted in an IRF's compliance percentage, the FIs and the affected IRFs will be given the specific procedures regarding what time period the FIs will use to verify compliance during the transition from the 75 percent rule to the compliance threshold as specified in revised § 412.23(b)(2)(i) and (b)(2)(ii).

Comment: Some commenters recommended that we continue to use data from an IRF's most recent 12-month cost reporting period to determine compliance with the proposed compliance threshold. Other commenters recommended that, due to seasonal variations of patients treated, we should use a full year of data, or use the most recent entire 12-month cost reporting period beginning after the effective date of the final rule. Some commenters were also concerned that patient data may overlap when making a determination over 2 consecutive 12-month periods.

Response: We believe that the use of a cost reporting period, usually of 12 months' duration, does not provide the FI sufficient time to collect 12 months of patient data, make a compliance determination, and administer the process necessary to possibly change an IRF's classification before the start of the subsequent cost reporting period if the requirements were not met. As stated in the proposed rule, the intent of the proposed provision is to ensure that a full 12-month period of time is used to determine compliance with the classification criteria. We recognize that the Regional Office (RO) and FI need 4 months to complete their compliance reviews. (The RO and FI need 4 months to complete the review because the FI must determine, before the start of an IRF's next cost reporting period, whether the IRF meets the threshold criteria and the FI must communicate the results of its compliance review to the RO. If the IRF failed to meet the compliance threshold, the RO would need sufficient time to notify the facility that it will no longer be classified as an IRF beginning with the start of its next cost reporting period.) We note that the 4-month period that the RO and FI need to perform their tasks presents a unique problem for any IRF that has a cost reporting period beginning on or after July 1, 2004 and before November 1, 2004 (that is, 4 months following the effective date of this final rule). This is because the FI cannot collect 12 months of the most recent, consecutive, and appropriate data from a period falling completely after, as opposed to before, the effective date of this final rule and have the 4 months lead time necessary to make the compliance determination. To illustrate, to determine whether a hospital with a cost reporting period beginning on July 1, 2004 should continue to be an excluded rehabilitation hospital for the cost reporting period beginning on July 1, 2005, the FI would have to start its compliance review at the end of February 2005. This means that the most recent, consecutive, and appropriate data from a period after, as opposed to before, the effective date of the final rule is July 1, 2004 through February 28, 2005. If the FI were forced to use 12 months of data from a period before March 1, 2005, the FI would be using 8 months of patient case data following the effective date of the final rule (July 1, 2004 to February 28, 2005) and 4 months of patient case data occurring before the effective date of this final rule (from June 2004 back to March 2004). We believe it is important to use patient case data from a period after the effective date of the final rule because we believe it is appropriate to apply our rules prospectively and not judge IRF behavior before July 1, 2004 by rules that were not effective until July 1, 2004. Therefore, because we do not want to use data before the effective date of the final rule, we have adopted a transition policy that accounts for the fact that FIs need 4 months to complete their compliance review. Also, IRFs should be judged by patient case data from a period after the effective date of the final rule to determine compliance with the classification criteria. (**Note:** It is only those IRFs that have a cost reporting period beginning on July 1, 2004 and before November 1, 2004 that will be judged on less than 12 months of data. As explained above, this occurrence is inevitable in this first year of implementation.)

In addition, we note that for FIs to base their compliance review on the most recent, consecutive, and appropriate data from a period falling after the effective date of this final rule, FIs will examine patient case data from all IRFs that occurs on or after July 1, 2004. Thus, the later an IRF's cost reporting period begins in 2004, the more patient case data an FI will have available to it to make the compliance determination. We have included a chart in this section of the preamble entitled ''Establishing The 12-Month Review Period'' that shows the initial compliance review time period for IRFs whose cost reporting periods begin during the first 12 months after the effective date of this final rule.

We will provide the FIs and affected IRFs with the following general

procedures regarding the establishment of the review period used to verify compliance with the applicable percentage:

- A determination of non-compliance with the compliance threshold will affect the IRF's classification for its cost reporting period that begins after the 12-month review period. Similar to the current procedures for converted beds, if an IRF loses its classification and wishes to reapply to obtain classification as an IRF in a subsequent cost reporting period, the IRF is responsible for contacting its FI and CMS Regional Office prior to the beginning of that affected cost reporting period. The FI and RO would tell the IRF what the most recent, consecutive, and appropriate 12-month period would be used as the review time period.
- Patient data from any period before the effective date of this final rule will not be included in the 12-month review period.
- The standard period of time FIs and ROs may take to make and administer a determination of compliance with revised § 412.23(b)(2)(i) and (b)(2)(ii) is 4 months. If for any reason the FI requires additional time to make a determination, the FI must consult with the IRF prior to changing the period subject to review and before using patient data that may overlap patient data from the previous 12-month review period. However, we expect that these exceptions will be relatively infrequent. Our instructions will provide guidance to the FI and CMS Regional Offices to establish and maintain a consistent 12-month review period from year to year for each IRF.

