

Rep. No. 106-479 at 854) characterizes the individual services that this legislation targets for exclusion as “* * * high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment [SNFs] receive under the prospective payment system * * *.” According to the conferees, section 103(a) “is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs * * *.” By contrast, we noted that the Congress declined to designate for exclusion any of the remaining services within those four categories (thus leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the July 31, 2000 final rule (65 FR 46790), any additional service codes that we might designate for exclusion under our discretionary authority must meet the same criteria that the Congress used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA: they must fall within one of the four service categories specified in the BBRA, and they also must meet the same standards of high cost and low probability in the SNF setting. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion “* * * as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice)” (65 FR 46791). In view of the amount of time that has elapsed since we made that statement, we invited public comments in the May 16, 2003 proposed rule (68 FR 26776) on codes in any of these four service categories which represent recent medical advances that might meet the BBRA criteria for exclusion from SNF consolidated billing.

Comment: Although the proposed rule specifically invited comments on possible exclusions within the specific service categories identified in the BBRA legislation, a number of commenters took this opportunity to reiterate concerns about other aspects of consolidated billing. For example, we received a number of comments concerning the possible exclusion of additional categories of services from SNF consolidated billing, beyond those specified in the BBRA. The commenters identified services such as modified barium swallows, stress tests, hyperbaric oxygen treatments, doppler studies, and nuclear medicine scans as

appropriate candidates for exclusion. In addition, a number of commenters recommended a further set of services for exclusion. These additional services are durable medical equipment (including, but not limited to, ventilators, speech devices, specialty beds, wheelchairs, wound care devices and diabetic shoes), antibiotics, TPN, and diagnostic tests.

Response: As enacted by section 4432(b) of the BBA, the original set of consolidated billing exclusions at section 1888(e)(2)(A)(ii) of the Act broadly excluded entire categories of services from consolidated billing (primarily, those of physicians and certain other types of medical practitioners). By contrast, the set of statutory exclusions at section 1888(e)(2)(A)(iii) of the Act, as subsequently enacted by section 103 of the BBRA, was more specifically targeted within a number of broader service categories. In the proposed rule, we noted that the original BBRA legislation (as well as the implementing regulations) provides the Secretary the authority to designate additional, individual services for exclusion within each of the BBRA-specified service categories. However, the statute does not provide the Secretary the authority to create additional categories of excluded services beyond those specified in the law. Therefore, based on the statute, we cannot exclude services and items from consolidated billing unless they fall into the categories of services provided in the statute and addressed in the BBRA.

Comment: Several commenters recommended that we exclude a variety of additional chemotherapy agents and radioisotopes used for cancer treatment. One commenter specifically recommended that we exclude Zevalin which is used in the treatment of non-Hodgkins lymphoma.

Response: The BBRA specified that certain chemotherapy drugs and radioisotope services (sections 1888(e)(2)(A)(iii)(II) and (IV) of the Act) be excluded from the SNF PPS payments. Specific chemotherapy drugs and radioisotope services were then identified by HCPCS code in the statute. The BBRA authorized us to update the list of excluded services to reflect advances in technology and medical practice.

We note that most of the chemotherapy drugs and radioisotope services mentioned by commenters were considered for exclusion under the BBRA, but were not adopted by the Congress in the BBRA list of excluded items and services.

However, we did identify a new radiopharmaceutical (that is, radiotherapeutic substance linked to a radioisotope administered to deliver therapeutic radioactivity), Zevalin, which combines elements of both the chemotherapy and radioisotope categories excluded under the BBRA. This radiopharmaceutical links monoclonal antibodies with a radioisotope. In the case of Zevalin, the monoclonal antibody it uses is a chemotherapy drug that is already excluded from the SNF PPS payments. In addition, the Food and Drug Administration (FDA) has recently approved Bexxar, a radiopharmaceutical equivalent to Zevalin. We believe that these two radiopharmaceutical agents meet the criteria that were used to create the original lists of items to be excluded, because they are high-cost services that are unlikely to be used in the SNF setting, and that could not have been reflected in the base year costs for the SNF PPS (since neither of these products were available at that time).

Accordingly, we will add Zevalin (HCPCS codes A9522 and A9523) and Bexxar (HCPCS code not yet available) to the list of items excluded from consolidated billing. These exclusions will appear in the Consolidated Billing Annual Update Program Memorandum that we will issue at the end of CY 2003, and will be effective as of January 1, 2004.

In excluding the additional services from consolidated billing and the SNF PPS (and, thus, qualifying them for separate payment under Part B), section 103 of the BBRA also mandated a corresponding proportional reduction in Part A SNF payments, beginning with FY 2001. Specifically, section 1888(e)(4)(G)(iii) of the Act provides that the Secretary “* * * shall provide for an appropriate proportional reduction in payments” so that the *aggregate* reduction in Part A payments is equal to the *aggregate* increase in Part B payments attributable to the exclusions provided under section 1888(e)(2)(A)(iii) of the Act. This requirement applies not only to the original legislation, but to the BBRA-authorized update process. Thus, the actual result of this provision’s mandatory Part A payment reduction is to take the expense of the excluded items (which could be financially devastating to an individual SNF that actually incurs it, if borne solely by that particular facility) and effectively redistribute it over the entire universe of providers. As we noted in the July 31, 2000 final rule (65 FR 46792), in much the same way that an insurance pool reduces the degree of financial risk to an