

inpatient rehabilitation for daily occupational and physical therapy sessions to strengthen his right lower limb to bear his entire weight and to improve the function of both shoulders as well as therapy for his joint replacement.

(2) A patient undergoes emergency coronary artery bypass graft surgery for sudden onset of ischemic chest pain (unstable angina) unresponsive to medical management. During the operation she suffers a stroke and wakes up after surgery unable to speak, swallow, or move her right arm and leg. Over the next several days, she regains some partial movements in her leg and arm with minimal speech return. At the time of discharge, she still has significant weakness of the right arm and leg such that she is unable to walk without a walker and therapist by her side and she is unable to make coordinated movements with her right arm to feed and dress herself. She also cannot swallow liquids and solid food without choking spells. She, therefore, requires inpatient rehabilitation of at least 3 hours daily of physical therapy to strengthen her leg and arm, occupational therapy to improve right arm and hand coordination for activities of daily living (that is, eating, dressing, transfer, and bathing), and speech therapy to learn how to swallow her meals without choking.

Examples of Clinical Scenarios That Would Not Be Included Under This Policy

(1) A patient with a motor polyneuropathy who wears an ankle foot orthosis on the right lower limb elects to undergo a knee replacement due to severe osteoarthritis of the knee. Although the rehabilitation of the knee replacement may be complicated by the polyneuropathy, this patient would not be counted as satisfying the proposed change in § 412.23(b)(2)(i) because the comorbidity does not, by itself, require intensive inpatient rehabilitation.

(2) A patient had a stroke 5 years ago with residual weakness and lack of motor control in the left lower leg and that requires the use of a walking cane. She is involved in a car accident and undergoes surgery for a broken bone in her right arm (humerus) and a broken bone in her right ankle. At the time of discharge 2 days later, her dominant arm (right) is immobilized so she still has difficulty feeding herself and transferring from bed to chair. Also, she must learn to use a rolling walker because she cannot bear weight on her right leg and she can't reach the handle on her cane with her immobilized right arm. Although the rehabilitation of the

right arm and right foot fracture may be complicated by the stroke, this patient would not be counted as satisfying the proposed change in § 412.23(b)(2)(i) because the comorbidity does not, by itself, require intensive inpatient rehabilitation. She has no caregiver (family or friend) support person at home so she is transferred to a skilled nursing facility where, over the next 5 days, she receives a daily physical therapy session to learn how to ambulate with a rolling walker and she receives a daily occupational therapy session to learn how to feed herself with her non-dominant left hand. She is then discharged home for follow-up with Outpatient Rehabilitation Therapy.

2. Proposed Alternative Methodology

As stated in the May 16, 2003 proposed rule (68 FR 26794), our analysis indicated the largest group of patients treated in IRFs that was not considered as matching one of the 10 conditions in the existing 75 percent rule is patients with major joint replacements, specifically knee and hip replacements. Thus, as an alternative to the proposed methodology above, we are also proposing an approach that would only apply to patients admitted to an IRF after hip or knee replacements. Under this alternative approach, only admissions to an IRF that are post-operative hip or knee joint replacements cases would be considered to count towards meeting the proposed 65 percent rule if the case also had a comorbidity that matches one or more of the 12 proposed conditions in proposed § 412.23(b)(2)(iii). Specifically, under this method we would count a case as meeting the proposed 65 percent rule if the patient matched all of the following criteria:

- Was postoperative following one or more hip or knee joint replacements that immediately preceded the transfer to an IRF.
- Had a condition at time of admission to an IRF that was complicated by an active comorbidity specified in proposed § 412.23(b)(2)(iii).
- Had an active comorbidity that resulted in a decline in the patient's function beyond the decline generally observed for other patients in that impairment category.
- Had an active comorbidity that substantially complicated the patient's rehabilitation to the point that it would improve only with the intensive, multidisciplinary rehabilitation treatment that is unique to inpatient rehabilitation facilities and that could not be performed in another setting (for example, skilled nursing facility,

inpatient hospital, home health, or outpatient).

D. Ongoing Assessment of Implementing the Proposed Policies and Potential Scheduled Phase-Out of the Proposed Policies

In proposing these changes to the criteria for classifying hospitals as IRFs, our intent is to clarify the conditions typically requiring intensive inpatient rehabilitation therapy under the IRF PPS. These proposals do not represent an expansion of existing coverage criteria, but provide clear, clinically meaningful guidance on the conditions that are most appropriately treated in IRFs as distinguished from care furnished in other settings.

The policy changes proposed in this rule represent one of the next steps in an ongoing process since the May 16, 2003 proposed rule and the May 19, 2003 Town Hall meeting to identify potential policy changes to enhance the effectiveness of the IRF PPS. We are aware of the intricacies of implementing these changes to the IRF compliance criteria, both in terms of the time needed for providers to make any necessary adjustments to their operations and in the risk of unanticipated changes impacting providers, beneficiaries, and the Medicare program.

Comments received on the proposed change to the compliance percentage and on the proposed clinical criteria to determine compliance will be an important step in our planned ongoing assessment of the effect these proposed changes may have on—

- The IRF industry; and
- The Medicare beneficiaries who require rehabilitative care.

The final rule will reflect all relevant comments received and relevant data obtained through the comment period that may result in us adopting the proposed policies or adopting alternative policies.

As part of the next step in our ongoing assessment, during the 3-year period after the final rule is effective, we intend to closely review both claims and patient assessment data to examine trends in admissions and overall utilization in IRFs. These analyses will allow us to monitor and evaluate the effect the policies adopted in the final rule had on utilization and beneficiary access. Specifically, we will use these data to determine the effectiveness that the adopted final policies had in achieving the objectives stated in this proposed rule, and we will assess the need for any future policy development related to provider compliance. Also, we will review whether the adopted