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Part III

**Department of
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Services**

Health Care Financing Administration

**42 CFR Parts 409, 411, 413, and 489
Medicare Program; Prospective Payment
System and Consolidated Billing for
Skilled Nursing Facilities—Update; Final
Rule and Notice**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 409, 411, 413, and 489

[HCFA-1913-F]

RIN 0938-A147

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule responds to comments submitted by the public on our May 12, 1998 interim final rule, that implemented provisions in section 4432 of the Balanced Budget Act of 1997 regarding Medicare payment for skilled nursing facility services. This legislation established a prospective payment system, a consolidated billing provision, and a number of related changes.

EFFECTIVE DATE: These regulations are effective on September 28, 1999.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: To assist readers in referencing sections contained in this preamble, we are providing the following table of contents.

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In addition, because of the many terms to which we refer by acronym in this rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

- ADLs Activities of daily living
- ASC Ambulatory Surgical Center
- BBA Balanced Budget Act of 1997
- CAH Critical access hospital
- CBO Congressional Budget Office
- CFR Code of Federal Regulations
- CORF Comprehensive Outpatient Rehabilitation Facility
- CPI Consumer Price Index
- CPI-U Consumer Price Index for All Urban Consumers
- CPT [Physicians'] Current Procedural Terminology
- DME Durable medical equipment
- ESRD End stage renal disease
- FI Fiscal intermediary
- GAO General Accounting Office
- HCFA Health Care Financing Administration
- HCPCS HCFA Common Procedure Coding System
- HIPPS Health Insurance Prospective Payment System
- ICD-9-CM International Classification of Diseases, Ninth Edition, Clinical Modification
- MDS Minimum Data Set
- MEDPAR Medicare Provider Analysis and Review File
- MGCRB Medicare Geographic Classification Review Board
- MIM-3 Medicare Intermediary Manual, Part 3
- MRI Magnetic Resonance Imaging
- MSA Metropolitan Statistical Area
- NHCMQD [Multistate] Nursing Home Case-mix and Quality Demonstration

- OBRA 87 Omnibus Budget Reconciliation Act of 1987
- OIG Office of the Inspector General
- OMRA Other Medicare Required Assessment
- PM Program Memorandum
- PPS Prospective payment system
- PRM Provider Reimbursement Manual
- PRO Peer Review Organization
- RAI Resident Assessment Instrument
- RAPs Resident Assessment Protocols
- RUG-III Resource Utilization Groups, version III
- SNF Skilled nursing facility
- SOM State Operations Manual
- STM Staff time measure

I. Background

Section 4432 of the Balanced Budget Act of 1997 (BBA) (Public Law 105-33) mandated the implementation of a per diem prospective payment system (PPS) for skilled nursing facilities (SNFs), covering all costs (routine, ancillary, and capital) of covered SNF services furnished to beneficiaries under Part A of the Medicare program, effective for cost reporting periods beginning on or after July 1, 1998. Major elements of the system include:

- **Rates:** Per diem Federal rates are established for urban and rural areas using allowable costs from fiscal year (FY) 1995 cost reports. These rates also include an estimate of the cost of services that, before July 1, 1998, had been paid under Part B but furnished to SNF residents during a Part A covered stay. Rates are case-mix adjusted using a resident classification system (Resource Utilization Groups, version III (RUG-III)) based on resident assessments (using the Minimum Data Set (MDS) 2.0). In addition, the Federal rates are adjusted by a wage index to account for geographic variation in wages. Finally, the rates will be adjusted annually using an SNF market basket index.

- **Transition:** The SNF PPS includes a 3-year transition that blends a facility-specific payment rate with the Federal case-mix adjusted rate. The blend that is used changes each cost reporting period after a facility migrates to the new system. For most facilities, the facility-specific rate is based on allowable costs from FY 1995.

- **Coverage:** The PPS legislation did not change Medicare's fundamental statutory requirements for SNF coverage. However, because RUG-III classification is based, in part, on the resident's need for skilled nursing care and therapy, we have attempted where possible to adapt the existing claims review procedures to coordinate them with the outputs of resident assessment and RUG-III classifying activities, as discussed later in this preamble.

- *Consolidated Billing:* The statute includes a billing provision that requires a SNF to submit consolidated Medicare bills for its residents for virtually all services that are covered under either Part A or Part B. The statute excludes a small list of services (primarily those of physicians and certain other types of practitioners). A related statutory provision requires SNFs to use HCFA Common Procedure Coding System (HCPCS) coding on all Part B bills, and specifies that they are to be paid an amount determined in accordance with the otherwise applicable Part B fee schedule for the particular item or service.