Given the general procedures described above, we have illustrated, in Chart 1 below, the establishment of review periods over the first 13 months of cost reporting periods affected by this final rule.

CHART 1.—ESTABLISHING THE 12-MONTH REVIEW PERIOD

For cost reporting periods beginning on:	Review period: (addmissions during)	Number of months in review period	Compliance determination applies to cost reporting period beginning on:
07/01/2004	07/01/2004–02/28/2005	8	07/01/2005
08/01/2004	07/01/2004–03/31/2005	9	08/01/2005
09/01/2004	07/01/2004–04/30/2005	10	09/01/2005
10/01/2004	07/01/2004–05/31/2005	11	10/01/2005
11/01/2004	07/01/2004–06/30/2005	12	11/01/2005
12/01/2004	08/01/2004–07/31/2005	12	12/01/2005
01/01/2005	09/01/2004–08/31/2005	12	01/01/2006
02/01/2005	10/01/2004–09/30/2005	12	02/01/2006
03/01/2005	11/01/2004–10/31/2005	12	03/01/2006
04/01/2005	12/01/2004–11/30/2005	12	04/01/2006
05/01/2005	01/01/2005–12/31/2005	12	05/01/2006
06/01/2005	02/01/2005–01/31/2006	12	06/01/2006
07/01/2005	03/01/2005–02/28/2006	12	07/01/2006

Using Chart 1, the transition period, where less than a 12-month period of time would be necessary, is for cost reporting periods beginning on or after July 1, 2004 and before November 1, 2004. For cost reporting periods beginning on November 1, 2004 and beyond, the most recent, consecutive, and appropriate 12-month period of time would be used, giving the FIs and CMS Regional Offices a 4-month time period to make and administer a compliance determination. We believe that the provision as proposed and described above achieves our basic intent of establishing a full 12-month review period that is equitable to the IRFs by accounting for any variations (including seasonal variations) in patients treated and to the authorities responsible for administering the compliance determinations. Therefore, we are not adopting the recommendations and are instead adopting the provisions as described earlier.

VII. Other Issues

A. General FI Operational Instructions

In the September 2003 proposed rule, we explained that 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 revised § 412.23(b)(2)(iii). In addition, we plan to instruct the FIs in the use of a presumptive eligibility test for verifying compliance with revised § 412.23(b)(2)(i) that includes only Medicare cases determined to be ''reasonable and necessary.''

B. Administrative Procedure Act

Comment: We received a number of comments asserting that some of the revisions we proposed (or the manner in which we proposed them) failed to comply with the requirements of the Administrative Procedure Act (APA). For example, commenters noted that we proposed to introduce certain qualifying criteria that would have to be met in order to include joint replacement cases with an underlying diagnosis of osteoarthritis under our proposed osteoarthritis definition. The commenters noted that such cases are currently included under the existing ''polyarthritis'' definition without having to meet the new qualifying criteria, and characterized our proposal as an abrupt change from longstanding practice for which we failed to provide an adequate explanation, and which, therefore, would not withstand scrutiny under the APA. Some of the commenters suggested that under our proposed criteria, facilities might turn away Medicare and non-Medicare patients with non-listed conditions in order to avoid jeopardizing their IRF status. These commenters argued that we failed to consider the impact this practice would have on the patients,

thus rendering our proposals arbitrary and capricious. They also argued that this practice would result in an irrational manner of allocating care that would not withstand scrutiny under the APA. Commenters also asserted that the proposed implementation date of January 1, 2004, which would occur 58 days after the close of the public comment period on the proposed rule, would leave insufficient time in developing a final rule to give adequate consideration to the comments that we received.

