

one of the excluded categories designated in the BBRA. Further, we believe that the Congress was clear in its intent regarding the particular items and services to be excluded from consolidated billing, by use of the HCPCS codes specified in the Act. Regarding the suggestion to exclude from consolidated billing those oral chemotherapy agents that are not separately billable to Part B (and are currently covered only under the Part A inpatient hospital and SNF benefits), we note that expanding the existing drug coverage available under Part B to include those drugs is not within our authority. Implementing this change would require legislation by the Congress to amend the law.

We note that some chemotherapy pharmaceuticals that commenters proposed for exclusion have already been included in the list of HCPCS codes excluded from the consolidated billing provisions. The most recent annual update regarding HCPCS exclusions from consolidating billing can be found in Program Memorandum A-02-118 (Change Request (CR) #2459), published November 8, 2002.

Comment: Two commenters requested an expansion of the dialysis exclusion to encompass dialysis services furnished directly by the SNF. In addition, several commenters noted that erythropoietin (EPO) currently is excluded from consolidated billing only when furnished in conjunction with the Part B dialysis benefit, and they recommended expanding this exclusion to encompass its use in connection with other, non-dialysis forms of treatment (such as chemotherapy).

Response: Under section 1888(e)(2)(A)(ii) of the Act, the exclusion of dialysis services from consolidated billing applies only to those services that meet the requirements for coverage under the separate Part B dialysis benefit at section 1861(s)(2)(F) of the Act. The Part B benefit allows for home dialysis and dialysis performed on the premises of a certified dialysis facility. By contrast, if the SNF itself elects to furnish dialysis services to a resident during a covered Part A stay (either directly with its own resources, or under an "arrangement" with a certified dialysis facility in which the SNF itself does the billing), the services are no longer considered Part B dialysis services, but rather, are Part A SNF services. Accordingly, they would no longer qualify for the statutory exclusion of Part B dialysis services from consolidated billing, and would instead be bundled into the comprehensive PPS per diem payment that the SNF receives for the package of

services that it furnishes during the resident's covered Part A stay. Any change in the scope of the dialysis exclusion from consolidated billing would require legislation by the Congress to amend the law. We note that we are proactively monitoring the impact of the SNF PPS to ensure that beneficiary access is not compromised. To that end, we have requested that the Office of the Inspector General (OIG) specifically examine the effect of the PPS on SNF residents' access to dialysis treatment. We will continue to gather extensive information from around the country with respect to SNF PPS implementation and will look to a variety of sources for objective information and evidence of the impact of this policy on access to quality care.

Similarly, under section 1888(e)(2)(A)(ii) of the Act, the exclusion of EPO from consolidated billing applies only to those services that meet the requirements for coverage under the separate Part B EPO benefit at section 1861(s)(2)(O) of the Act. Section 1861(s)(2)(O) of the Act permits coverage of EPO and items related to its administration for those dialysis patients who can self-administer the drug, subject to methods and standards established by the Secretary for its safe and effective use (as described in § 405.2163(g) and (h)). Since EPO that is used for non-dialysis patients does not fall within the scope of section 1861(s)(2)(O) of the Act, that usage does not fall within the scope of the EPO exclusion from consolidated billing.

Comment: One commenter requested that we "develop a system to eliminate the billing of SNFs for extraneous physician visits."

Response: Under section 1888(e)(2)(A)(ii) of the Act and § 411.15(p)(2)(i) of the regulations, physician services that meet the criteria for payment on a fee schedule basis are excluded from consolidated billing and, accordingly, can already be billed directly to the Part B carrier by physicians themselves.

Comment: A few commenters recommended expanding the consolidated billing exclusions to provide short-term relief pending the implementation of SNF PPS refinements. They urged this course of action as a way of ensuring continued access to SNF care for beneficiaries with heavy non-therapy ancillary needs.

Response: We agree that the SNF PPS needs to identify more accurately those beneficiaries with high pharmaceutical and other non-therapy ancillary needs, and we are actively conducting research designed to address these issues. However, we do not have the authority,

nor do we believe it is appropriate, to expand the consolidated billing exclusions as a substitute for actual refinements. As we noted in the July 31, 2001 final rule (66 FR 39588) in response to similar comments,

* * * we do not share the view of those commenters who suggested that the creation of additional exclusions from consolidated billing could serve, in effect, as an interim substitute for implementing case-mix refinements. We believe that payment adjustments relating to case-mix would best be accomplished directly through refinements in the case-mix classification system. Further, we note that the Congress has already provided an interim adjustment until the refinements can be implemented, in the form of the temporary rate increases for certain specified RUG-III groups [enacted by section 101(a) of the BBRA, as amended by section 314 of the BIPA].

J. Application of the SNF PPS to SNF Services Furnished by Swing-Bed Hospitals

In the July 31, 2001 final rule (66 FR 39562), we announced the conversion of swing-bed hospitals to the SNF PPS, effective with the start of the provider's first cost reporting period beginning on or after July 1, 2002. We selected this date consistent with the statutory provision to integrate swing-bed hospitals into the SNF PPS by the end of the SNF transition period, that is, June 30, 2002.

As of July 31, 2003, the SNF PPS covers all swing-bed rural hospitals (as noted previously in section I.D of this final rule, section 203 of the BIPA exempted critical access hospital (CAH) swing-beds from the SNF PPS). Therefore, all rates and wage indices outlined in earlier sections of this final rule for SNF PPS also apply to all swing-bed hospitals. A complete discussion of assessment schedules, the MDS and the transmission software, Raven-SB for Swing Beds, can be found in the July 31, 2001 final rule (66 FR 39562). The latest changes in the MDS for swing-bed hospitals are listed on our SNF PPS Web site, http://www.cms.hhs.gov/providers/snfpps/snfpps_mds.asp.

K. Distinct Part Definition

In the May 16, 2003 proposed rule (68 FR 26777), we noted that while some SNFs function as separate, independent entities, we have recognized since the inception of the Medicare program that it is also possible for a SNF to operate as a component, or "distinct part" of a larger organization. However, there was no precise definition of a "distinct part." In this final rule, we are clarifying the definition of a distinct part, by adopting a set of criteria that provides