- *Effective Date:* The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998. The law provides that the consolidated billing and coding requirements are effective for services and items furnished on or after July 1, 1998.

An interim final rule implementing the SNF PPS was published in the **Federal Register** on May 12, 1998 (63 FR 26252), and the comment period was initially scheduled to close on July 13, 1998. A follow-up notice (63 FR 37498, July 13, 1998) extended the public comment period for an additional 60 days, and a second notice (63 FR 65561, November 27, 1998) reopened the comment period for another 30 days. In addition, a correction notice (63 FR 53301, October 5, 1998) made a number of minor technical and editorial corrections to the interim final rule. We have also issued several Program Memorandums (PMs) on claims processing and billing under the SNF PPS that are available on the SNF PPS home page at the HCFA website on the Internet, at the following location: www.hcfa.gov/medicare/snfpps.htm.

As described in the interim final rule, the BBA requires implementation of a Medicare SNF PPS for cost reporting periods beginning on or after July 1, 1998. Under the PPS, SNFs are no longer paid under the previous, reasonable cost-based system, but rather through per diem prospective case-mix adjusted payment rates applicable to all covered SNF services. These payment rates cover all the costs of furnishing covered skilled nursing services (that is, routine, ancillary, and capital-related costs) other than costs associated with approved educational activities. Covered SNF services include posthospital SNF services for which benefits are provided under Part A and all items and services that, prior to July 1, 1998, had been paid under Part B (other than physician and certain other services specifically excluded under the

BBA), but furnished to SNF residents during a Part A covered stay.

A. Payment Provisions—Federal Rate

The statute sets forth a fairly prescriptive methodology for calculating the amount of payments under the SNF PPS. The PPS uses per diem Federal payment rates based on mean SNF costs in a base year updated for inflation to the first effective period of the system. We developed the Federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports during the base year (that is, for reporting periods that began in FY 1995). The data used in developing the Federal rates also incorporate an estimate of the amounts that were paid separately under Part B for covered SNF services furnished during the base year to individuals who were residents of a facility and receiving Part A covered services.

In developing the rates, we update costs to the first effective year of the PPS (15-month period beginning July 1, 1998) using an SNF market basket index, and standardize for facility differences in case-mix and for geographic variations in wages. Providers that received “new provider” exemptions from the routine cost limits are excluded from the data base used to compute the Federal payment rates. In addition, costs related to payments for exceptions to the routine cost limits are excluded from the data base used to compute the Federal payment rates. In accordance with the formula prescribed in the BBA, we set the Federal rates at a level equal to a weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and a weighted mean of all SNF costs (hospital-based and freestanding) combined. We compute and apply separately payment rates for facilities located in urban and rural areas.

The Federal rate also incorporates adjustments to account for facility case-mix using a resident classification system that accounts for the relative resource utilization of different patient types. This classification system, RUG-III, uses resident assessment data (from the MDS) completed by SNFs to assign residents into one of 44 groups. SNFs complete these assessments according to an assessment schedule specifically designed for Medicare payment (that is, on the 5th, 14th, 30th, 60th, and 90th days after admission to the SNF).

For Medicare billing purposes, there are specific codes associated with each of the 44 RUG-III groups, and each assessment applies to specific days within a resident’s SNF stay. SNFs that fail to perform assessments timely are

paid a default payment for the days of a patient’s care for which they are not in compliance with this schedule. In addition, we adjust the portion of the Federal rate attributable to wage-related costs by a wage index.

For the initial period of the PPS, beginning on July 1, 1998, and ending on September 30, 1999, the payment rates were contained in the interim final rule. For each succeeding fiscal year, we will publish the rates in the **Federal Register** before August 1 of the year preceding the affected Federal fiscal year. Pursuant to section 1888(e)(4)(E)(ii) of the Social Security Act (the Act), for FY 2000 through 2002, we will increase the rates each year by a factor equal to the SNF market basket change minus one percentage point. For subsequent fiscal years, we will increase the rates by the applicable SNF market basket change.

