

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

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

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

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

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

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

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

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

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

## II. Provisions of the Proposed Rule

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

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