Response: Regarding the policy on including joint replacements under the proposed osteoarthritis definition, we note that in section II.B of the proposed rule, we specifically acknowledged ''* * * that the industry has interpreted polyarthritis to include hip and knee joint replacement cases * * *'' (68 FR 53271). We went on to observe, however, that merely because some joint replacement cases are currently being treated in IRFs does not, in itself, establish this setting as being the most appropriate one for these cases. Rather, we expressed our belief that the current use of this particular setting for those cases may well be driven by other, non-medical factors, such as the presence of strong reimbursement incentives to send patients to IRFs, which have influenced the choice of setting for patients' care. Accordingly, we proposed the additional criteria in connection with a new osteoarthritis definition in order to ensure that the cases identified by this new definition are, in fact, the ones that are clinically appropriate for treatment in this particular setting. It was precisely because the proposed osteoarthritis definition represented a change from current policy that we included it in the proposed rule, in order to provide the opportunity for public comment on it. In this context, we also specifically invited the submission of any ''* * * data or studies that might provide evidence about whether certain patients had better outcomes as a result of care in IRFs'' (68 FR 53272). Regarding the comments on the potential impact that our proposed changes might have on access to care, we most certainly crafted our proposed policies to ensure that patients needing intensive rehabilitation services continue to receive such care. We note that the proposed rule set forth our plans to conduct a detailed 3-year analysis of ''* * * both claims and patient assessment data to examine trends in admissions and overall utilization in IRFs'' (68 FR 53273). Further, we proposed to lower the threshold percentage of cases that serve to identify an institution as an IRF from 75 percent to 65 percent during this 3-year period, specifically in order to mitigate any unintended effects on access to care while we perform this analysis (68 FR 53270).

Finally, regarding the concerns expressed about our ability to adequately consider and respond to public comments due to the timeframe between the close of the comment period and the proposed implementation of a final rule, we assure the public that we have given meaningful consideration to the public comments timely received. We fully consider all public comments timely received on proposed rules, regardless of the timeframe between the close of a comment period and the publication and implementation of a final rule. (In addition, we note that publication of this final rule is more than 100 days after the close of the public comment period and implementation is more than 180 days after the close of the comment period.) We believe that IRFs will have sufficient time, after publication of this final rule, to begin to make any necessary adjustments to their patient populations in order to meet the compliance threshold for being classified as an IRF.

C. Assumptions Used for Impact Analysis Section

For the impact analysis in the September 9, 2003 proposed rule (68 FR 53276), it was necessary to make certain assumptions about the effects of amending § 412.23(b)(2). The diagnoses 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 current 75 percent rule. The report showed that a large number of cases with possible arthritis-related joint replacements did not meet the current 75 percent rule. We stated in the September 9, 2003 proposed rule that 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 2, we chose the assumption that an additional 35 percent (we considered the range of 20 percent to 60 percent in the proposed rule, 35 percent is approximately in the middle of that range) of the joint replacement cases would meet the proposed clinical criteria as set forth in the proposed rule.

Comment: Some commenters disagreed with our assumption that an additional 35 percent of the joint replacement cases would meet the clinical criteria set forth in the proposed rule. Another commenter believed that the percent would probably be higher than 35 percent. Other commenters thought that 35 percent was probably too high because the criteria were rather restrictive, in their opinion. Several commenters stated that our assumption of an additional 35 percent was reasonable based on their professional experience.

Response: After considering all comments and adopting the clinical criteria as stated in section V, we believe that between 40 percent and 70 percent of joint replacement patients will count toward meeting the compliance threshold as specified in § 412.23(b)(2)(i) and (b)(2)(ii). We believe these changes, such as the clarifications to arthritis medical condition, will increase the number of joint replacement patients counting in the new 50 percent requirement more than what we assumed in the proposed rule. These final criteria are less restrictive than those in the proposal when we assumed a range of 20 percent to 60 percent. Therefore, we believe that the 40 to 70 percent range is reasonable and will be used in the impact analysis of the final rule in section XII.

Comment: Commenters disagreed with our suggestion that reimbursement incentives or incorrect FI interpretations, rather than medical advances, have led to changing IRF populations.

Response: It is well recognized that reimbursement incentives influence providers' practices. For example, Leighton Chan et al showed that Medicare's payment system for rehabilitation hospitals under the Tax Equity and Fiscal Responsibility Act (TEFRA) appears to have increased the length of stay and costs of care in rehabilitation hospitals (Chan, L. Koepsell, TD. *et al.*, The Effect of Medicare's Payment System for Rehabilitation Hospitals on Length of Stay, Charges, and Total Payments, New England Journal of Medicine 337:978–985, 1997.) Although there are no studies that directly assess the effect of reimbursement incentives, a recent study which examines post-operative rehabilitation practices in the U.S. compared to in England and in Australia suggests that reimbursement practices in the various countries affect the site of service for certain types of patients. (Lingard, EA. Berven, S. Katz, JN. and Kinemax Outcome Group, Management and Care of Patients Undergoing Total Knee Arthroplasty: Variation Across Different Health Care

Settings, Arthritis Care and Research, 13:129–136, 2000) These authors found that ''in the combined U.S. cohort, type of health insurance significantly influenced whether or not a patient went to an extended care facility (a rehabilitation hospital or a SNF) with Medicare 55 percent and 33 percent non-Medicare'' and that ''use of inpatient rehabilitation following discharge from the acute hospital is extremely rare in the UK.'' Rehabilitation use in Australia also varied with payment mechanism, suggesting that the influence of payment on medical practices is not limited to the U.S.