B. Payment Provisions—Transition Period

Beginning with a provider’s first cost reporting period beginning on or after July 1, 1998, there is a transition period covering three cost reporting periods. During this transition phase, SNFs receive a payment rate comprising a blend between the Federal rate and a facility-specific rate based on each facility’s FY 1995 cost report. Under section 1888(e)(2)(E)(ii) of the Act, SNFs that received their first payment from Medicare on or after October 1, 1995, receive payment according to the Federal rates only.

For SNFs subject to the transition, the composition of the blended rate varies depending on the year of the transition. For the first cost reporting period beginning on or after July 1, 1998, we make payment based on 75 percent of the facility-specific rate and 25 percent of the Federal rate. In the next cost reporting period, the rate consists of 50 percent of the facility-specific rate and 50 percent of the Federal rate. In the following cost reporting period, the rate consists of 25 percent of the facility-specific rate and 75 percent of the Federal rate. For all subsequent cost reporting periods, we base payment entirely on the Federal rate.

C. Payment Provisions—Facility-Specific Rate

For most facilities, we compute the facility-specific payment rate used for the transition using the allowable costs of SNF services for cost reporting periods that began in FY 1995 (cost reporting periods beginning on or after October 1, 1994, and before October 1, 1995). Included in the facility-specific per diem rate for most facilities is an

estimate of the amount that was paid separately under Part B for covered SNF services furnished during the base year to individuals who were residents of the facility and receiving Part A covered services. Under section 1888(e)(3)(A) of the Act, the facility-specific rate (in contrast to the Federal rates) includes amounts paid to SNFs for exceptions to the routine cost limits. In addition, we also take into account "new provider" exemptions from the routine cost limits, but only to the extent that routine costs do not exceed 150 percent of the routine cost limit.

We update the facility-specific rate for each cost reporting period after FY 1995 to the first cost reporting period beginning on or after July 1, 1998 (the initial period of the PPS) by a factor equal to the SNF market basket percentage increase minus 1 percentage point. For the FYs 1998 and 1999, we update this rate by a factor equal to the SNF market basket increase minus 1 percentage point, and, for each subsequent year, we update it by the applicable SNF market basket increase.

D. Consolidated Billing for Skilled Nursing Facilities

Section 4432(b) of the BBA sets forth a consolidated billing requirement applicable to all SNFs providing Medicare services. SNF consolidated billing is a comprehensive billing requirement (similar to the one that has been in effect for inpatient hospital services for well over a decade), under which the SNF itself is responsible for billing Medicare for virtually all of the services that its residents receive. As with hospital bundling, the SNF consolidated billing requirement does not apply to the services of physicians and certain other types of medical practitioners. In a related provision, section 4432(b)(3) of the BBA requires the use of fee schedules and uniform coding specified by the Secretary of Health and Human Services (the Secretary) for SNF Part B bills. The law provides that these requirements are effective for services furnished on or after July 1, 1998.

II. Provisions of the Interim Final Rule

In the interim final rule that was published on May 12, 1998, we made a number of revisions in the regulations in order to implement both the PPS and the SNF consolidated billing provision and its conforming statutory changes:

- With regard to payment, we revised the regulations in 42 CFR part 413, subpart A (that deal with Medicare payment to providers of services) to reflect the replacement of the existing reasonable cost reimbursement

methodology for SNFs by the new SNF PPS.

- We revised the regulations to provide that for SNF residents who are in a covered Part A stay, Medicare makes payment under the PPS described in new subpart J of part 413, effective with cost reporting periods beginning on or after July 1, 1998.

- For SNF residents who are not in a covered Part A stay, we revised the regulations to provide that Medicare makes payment on the basis of the otherwise applicable Part B fee schedule amounts, effective for services furnished on or after July 1, 1998.

- We made a conforming change in subpart B of part 483 (requirements for long term care facilities) to indicate that the frequency of resident assessments is subject to the timeframes prescribed under the SNF PPS in the new subpart J of part 413.

- We made a number of revisions to implement the consolidated billing provision, under which the SNF itself has the Medicare billing responsibility for virtually all of the services that its residents receive.

- We revised the regulations in part 410 (payment of benefits under Part B) to provide that Part B makes payment for these services to the SNF rather than to the beneficiary. We also made conforming changes with regard to Part B coverage of certain individual medical and other health services.

- We revised part 411 (exclusions from coverage) to exclude from coverage any service furnished to an SNF resident (other than certain specified service categories) when billed to Medicare by an entity other than the SNF itself, and we added a definition of an SNF "resident" for purposes of this provision.

- We revised the regulations in subpart B of part 489 (Medicare provider agreements) to add compliance with the consolidated billing provision to the specific terms of an SNF's provider agreement.

