

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

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

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

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

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

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

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

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

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

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

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

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

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