We would again welcome any additional studies on this issue, and we encourage researchers to engage in appropriate studies to provide additional knowledge on this issue.

Comment: Some commenters suggested that the standard to determine compliance be changed from using ''admissions'' to using ''patient days.''

Response: Using days of care is a lower standard than admissions and considerably loosens the existing standard. Analysis of historical data shows that 50 percent of admissions was the same as 63 percent of patient days. Furthermore, this percentage is easily modified either by shortening lengths of stays of patients who will not count towards the standard or lengthening a patient stay that counts towards the standard. If we want to assure that a hospital has the capacity to serve patients with certain types of conditions, then we should count admissions rather than patient days. As was stated in our earlier response to comments, we continue to believe that a hospital should be categorized by the types of patients admitted, not by their lengths of stay.

We addressed a similar comment described in the January 3, 1984 final rule (49 FR 240) whereby the commenter asked to specify whether the 75 percent rule is applied to discharges or patient days. In our response to that comment, we stated that, ''The 75 percent rule applies to the inpatient population. The population could be measured by either the number of admissions or discharges from a hospital or a unit * * * but not by its number of patient-days. This approach is consistent with the study used to develop the sample screening criteria, which showed that 75 percent of the admissions included in the study data were for certain medical conditions''. We continue to believe that admissions or discharges are the most appropriate measure for determining compliance with the compliance threshold. Therefore, we are not adopting the commenter's suggestion.

VIII. Provisions of the Final Regulations

This final rule adopts the provisions of the September 9, 2003 proposed rule except as we have specified in the preamble. We have made the following changes from the proposed rule:

- We are modifying the ''sunset'' policy specified in the September 2003 proposed rule that lowered the threshold from 75 percent to 65 percent during the time period from January 1, 2004, to December 31, 2006, the compliance. For cost reporting periods beginning on or after July 1, 2004, the compliance threshold will be as follows:

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

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

—For cost reporting periods beginning on or after July 1, 2006 and before July 1, 2007, the compliance threshold will be 65 percent of the IRF's total patient population.

—For cost reporting periods beginning on or after July 1, 2007, the compliance threshold will be 75 percent of the IRF's total patient population. Also a patient's comorbidity is not included in the inpatient population that counts towards the required 75 percent.

- We are amending § 412.23(b)(2) by removing the medical condition ''Polyarthritis, including rheumatoid arthritis'' and substituting four groups of medical conditions. This provision will amend the standard for osteoarthritis. We will now consider a patient as meeting the compliance threshold if the patient has two major, weight-bearing joints (that is, shoulders, elbows, hips, and knees) with severe osteoarthritis manifested by the following:

+ Joint deformity.
+ Substantial loss of range of motion.
+ Atrophy of surrounding muscles.
+ Significant functional impairment of ambulation and other activities of daily living, as described in the proposed rule.

In addition, we are adding a new condition for a total of 13 conditions. The new condition applies to a patient that has a knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and the patient also meets one or more of the specific criteria in § 412.23(b)(2)(iii)(M).

We will count the above as meeting the compliance threshold in the revised § 412.23(b)(2)(iii).

CMS will issue instructions to the fiscal intermediaries regarding how these policies are to be implemented and enforced as discussed in section VII.A.

IX. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The following information collection requirements and associated burdens are subject to the PRA.

Section 412.23 Excluded Hospitals: Classifications

Under paragraph (b)(2) 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.

We believe that the current 1210 IRF hospitals will be affected by this requirement. The burden of this section is the time it takes to document that it served an inpatient population meeting the appropriate criteria and provide the documentation to CMS upon request. An IRF hospital will be required to maintain documentation associated with meeting the requirements of this section. The time it will take to furnish the documentation to CMS will vary

depending on the size of the sample that the fiscal intermediary requests.

However, the burden associated with these requirements is currently approved under OMB number 0938–0358, ''Psychiatric Unit Criteria Work Sheet, Rehabilitation Hospital Criteria Work Sheet, Rehabilitation Unit Criteria Work Sheet'', with a current expiration date of March 31, 2007. Upon the publication of this regulation, CMS will amend this collection to properly reflect the revised regulatory requirements associated with this collection.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Dawn Willinghan, CMS–1262–F, Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

Comments submitted to OMB may also be emailed to the following address: e-mail: *baguilar@omb.eop.gov;* fax to OMB: (202) 395–6974.