- We revised subpart C of part 424 (claims for payment) to require the inclusion of an SNF's Medicare provider number on claims for physician services furnished to an SNF resident, and the inclusion of HCPCS coding on an SNF's Part B claims.

- We made a number of conforming changes in subparts C, D, and F of part 409 of the regulations which describe, respectively, the scope of covered SNF benefits under Part A, the criteria for determining a covered SNF level of care, and benefit period determinations.

As noted previously, the PPS legislation did not change the basic statutory definition of an SNF level of

care. However, because RUG-III classification is based, in part, on the resident's need for skilled nursing care and therapy, our revisions in the level of care criteria reflected an attempt where possible to coordinate claims review procedures with the outputs of resident assessment and RUG-III classifying activities. For example, we believe that an initial 5-day assessment, properly completed, that places the resident in one of the upper 26 RUG-III classifications provides the basis for us to assume that the resident needed a covered level of SNF care upon admission and at least up until the assessment reference date of the initial Medicare-required 5-day assessment. We will, however, continue to make individual review determinations for claims of individuals who classify in the lower 18 RUG-III categories.

III. Analysis of and Responses to Public Comments

We received almost 500 comments on the SNF PPS interim final rule published on May 12, 1998 (63 FR 26302). Comments were submitted by nursing homes and other providers, suppliers and practitioners (both individually, and through their respective trade associations), State agencies, nursing home resident advocacy groups, elected officials, health care consulting firms, and private citizens.

The comments basically fell into three broad areas. The first involved the payment rates, including treatment of "outlier" situations and non-therapy ancillaries, calculation of the Federal rates themselves and of the Part B add-on, and the transition from facility-specific rates to the Federal rates. The second area concerned the clinical aspects of the SNF PPS, including MDS assessment and scheduling requirements, certification and recertification procedures, medical review criteria, treatment of rehabilitation therapy under the RUG-III classification system, nurse staffing and staff time measurement studies, and coverage and level of care determinations. The third broad area involved the consolidated billing requirement and the scope of the extended care benefit.

As noted in the interim final rule, because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are unable to acknowledge or respond to them individually. In particular, a number of commenters on the interim final rule raised extremely technical and detailed questions regarding the MDS and the

billing process. These questions are of a nature that would more appropriately be addressed through manual instructions and other issuances than in these regulations. In this final rule, we are addressing the general concerns raised by the commenters. A summary of the major issues and our responses follows:

A. Federal Rates—Outliers/Non-therapy Ancillaries (NTAs)

Comment: We received a number of comments expressing concern over the ability of the PPS to provide adequate payment for certain outlier or extraordinary cases. Several of the comments noted specific examples of these cases, such as HIV-infected patients with significant drug therapy needs, patients receiving intravenous (IV) drug therapy for antibiotic-resistant infections, ventilator-dependent patients, or simply patients with generally high costs. A number of commenters recommended the adoption of an outlier payment process or exceptions process to provide higher payments for these cases.

Other comments suggested use of a later base year (for example, FY 1997) or add-on to the rates in order to recognize changes made by facilities after 1995, the year on which the rates are based. These commenters argued that many facilities increased the scope of services provided to beneficiaries and served a higher acuity resident population after 1995 and, therefore, the costs associated with providing this higher level of care were not reflected in the calculation of the Federal rate.

Response: Section 1888(e)(4) of the Act provides specific requirements related to the formula and cost data to be used in computing the Federal rates. The statute provides that “the amount of the payment for all costs * * * of covered skilled nursing facility services” during the transition period is “equal to” a prescribed blended payment, and after the transition period is “equal to” the applicable adjusted Federal per diem rate. The statute does not provide for additional payments over and above these prescribed amounts. While the Act includes specific statutory authority for the application of outlier policies in relation to the acute care hospital PPS (section 1886(d) through (f) of the Act), home health PPS (section 1895 of the Act), and inpatient rehabilitation PPS (section 1886(j) of the Act), it does not provide such explicit authority with regard to the SNF PPS. However, we are concerned about this matter and are pursuing the basic issue of the accuracy of payments through an examination of the case-mix classification system.

In addition, the statute mandates use of the FY 1995 cost data in the development of the payment rates. It should be noted that when the rates were computed, the FY 1995 data were the latest available to compute the rates. We believe the Congress took this into consideration when developing the statutory language related to the computation of the Federal rates as well as the specific impact of using the 1995 data on the accumulation of Medicare savings, a key goal of the BBA.

