

services is a primary, rather than a secondary, goal.” (48 FR 39756) Using a similar line of reasoning, we made compliance with the 75 percent rule one of the characteristics that defined 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 8 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 PSRO of the American Academy of Physical Medicine and Rehabilitation and the American Congress of Rehabilitation Medicine. In addition, we received input from with the National Association of Rehabilitation Facilities, and the American Hospital Association.

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 75 percent rule’s list of medical conditions. 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 75 percent rule’s original list of 8 medical conditions. (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, which proposed that when an IRF could not meet the 75 percent rule the facility could 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 when a

rehabilitation unit wanted to expand its size by adding beds.

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 into § 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 new rehabilitation unit, or an existing excluded rehabilitation unit which was to be expanded by the addition of new beds, to be excluded from the acute care 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 CMS 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 acute care hospital PPS, 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 such 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, as well as 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 rule, we stated that we had miscellaneous comments requesting that oncology cases, pulmonary disorders, cardiac disorders, and chronic pain be added to the 75 percent rule’s list of medical conditions. (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 75 percent rule’s list of medical conditions, or eliminate the 75 percent rule. (66 FR 41321) We responded that in our IRF PPS proposed rule we had not proposed changing the 75 percent rule, believed that the existing 75 percent rule was appropriate, and, therefore, would not be revising the 75 percent rule. However, we also stated that data obtained after we implemented the IRF PPS could lead us to reconsider revising the 75 percent rule.

C. CMS Evaluation of the 75 Percent Rule

In the spring of 2002 we surveyed the fiscal intermediaries (FIs) in order to ascertain what methods were being used to verify if IRFs were complying with the 75 percent rule. Analysis of the survey data made us aware that inconsistent methods were being used to determine if an IRF was in compliance with the 75 percent rule, and that some IRFs were not being reviewed to determine if they were in compliance with the 75 percent rule. These survey results led us to become concerned that some IRFs may be out of compliance with the regulations. In addition, we were concerned that some FIs might be using methods to verify compliance with the 75 percent rule, which may cause an IRF to incorrectly be found out of compliance with the rule; this would thus cause an IRF to inappropriately lose its classification as an IRF. Therefore, on June 7, 2002, we suspended enforcement of the 75 percent rule until we conducted a careful examination of this area and determined whether changes were needed to the regulation, and the operating procedures that govern how compliance with the regulation is verified.

In addition to our review of FI administrative procedures, we conducted an analysis of CMS administrative data to attempt to estimate overall compliance with the regulation. We examined both IRF–PAI data and claims from the years 1998, 1999, and 2002. Before discussing the results of this analysis, we note that the data does have some limitations. First, it is not possible to discern from the diagnosis data on the IRF–PAI or the claim whether or not there was a medical need to furnish the patient “intensive rehabilitation.” The diagnosis is a determination of a