X. Regulatory Impact

A. Introduction

This final rule revises the classification criterion, currently known as the ''75 percent rule,'' used to classify a hospital as an inpatient rehabilitation facility (IRF). Among other changes, this final rule modifies and expands the medical conditions listed in the current 75 percent rule regulatory requirements as well as lowers the percentage of patients required to fall within one of the specified list of medical criteria from 75 percent to 50 percent. In addition, this final rule responds to public comments on the September 9, 2003 proposed rule (68 FR 53266).

We have examined the impacts of this final 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 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 any 1 year).

We estimate the savings to the Medicare program, and the annual effects to the overall economy, will be more than $100 million. Therefore, similar to our determination in the RIA of the proposed rule, this final rule is 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 November 17, 2000 regulation, at 65 FR 69432, that sets 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 FIs 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 rule will 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 final rule will 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 final rule will not have a substantial effect on the governments mentioned, or on private sector costs.

E. Executive Order 13132

We examined this final rule in accordance with Executive Order 13132 and determined that it will 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 the policies set forth in this final rule will have a significant impact on all IRFs (small entities and small rural hospitals).

G. Anticipated Effects of the Final 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 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 policies are fair and achieve the intended policy objectives. The policy objective of the current and new § 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 will ''typically require intensive inpatient rehabilitation'' in IRFs because rehabilitation in general can be

delivered in a variety of settings, such as acute care hospitals, SNFs, 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 achieved these objectives to the extent we had intended. The policies set forth in this final 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 those patients who will need and benefit from intensive inpatient rehabilitative services. Therefore, although the impacts of the final policy changes shown below illustrate that IRFs may experience somewhat reduced Medicare payments from these final policies, we believe the impacts will show an even greater reduction in Medicare payments to IRFs if the existing policies were more effectively enforced.

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

- As stated in section I.D. of this final rule, we used patient assessment data from January to August 2002 to estimate compliance with the 75 percent rule as published in the May 16, 2003 proposed rule. We are using the same patient assessment data to construct the impact analysis set forth in this final 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 final 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 that this final rule may affect, CMS does not have enough information to quantitatively estimate the impact to non-Medicare IRF cases.
- 10 percent of the cases that did not meet the criteria will meet the criteria due to more accurate coding and removing the moratorium of the classification rule.
- 10 percent of the cases that did not meet the criteria with the limited Medicare administrative data used in our analysis will meet the criteria using more extensive medical record data.
- The diagnoses listed in Appendix A in the ''Case Mix Certification Rule for Inpatient Rehabilitation Facilities'' report, developed by Rand, identified cases that would meet the current 75 percent rule. The report showed that a large number of cases with possible arthritis-related joint replacements did not meet the current 75 percent rule. We believe that the clarifications to arthritis medical conditions in this final rule may increase the number of these cases that will count towards meeting the new 50 percent rule, as described in Section V of this final rule. However, it is difficult to determine the exact number of joint replacement cases that will meet the criteria without extensive medical record data. Therefore, to estimate the impacts on the various classifications of IRFs shown in Chart 3, we chose the assumption that 50 percent of the joint replacement cases will meet the clinical criteria as set forth in this final rule.
- We assume that a percentage of Medicare cases being admitted under the current practices will not be admitted to an IRF under the revised criteria. We believe that these cases will be admitted or treated in extended hospital inpatient stays, outpatient departments, or other post acute care settings. We estimated that it will 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 SNF. Accordingly, we estimated that SNFs will have a higher probability than other settings of absorbing the cases not admitted to IRFs. Since long term care hospitals need to meet the average 25-day LOS requirement and the average IRF LOS is 14 days, we estimated that long term care hospitals will absorb a smaller portion of the cases not admitted to IRFs.

Because the provisions in this final rule are effective for cost reporting periods beginning on or after July 1, 2004, we've assumed a blended payment amount accounting for 3 months at the FY 2004 payment rate and 9 months at an estimated FY 2005 payment rate.

Based on the above assumptions and the average payments for their respective settings, we have estimated the average FY 2004 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 FY 2004 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 in FY 2004. For fiscal year 2005, we estimated the IRF standardized payment to be $12,926 after rounding and the average for other settings to be $7,216 after rounding for a difference of $5,709 per case after rounding.

Note that this result also assumes that all IRFs will continue to want to be classified as an IRF and admit those patients that will allow them to meet the revised criteria set forth in this final rule.

1. Impact Summary

Dependent on the range of assumptions related to joint replacement cases described above, we project a net savings to the Medicare program between $1 million and $4 million for the first full year after implementation. Specifically, the estimated net savings will be $4 million if we assume that an additional 40 percent of joint replacement cases meet the criteria, $1 million if 70 percent of additional joint replacement cases meet the criteria, and $2 million if 50 percent of additional joint replacement cases meet the criteria. This net savings to Medicare will 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, will experience an increase in Medicare payments if they experience a net increase in Medicare cases.