We also note that while the Congress provided for Medicare budgetary savings through the SNF PPS (which had an obvious downward effect on the rates), there are numerous reports by the U.S. General Accounting Office (GAO) and Office of the Inspector General (OIG) suggesting Medicare payment for SNF ancillary services under cost reimbursement was inappropriately inflated in the past. If correct, this would mitigate the impact of the budgetary savings. The OIG includes an expanded discussion of this concept in a 1998 report on the SNF PPS titled “Review of the Health Care Financing Administration’s Development of a Prospective Payment System for Skilled Nursing Facilities” (Number A-14-98-00350).

We understand the concerns expressed in the comments related to this issue. As discussed in the impact analysis accompanying the interim final rule, the SNF PPS will have a varying impact on providers. Because “prices” are based on averages, SNFs should expect that certain patients cost more than payments and others less. The extent to which certain facilities can provide quality care, while incorporating efficiencies in their purchasing of services and operations, will affect how well they manage under this payment system, which uses mean-based prices rather than reasonable costs. Financial performance should, therefore, be determined by looking across each facility’s Medicare population, not on a patient specific comparison of costs and the payment rate under which the rate would become essentially a limit.

We will focus our efforts on ensuring that these prices are as accurate as possible with respect to the resources used by Medicare beneficiaries. The SNF PPS, through case-mix classification and adjustment, currently reflects a full range of SNF patient types with varying characteristics and degrees of resource intensity. Through research and refinements to the PPS, we will try to ensure that the PPS not only continues to account for a high level of resource intensity, but improves in

terms of its sensitivity to less common conditions or patient types. This aspect of our plan is discussed later in the context of the comments on payment for certain ancillary services.

Comment: There were a number of comments expressing concern with the adequacy of the PPS rates to cover the costs of ancillary services other than occupational, physical, and speech therapy (non-therapy ancillaries), including such things as drugs, laboratory services, respiratory therapy, and medical supplies. Prescription drugs or medication therapy were frequently noted areas of concern due to their potentially high cost for particular residents. Some commenters suggested that the RUG-III case-mix classification methodology does not adequately provide for payments that account for the variation in, or the real costs of, these services provided to their residents. A number of commenters stated their belief that the payment rates do not generally reflect the costs of certain of these services (for example, drugs or respiratory therapy).

Recommendations from commenters included removing all or some of these services from the PPS rates and continuing to pay for them on a cost basis, and making changes to the case-mix system and indices to account for these services more accurately.

Response: We are aware of the challenges certain providers have faced as they transition from a payment system based on reasonable costs to one that uses mean-based prices such as the SNF PPS. In fact, many of the same concerns raised in the comments to the interim final rule were voiced by hospitals when we implemented the hospital PPS system in the early 1980s. However, we believe this is an important issue that calls for a broader discussion of the PPS itself, and requires the clarification of certain technical issues related to the PPS and to the statute.

Section 1888(e)(1) of the Act requires that the PPS provide payment for “all costs” (including routine, ancillary, and capital related costs) of covered SNF services. Consistent with the statute, the PPS rates are based on 1995 allowable costs calculated from Medicare Part A cost report data and applicable Part B allowable charges. Thus, a facility’s historical costs (from FY 1995) of drugs, laboratory services, respiratory therapy, and other non-therapy ancillary services were captured in these cost reports and reflected in both the Federal and facility-specific transition rates.

In addition, many of these non-therapy ancillary services (for example, respiratory therapy, IV medications, and

IV feedings) are captured both directly and indirectly in the case-mix methodology and result in higher payments for SNFs. The issue of whether the nursing case-mix index adequately reflects the relative costs of non-therapy ancillary services was one that was studied in the development of the interim final rule and the associated payment rates.

As indicated in the preamble of that rule, using MDS assessments to classify patients into RUG-III groups, we compared the relative charges for non-therapy ancillaries to the nursing case-mix indices for each RUG-III group. We found that the pattern of the two relative amounts was similar across the RUG-III groups. That is, RUG-III groups with high nursing weights also tended to have relatively high charges per stay for non-therapy ancillaries.

Based on this comparison, we concluded that it was reasonable to include non-therapy ancillary costs in the nursing component of the rate. Accordingly, the idea that the PPS rates do not reflect the cost of respiratory therapy, drugs, and other non-therapy ancillaries is simply not accurate. Whether the accuracy of the rates can be enhanced in this regard is a subject for research and development that we discuss below.

