

final policies (including considering comorbidities in determining compliance if we adopt that policy) have led to significant shifts in the site of treatment of beneficiaries with particular conditions, and whether the adopted final policies have led to inadvertent and substantial expansions in either the number of IRFs or in aggregate utilization and expenditures.

In addition, we are encouraging rehabilitation professionals, the rehabilitation industry, researchers, academia, and other relevant sources to consider the 3-year period after the effective date of the final rule as an opportunity to conduct literature reviews, clinical studies, and other objective analyses so that we may be better informed about the situations in which patients require the intensive inpatient rehabilitation treatment available in an IRF compared to other settings. Furthermore, during this 3-year period, we plan to seek information and obtain data from rehabilitation experts, the rehabilitation industry, researchers, academia, and other relevant sources. The data we plan to obtain include clinical data, data from clinical outcomes analyses, and data from well-designed analytical studies specific to rehabilitative care. We believe that significant, objective data obtained from these sources would be informative as we deliberate whether changes to the clinical criteria and/or to the compliance percentage adopted in the final rule are justified.

However, no later than 3 years after the effective date of our final rule, in the absence of any significant, objective data as described above, we are proposing to change the classification criteria under proposed § 412.23(b)(2)(ii) as follows: In place of the proposed 65 percent compliance threshold discussed in section II.A., we would determine compliance by verifying that 75 percent of all inpatients have one of the 12 proposed conditions listed in proposed § 412.23(b)(2)(iii), and we would phase-out the use of the proposed comorbidity compliance policy discussed in section II.C. If, as we anticipate, the effective date of the final rule will apply to cost reporting periods that begin on or after January 1, 2004, this proposed change to the classification criteria, as noted below, would be effective for cost reporting periods beginning on or after January 1, 2007. Accordingly, the proposed changes specified in proposed § 412.23(b)(2)(ii) would occur automatically for cost reporting periods beginning on or after January 1, 2007 unless before that date we propose new criteria to determine compliance or validate the criteria as adopted in our

final rule for identifying an IRF based on the data that CMS has obtained over the preceding 3 years including data from rehabilitation experts, the rehabilitation industry, researchers, academia, or other relevant sources.

As a future step in our ongoing assessment, we plan every 3 years after the initial 3 year assessment described above, to obtain objective updated clinical data from relevant sources and, if appropriate and justified, we may propose changes to the clinical criteria and/or the compliance percentage based on that updated data.

E. Proposed Change to the Time Period To Determine Compliance

Except for new IRFs, § 412.23(b)(2) for freestanding IRFs and § 412.30 for IRF converted/expanded units would require the use of the most recent 12-month cost reporting period to determine if the IRF was compliant with existing § 412.23(b)(2). In addition, existing § 412.23(i) and § 412.25(f) state that the classification of a hospital or unit, respectively, is effective for the hospital's or unit's entire cost reporting period and that any changes in the classification of a hospital or unit are made only at the start of a cost reporting period. We believe that the application of both of these regulations has resulted in much confusion as to the data used to determine compliance with existing § 412.23(b)(2). For example, if an IRF's cost reporting period begins January 1, 2005 and ends December 31, 2005, this period would represent the most recent 12-month cost reporting period used to determine if the classification of the IRF is correct for the next cost reporting period that begins on January 1, 2006 in accordance with existing § 412.23(b)(2) and § 412.23(i) or § 412.25(f). However, the process of reviewing the data, making a determination of compliance with existing § 412.23(b)(2), and notifying the IRF of its non-compliance (and de-certification as an IRF) may take at least 3 to 4 months. Therefore, in order to make a determination of compliance and implement any changes before the start of the January 1, 2006 cost reporting period, data for only the first 8 to 9 months from the most recent 12-month cost reporting period would be available.

In order to have the proposed regulation more precisely reflect the necessary operational procedures of our FIs, we are proposing to change § 412.23(b)(2), § 412.30(c), and § 412.30(d)(2)(ii) to specify that data from the most recent, consecutive, and appropriate 12-month period of time be used to determine compliance with the proposed policies set forth in this

proposed rule. Accordingly, using the example above, the last 3 to 4 months of data from the cost reporting period ending December 31, 2004, and the first 8 to 9 months of data from the cost reporting period ending December 31, 2005, could be used (for a total of 12-months of data from the most recent, consecutive, and appropriate period of time) to determine compliance with the proposed policies set forth in this proposed rule. These time periods may be different depending on the workload of the FIs and CMS Regional Offices. We believe that this change will give FIs and CMS Regional Offices the flexibility to make a determination and give the IRF sufficient time to adjust to any Medicare de-certification action. We are not proposing to make a similar change to the regulatory policies for new freestanding IRFs or new IRF units, because they can provide written certification for the first full 12-month cost reporting period after Medicare certification that they intend to meet the requirements of proposed § 412.23(b)(2).

The intent of this proposed change is to ensure that the patient data used to determine compliance with the requirements of proposed § 412.23(b)(2) are from the most recent, consecutive, and appropriate 12-month period of time. However, we recognize that 12 months of patient data for the initial cost reporting periods affected by these proposed changes will be from a period that is before the effective date of the final rule. Therefore, it will be necessary to institute a transition period for those cost reporting periods where the most recent 12-month period of time includes admissions that occur before the effective date of the final rule. Accordingly, to ensure that admissions that occur before the effective date of the final rule are not counted in an IRF's compliance percentage, the FIs and affected IRFs will be given the specific procedures regarding what time period the FIs will use to verify compliance during the transition from the existing requirements at § 412.23(b)(2) to the proposed changes specified in proposed § 412.23(b)(2).

F. General FI Operational Instructions

We will take the necessary action to ensure that the proposed compliance policies are consistently enforced on IRFs across all FIs. We will issue instructions to the FIs and provide guidance to the clinical/medical FI personnel responsible for performing the compliance reviews to ensure that they use a method that consistently counts only cases with a diagnosis that both serves as the basis for the intensive rehabilitation services that the IRF