2. Medicare Savings During Transition

Chart 2 below shows the Medicare savings for each federal budget fiscal year during the transition period. Because the provisions in this final rule are effective for cost reporting periods beginning on our after July 1, 2004, the compliance threshold will change during the fiscal year. These savings include a projected increase in the market basket and changes in the number of beneficiaries. The net

Medicare savings for each year is rounded to the nearest 10 million dollars.

CHART 2.—MEDICARE SAVINGS THROUGH THE TRANSITION PERIOD BY FISCAL YEAR

Fiscal year	Compliance threshold	Medicare savings
2004	3 months at 50%	[1] 0
2005	9 months at 50%, 3 months at 60%.	10
2006	9 months at 60%, 3 months at 65%.	30
2007	9 months at 65%, 3 months at 75%.	90
2008	12 months at 75%	190

[1] The impact for 2004 is $0.4 million before rounding.

3. Calculation of Impacts

To determine the estimated effects of implementing the policies in this final rule, we have developed Chart 3 to show the estimated impact on the Medicare program among various classifications of IRFs. Chart 3 assumes a middle estimate of 50 percent of joint replacement cases meeting the new criteria. The columns in Chart 3—Projected Impact of the 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 will no longer be treated in an IRF due to the final policies set forth in this final rule.
- The fifth column represents the estimated 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 nine.
- The sixth column, All Setting Cost/Saving in Millions, indicates the estimated 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 will 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 Step 1 and multiply these cases by 0.25 (to represent 3 months of payments) times $12,525 (07/01/2004–09/30/2004, the standardized FY 2004 payment amount) and add it to the number of cases calculated in Step 1 multiplied by 0.75 (to represent 9 months of payments) times $12,926 (10/01/2004–6/30/2005, an estimated standardized payment amount for FY 2005) to determine the estimated Medicare payment impact to IRFs.

—Step 3—We then estimate the amount of Medicare payments that these cases may generate in other settings. Specifically, we multiply $7,000 by 0.25 times the number of Medicare cases estimated from Step 1 (the number of Medicare cases that may not be admitted to IRFs) to represent the number of cases at FY 2004 rates and add it to $7,216 multiplied by 0.75 times the number of Medicare cases estimated from Step 1 to represent the number of cases at FY 2005 rates.

—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 estimated Medicare cases that will not be admitted to IRFs. We then take the total number of projected Medicare cases that will not be admitted to IRFs and multiply these cases by 0.25 times $12,525 and add it to the number of cases multiplied by 0.75 times $12,926, to estimate column seven, IRF Medicare Payment Impact in Millions.
- The eighth column, IRF Medicare Payment Impact Percentage, represents the estimated percentage impact on Medicare payments specific to IRFs.
- The ninth column, Current IRF Medicare Payments in Millions, is the number of Medicare cases reflected in column three multiplied by 0.25 times $12,525 and added to the number of cases in column three multiplied by 0.75 times $12,926.
- The tenth 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 final 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 nine).

CHART 3.—PROJECTED IMPACT OF THE CHANGES TO THE 75 PERCENT RULE ON THE MEDICARE PROGRAM FOR THE FIRST FULL YEAR AFTER IMPLEMENTATION

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	All setting cost/saving in millions	IRF medicare payment impact in millions	IRF payment impact percentage	Current IRF Medicare payments in millions	Projected IRF Medicare payments in millions
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8	Column 9	Column 10
Total	1,170	459,682	0.1%	0.0%	−2.4	−5.4	−0.1	5,895.8	5,890.4
Census:									
1: New England	38	20,133	0.1%	−0.1%	−0.2	−0.3	−0.1	258.2	257.9
2: Middle Atlantic	170	87,639	0.4%	−0.2%	−1.8	−4.1	−0.4	1,124.0	1,119.9

CHART 3.—PROJECTED IMPACT OF THE CHANGES TO THE 75 PERCENT RULE ON THE MEDICARE PROGRAM FOR THE FIRST FULL YEAR AFTER IMPLEMENTATION—Continued

