

another treatment setting. However, we recognize that the conditions listed in proposed § 412.23(b)(2)(iii) describe groups of patients who typically require intensive inpatient rehabilitation. To allow IRFs to care for some atypical patients who require intensive inpatient rehabilitation and still maintain their status as an IRF, we would allow the percentage of cases in the conditions specified in proposed § 412.23(b)(2)(iii) to be lowered to 65 percent. As part of our ongoing analysis described in section II.D., 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 that are listed in proposed § 412.23(b)(2)(iii).

Various commenters have suggested that we add cancer, cardiac, pulmonary, and pain to the list of conditions defining IRFs. We note that patients with cancer affecting the brain and spinal cord may be considered under the proposed clarification of the existing conditions to have non-traumatic brain or spinal cord injuries and can be counted in defining IRFs.

As has been commented on in the past, the result of adding cancer, cardiac, pulmonary, and pain conditions would be that almost all patients admitted to acute hospitals would qualify as being the types of patients that would be used to distinguish IRFs from acute care hospitals. Furthermore, we have seen no studies that demonstrate that patients from these categories have improved outcomes when cared for in IRFs as compared to other settings. We have reviewed studies that show that cardiac and pulmonary patients improve when treated in IRFs, but none of the studies provided evidence that the improvement required the unique characteristics of IRFs and compared the improvements of equivalent patients in other settings.

We continue to believe it is the total patient population that should determine whether a facility is classified as an IRF. This is the best indication that a facility (as a whole) is primarily engaged in furnishing intensive rehabilitation services. For a provider to be primarily engaged in furnishing intensive rehabilitation services implies that it is furnishing these services to its entire patient population. Therefore, we believe it is appropriate for Medicare to continue to use the entire IRF patient population as one of the criteria used to classify a facility as an IRF. This approach is part of CMS' existing policy that we plan to maintain.

In proposing 65 percent of an IRF's total patient population to determine compliance with proposed § 412.23(b)(2)(i) we still wanted to find methods of verification for the FIs that were not difficult operationally to automate. RAND's analysis of IRF compliance with existing requirements at § 412.23(b)(2) found that Medicare cases were highly predictive of the percentage of an IRF's total patient population with respect to the medical conditions specified in the regulation. We plan to instruct the FIs to initially utilize a presumptive eligibility test that uses Medicare data to assess compliance with proposed § 412.23(b)(2)(i). However, if an IRF appears to comply with proposed § 412.23(b)(2)(i) using only Medicare data, we may still consider other available information before making a final compliance determination. If the IRF does not comply with proposed § 412.23(b)(2)(i) based on the presumptive eligibility test that uses Medicare data, we would consider the IRF's total case-mix. In any case, 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. We believe that the compliance verification method described above offers Medicare adequate program protection and may reduce the burden on IRFs and the FIs related to enforcement of proposed § 412.23(b)(2)(i).

B. Change in the Medical Conditions

As noted in the May 16, 2003 proposed rule, we were concerned that some FIs inappropriately were using methods to verify compliance with the 75 percent rule. These inappropriate methods included incorrectly interpreting which patient diagnoses met the medical conditions listed in the 75 percent rule.

As in the present policies under the proposed IRF-PPS policies, Medicare will pay for the services an IRF furnishes to some patients who have a medical need for intensive inpatient rehabilitation services but do not have one of the medical conditions specified in proposed § 412.23(b)(2)(iii). The medical conditions specified in proposed § 412.23(b)(2)(iii) are used to determine whether a facility qualifies as an IRF and, thus, may be paid under the IRF PPS. However, the criteria for admission of any individual patient is based upon medical necessity; as a result, some patients with conditions listed in proposed § 412.23(b)(2)(iii) may still not meet the medical necessity criteria. Providers also have discretion over which patients are admitted, so we

believe an IRF can manage its case-mix and, thus, ensure that its patient population during a cost reporting period would allow it to achieve compliance with proposed § 412.23(b)(2)(i).

We recognize, however, that one of the listed conditions in the existing regulation at § 412.23(b)(2), specifically polyarthritis, has been a source of confusion and is acknowledged by many not to represent any clearly defined clinical condition. We are proposing to remove this term from the list of 10 conditions and substitute instead 3 more clearly defined arthritis-related conditions, as specified above in the introduction to section II of this preamble, that comprise the range of diagnoses that the term "polyarthritis" was intended to encompass. This clarification was developed in part from information gathered from experts in rheumatology and rehabilitation as well as a review of the literature. We are proposing to adopt in § 412.23(b)(2)(iii) the other conditions currently listed in § 412.23(b)(2) because we believe these other conditions are the most appropriate conditions for treatment in an IRF. We are limiting the conditions to those that are sufficiently severe and in which intensive inpatient rehabilitation may be an appropriate modality of treatment. Although we acknowledge that "arthritis" may affect joints other than those specified (shoulders, elbows, hips and knees), such as those in the hands or spine, we do not believe these conditions require intensive rehabilitation care. Thus, we are limiting the focus to conditions that more commonly require intensive inpatient rehabilitation treatment. For this reason, conditions other than the types specified in this proposed rule are not included in the identified conditions to be listed in proposed § 412.23(b)(2)(iii). If a patient has a type of "arthritis" not included in the proposed conditions that we described earlier in this section then that patient would be included in the percent of cases that IRFs can admit which are not included in the proposed 65 percent of the proposed § 412.23(b)(2)(iii) conditions (assuming the care is medically necessary).

We acknowledge that the industry has interpreted polyarthritis to include hip and knee joint replacement cases and these should be included in the conditions counted in existing § 412.23(b)(2). Although some joint replacement cases are currently being treated in IRFs, we are not aware of any research that identifies the factors determining which patients are more appropriately treated in the intensive