

individual member of the pool in the event of a catastrophic loss, effectively spreading the expense of the excluded items over such a large provider population helps minimize the potential financial liability that any individual provider might otherwise incur.

The consolidated billing exclusions addressed under the BBRA were items and services that had been in use for many years. We had data for the SNF PPS base year that were used to determine utilization of these services and make the appropriate adjustment. In our July 31, 2001 final rule, we implemented a \$.05 reduction in the SNF PPS rate to reflect this proportional adjustment.

The situation is slightly different when applied to these new consolidated billing exclusions. Since these two radiopharmaceuticals were not in existence during the SNF PPS base year, we cannot rely on historical utilization data to develop an appropriate reduction. In addition, as a new class of treatment, there may not be a relationship between the use of these radiopharmaceuticals and the use of other chemotherapy agents or radioisotopes used during the SNF PPS base year.

In light of these considerations, we have developed the following approach. We estimate the combined utilization of these two radiopharmaceuticals to be approximately 25 doses per year, which most closely equates to a \$.01 reduction to the unadjusted urban and rural SNF PPS per diem rates to reflect the FY 2004 revision of the consolidated billing exclusions. (For comparison purposes, as stated above, the offset used to adjust for the complete list of BBRA exclusions was a negative \$.05 adjustment.) Once we have collected actual utilization data on the use of these new radiopharmaceuticals (as well as on changes in utilization in other chemotherapy and radioisotope agents), we will reassess whether the \$.01 offset most accurately represents an "appropriate proportional reduction" in Part A SNF payments under section 1888(e)(4)(G)(iii) of the Act, and will make any appropriate adjustments in the amount of that offset. This aggregate adjustment could involve either an increase or decrease in the interim \$.01 offset amount applied for FY 2004, in order to ensure that the final adjustment most accurately reflects the "appropriate proportional reduction" required under section 1888(e)(4)(G)(iii) of the Act.

Comment: Some commenters cited the existing list of exclusions (in § 411.15(p)(3)(iii)) for certain high-intensity outpatient hospital services,

and expressed the view that these exclusions should not be limited to only those services that actually require the intensity of a hospital setting, but rather, should also encompass services furnished in other, nonhospital settings as well. As an example, they cited services such as magnetic resonance imaging (MRIs) furnished in freestanding imaging centers and radiation therapy furnished in freestanding oncology centers, both of which may be cheaper and more accessible in certain particular localities than those furnished by hospitals.

Response: As we noted in the May 12, 1998 interim final rule (63 FR 26298), and again in the July 31, 2000 final rule (65 FR 46790 through 46791), the exclusion of certain outpatient hospital services (in § 411.15(p)(3)(iii)) is targeted specifically at those services " * * * that, under commonly accepted standards of medical practice, lie *exclusively* within the purview of hospitals * * * " (emphasis added); that is, services which generally require the intensity of the hospital setting in order to be furnished safely and effectively. Basically, we determined that this high level of outpatient hospital care is beyond the scope of SNF comprehensive care plans and should be excluded from consolidated billing. The intensive outpatient hospital services identified under this exclusion were not subject to consolidated billing. However, this exclusion does not encompass services furnished in any other health care setting. Thus, to the extent that advances in medical practice over time may make it feasible to perform such a service more widely in a less intensive, nonhospital setting, this would not argue in favor of unbundling the nonhospital performance of the service under these regulations, but rather, of considering whether to rebundle the service entirely back to the SNF. In addition, we note that unlike the outpatient hospital exclusions in § 411.15(p)(3)(iii), the statutory exclusions enacted by the BBRA for certain chemotherapy and other services apply regardless of the setting (hospital versus freestanding) in which the services are furnished. Adding services such as MRIs and radiation therapy to the existing statutory list of exclusions would require legislation by the Congress to amend the law itself.

Comment: One commenter requested the exclusion of specific speech-language pathology evaluations and treatments.

Response: As we noted in the FY 2002 proposed rule (66 FR 24020), we regard the provision of therapy services as an inherent and integral function of an

SNF, and we believe that the statutory provisions on consolidated billing clearly reflect this position. Section 1888(e)(2)(A)(ii) of the Act provides that physical, occupational, and speech-language therapy services are subject to consolidated billing, even when performed by a type of practitioner (for example, a physician) whose services would otherwise be excluded. In addition, section 1862(a)(18) of the Act specifies that consolidated billing applies to these services when furnished to *any* resident of an SNF, even if Part A does not cover the resident's stay. Accordingly, all physical, occupational, and speech-language therapy services furnished to SNF residents are subject to consolidated billing, and any changes to this aspect of the provision would require legislation by the Congress to amend the law.

Comment: Several commenters also proposed expanding the list of excluded services by redefining categories of service that are currently excluded from consolidated billing. For example, while the BBRA excludes specific chemotherapy services by HCPCS codes, these commenters recommended not only adding to the list of excluded chemotherapy pharmaceuticals, but expanding the exclusion to encompass all related services associated with a chemotherapy treatment, such as supplies and other pharmaceuticals used to treat side effects. In addition, several commenters recommended exclusion of oral chemotherapy agents that are not separately billable to Medicare Part B for any beneficiary, and are currently covered only as part of the overall package of services furnished under the Part A inpatient hospital or SNF benefits.

Response: In the proposed rule, we noted that the BBRA's list of services excluded by HCPCS code is a targeted list, narrowly carving out only certain individual "high-cost, low probability" services *within* a number of broader service categories—such as chemotherapy services—that otherwise remained subject to consolidated billing. As we noted in the proposed rule (68 FR 26776), the BBRA provides the Secretary the authority to designate additional, individual services for exclusion within each of the service categories that it specifies. However, the statute does not provide authority to exclude other services that, while related, fall outside of the specified service categories themselves. For example, although anti-nausea drugs are commonly used *in conjunction with* chemotherapy, they are not in themselves chemotherapeutic agents and, consequently, do not fall within