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	All setting cost/saving in millions	IRF medicare payment impact in millions	IRF payment impact percentage	Current IRF Medicare payments in millions	Projected IRF Medicare payments in millions
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8	Column 9	Column 10
3: South Atlantic	143	75,808	0.0%	0.0%	0.0	0.0	0.0	972.3	972.3
4: East North Central	220	74,361	0.0%	0.0%	−0.1	−0.3	0.0	953.7	953.4
5: East South Central	66	35,764	0.0%	0.0%	0.0	0.0	0.0	458.7	458.7
6: West North Central	99	26,672	0.0%	0.0%	−0.1	−0.1	0.0	342.1	342.0
7: West South Central	235	87,206	0.0%	0.0%	−0.2	−0.3	0.0	1,118.5	1,118.1
8: Mountain	78	24,522	0.0%	0.0%	0.0	−0.1	0.0	314.5	314.4
9: Pacific	121	27,577	0.0%	0.0%	0.0	0.0	0.0	353.7	353.7
Free Standing/Unit Facility:									
Free	214	165,593	0.0%	0.0%	−0.3	−0.7	0.0	2,123.9	2,123.2
Unit	956	294,089	0.1	−0.1%	−2.1	−4.7	−0.1	3,771.9	3,767.2
Teaching Status:									
Missing	180	37,039	0.1%	0.0%	−0.2	−0.4	−0.1	475.1	474.7
Non-teaching	845	344,216	0.0%	0.0%	−0.9	−2.0	0.0	4,414.8	4,412.8
Teaching	145	78,427	0.3%	−0.1%	−1.3	−3.0	−0.3	1,005.9	1,002.9
DSH:									
<0.05	226	80,921	0.1%	−0.1%	−0.6	−1.4	−0.1	1,037.9	1,036.4
≧0.2	145	45,549	0.0%	0.0%	0.0	−0.1	0.0	584.2	584.1
0.05–01	339	161,550	0.1%	0.0%	−1.0	−2.2	−0.1	2,072.0	2,069.8
0.1–0.2	313	143,173	0.1%	0.0%	−0.6	−1.4	−0.1	1,836.3	1,834.9
Missing	147	28,489	0.1%	0.0%	−0.1	−0.3	−0.1	365.4	365.1
Facility Control:									
Government	135	38,942	0.0%	0.0%	−0.1	−0.2	0.0	499.5	499.3
Missing	76	10,264	0.2%	−0.1%	−0.1	−0.3	−0.2	131.6	131.4
Proprietary	259	140,311	0.0%	0.0%	−0.2	−0.6	0.0	1,799.6	1,799.0
Voluntary	700	270,165	0.1%	−0.1%	−1.9	−4.4	−0.1	3,465.1	3,460.7
Urban/Rural:									
Large Urban	493	209,489	0.1%	0.0%	−0.8	−1.9	−0.1	2,686.9	2,684.9
Missing	103	18,881	0.1%	−0.1%	−0.1	−0.3	−0.1	242.2	241.8
Other Urban	404	188,494	0.1%	−0.1%	−1.3	−3.0	−0.1	2,417.6	1,414.6
Rural	170	42,818	0.0%	0.0%	−0.1	−0.2	0.0	549.2	549.0
Size:									
Large	201	172,951	0.1%	0.0%	−0.5	−1.2	−0.1	2,218.2	2,217.0
Medium	502	198,451	0.1%	−0.1%	−1.6	−3.6	−0.1	2,545.3	2,541.7
Missing	158	31,400	0.1%	0.0%	−0.1	−0.3	−0.1	402.7	402.4
Small	309	56,880	0.0%	0.0%	−0.1	−0.3	0.0	729.5	729.3
Size by free Standing/Unit Facility:									
Free:									
Large	74	91,409	0.0%	0.0%	0.0	0.0	0.0	1,172.4	1,172.4
Medium	71	53,640	0.1%	0.0%	−0.2	−0.6	−0.1	688.0	687.4
Missing	38	10,817	0.1%	0.0%	−0.1	−0.1	−0.1	138.7	138.6
Small	31	9,727	0.0%	0.0%	0.0	0.0	0.0	124.8	124.8
Unit:									
Large	127	81,542	0.1%	−0.1%	−0.5	−1.2	−0.1	1,045.8	1,044.6
Medium	431	144,811	0.2%	−0.1%	−1.3	−3.0	−0.2	1,857.3	1,854.3
Missing	120	20,583	0.1%	0.0%	−0.1	−0.2	−0.1	264.0	263.8
Small	278	47,153	0.0%	0.0%	−0.1	−0.3	0.0	604.8	604.5

Due to rounding, there may be slight differences in the numbers presented versus the numbers used for calculation purposes.

Chart 3 breaks down the projected 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 final rule. As can be seen from Chart 3, the impacts vary by specific types of providers and by location. For example, the Middle Atlantic experiences slightly larger payment decreases than all other regions.

Column seven in Chart 3 shows that IRFs are expected to experience a reduction in Medicare payments from the final rule of approximately $5 million, less than a one percent reduction as seen in column 8. This is a net savings to Medicare of approximately $2 million for all Medicare providers. Applying the different assumptions regarding qualifying joint replacement cases yields a Medicare savings range of $1 million (70 percent qualifying) to $4 million (40 percent qualifying).

