

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

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

#### *B. Recent Developments on the 75 Percent Rule*

##### 1. May 2003 Proposed Rule

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

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

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

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

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

##### 2. Classification as an IRF Under the 75 Percent Rule

As stated in the August 7, 2001 final rule, we did not change the survey and certification procedures for classification as an IRF. Currently, a hospital or unit of a hospital must first be deemed excluded from the diagnosis-related group (DRG)-based acute care hospital PPS to be paid under the IRF PPS and must meet the general requirements in subpart B of part 412. Secondly, the excluded hospital or unit of the hospital must meet the conditions for payment under the IRF PPS at § 412.604. As specified at § 412.604(b), a provider, among other things, must be in compliance with all the criteria specified in § 412.23(b) to be classified as an IRF.

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

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

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

#### *C. Statutory and Regulatory Background on the 75 Percent Rule*

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

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