For the purposes of the RFA analysis, below we discuss IRF impacts in more detail as well as the 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 for the next year for all Medicare discharges assuming the status quo (varying levels of compliance to the existing 75 percent rule). As we previously stated in this final rule, although the impacts of the policy changes illustrate IRFs may experience some reduction in payments, we believe the impacts will show a greater reduction in payments to IRFs if the existing policies were more effectively enforced. Further, we believe this reduction in Medicare payments appropriately reflects the existing policy objectives described above.

Because we have determined that this final rule will have a significant economic impact on IRFs, we will discuss the alternative changes to the 75 percent rule that we considered. We reviewed the options considered in the proposed rule, took into consideration comments received during the public comment period, and amended § 412.23(b)(2) as discussed in the preamble.

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 § 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 amended § 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 settings, such as acute care hospitals, SNFs, and outpatient 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 estimated, as calculated in the proposed rule, 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 that would add joint replacements, cardiac, pulmonary, pain, and cancer patients to the list of conditions, as discussed in the preamble of the proposed rule 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, as calculated in the proposed rule, 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 50 percent, but recognize the clinical criteria adopted in this final rule. This option is similar to enforcement of the current policy and, thus, would further reduce Medicare payments to all IRFs over the policies in this rule. Specifically, total estimated payments to all IRFs would be decreased by $459 million (under a 75 percent compliance threshold, assuming a middle estimate of 50 percent of joint replacement cases meeting the criteria) instead of a decrease of only $5 million (under the policies in this final rule, assuming a middle estimate of 50 percent of joint replacement cases meeting the criteria). However, this option would provide a net savings to the Medicare program of $203 million instead of only $2 million in the first full year after implementation.

Option D would be to implement the proposed rule. Lowering the compliance percentage from 75 percent to 65 percent in the proposed rule helped mitigate the impact on IRFs. However, after reviewing comments to the proposed rule we recognize that IRFs may need some additional time to adjust to the amended regulations. The reduction in payments to IRFs for the proposed rule was $223 million (as calculated in the proposed rule, assuming a middle estimate of 35 percent of joint replacement cases meeting the criteria) providing savings of $98 million to the Medicare program.

Additional options not specifically listed here were considered. Among them were the other options mentioned in the proposed rule, varying sunset provisions, and incremental additions of the clinical criteria adopted in amended § 412.23(b)(2).

We believe that the clinical criteria for this final rule reduce the impacts to IRFs considerably from those in the proposed rule, while still ensuring our intent that IRFs are unique compared to other hospitals in that they provide intensive rehabilitation services in an inpatient setting.

We believe that the changes to the clinical criteria in new § 412.23(b)(2) are adequate to distinguish the intensive inpatient rehabilitation provided in IRFs from rehabilitation services provided in other settings. In addition, while the changes to the clinical criteria and the reduction in the compliance percentage to 50 percent do reduce Medicare payments to IRFs ($3 to $9 million), the impact is less than the impact from other alternatives and less than the option considered in the proposed rule ($93 to $371 million). (See Chart 4—Comparison of IRF Medicare Payment Impacts). 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 SNF. We anticipate that in the future, some of the patients currently treated in the IRF will be treated in the SNF unit in these hospital complexes.

CHART 4.—COMPARISON OF IRF MEDICARE PAYMENT IMPACTS

	Compliance percentage	Range of additional joint replacements qualifying [1]	Range of IRF Medicare payment impact in millions
Proposed Rule	65	20%–60%	$93–$371
Final Rule	50	40%–70%	$3–$9

[1] The range of additional joint replacement cases qualifying increased from the proposal to the final due to the changes to the clinical criteria, particularly § 412.23(b)(2)(iii)(M).

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

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 amends 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 July 1, 2004 and before July 1, 2005, the hospital has served an inpatient population of whom at least 50 percent, and for cost reporting periods beginning on or after July 1, 2005 and before July 1, 2006, the hospital has served an inpatient population of whom at least 60 percent, and for cost reporting periods beginning on or after July 1, 2006 and before July 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 applicable percentage if—

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

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

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

(ii) For cost reporting periods beginning on or after July 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 in paragraph (b)(2)(iii) of this section. A patient with comorbidity as described in paragraph (b)(2)(i) is not included in the inpatient population that counts towards the required 75 percent.

(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 that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

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

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

have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

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

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

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

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

* * * * *

■ 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: March 12, 2004.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: March 30, 2004.

Tommy G. Thompson,

Secretary.

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