The recommendation to remove or "carve out" these services as a class from the PPS rates and continue to pay for them on a cost basis raises some fundamental concerns related to both the statutory and conceptual framework of the PPS. As discussed above, section 1888(e)(A)(1) of the Act requires that the PPS provide payment for "all costs" (including routine, ancillary, and capital related costs) of covered SNF services. The conference report associated with section 4432 of the BBA explicitly states that under the SNF PPS, "services and supplies provided to residents will be included in pre-determined per diem payment rates."

Beyond the threshold issue of statutory language, the issue of whether specific services should be identified and paid separately appears to conflict with certain fundamental concepts embodied in a PPS. Carried to its logical conclusion, this approach is antithetical to the very concept of the SNF PPS itself, which is based on bundling services for similar patients and paying an average, prospectively determined amount for all services included in the bundle. The PPS rate already recognizes differences between nursing, rehabilitation therapy, and ancillary services, as well as non-case-mix components.

It is important to consider the budgetary impact of the commenters' proposal to remove certain services from the PPS rates and to continue paying for them on a cost basis. The budgetary impact would be significant and would reduce the savings to Medicare associated with the SNF PPS provisions of the BBA. Implementing the provision in a way that would have a budget neutral impact on savings (for example, a downward adjustment to the Federal rates) would penalize providers that have made changes to their operations in order to provide services more efficiently, and would benefit those that have not. Therefore, we believe that further disaggregation of the payment rate would not be consistent with the objectives of prospective payment from a conceptual, statutory, or budgetary perspective.

Finally, we agree with the commenters' recommendation that we explore the potential for refinements to the PPS and, more specifically, the case-mix classification system (RUG-III) to ensure that it continues to account more accurately for the services provided to SNF residents. We consider the continuing adequacy of the PPS rates, and the case-mix methodology in particular, to be a high priority. We believe very strongly that the case-mix methodology should be periodically evaluated to determine the appropriateness of the RUG-III groups in relation to changes in patient care practices and the Medicare population.

In addition, the conference report language associated with section 4432 of the BBA specifically recommended examining payment for medication therapy in the context of the SNF PPS. Accordingly, we are funding substantial research to examine the potential for refinements to the case-mix methodology, including an examination of medication therapy, medically complex patients, and other non-therapy ancillary services.

We are currently funding two research contracts to determine the potential for refinements to the RUG-III model. The first contract was awarded in FY 1997 and provides preliminary analysis and alternatives for refinements using a limited database. The next phase of the research focuses on fully developing these options using more extensive data. Completion of the research is targeted for January 1, 2000. Potential refinements to the case-mix model may include the division of the current 44 groups or the addition of new ones based on items currently on the MDS 2.0 (for example, new extensive care groups combining both medical ancillaries and rehabilitation).

In addition, a new payment index (or set of relative weights) based on ancillary charges, rather than the current staff-time based indices, is being explored for the non-therapy ancillary component of the PPS rates. Any refinements to the RUG-III model and case-mix indices that result from this research would have a distributional effect on payments resulting in a new set of payment weights across the various groups. If the research supports refinements, we anticipate their implementation in conjunction with the October 1, 2000, update to the PPS rates. This time line is dictated by the complexity of the research and by operational and regulatory requirements, including publication of a proposed rule.

It should be noted that the BBA provisions establishing the SNF PPS provided for over \$9 billion in savings to Medicare (in fee for service) as a result of the statutory formula used for developing the rates. Accordingly, an SNF's current costs may well exceed the PPS rates if the SNF does not revise the historical purchasing and charging practices that it followed under the preexisting cost-based payment system.

B. Federal Rate Calculation

Section 4432(a) of the BBA amended section 1888 of the Act by adding a new paragraph (e) that provides for the establishment of per diem Federal payment rates under the SNF PPS. These rates encompass all costs of furnishing covered skilled nursing services (that is, routine, ancillary, and capital-related costs), other than costs associated with approved educational activities. In the interim final rule, we established a new subpart J in the regulations at 42 CFR part 413, that describes this new payment methodology. In this section of the preamble, we are providing responses to comments on a number of important issues related to the Federal rates. These include payment for non-rehabilitation ancillary services, outlier cases, and a variety of issues related to the data and design of the Federal payment rates. In addition, we are providing for a minor increase in the unadjusted rates effective October 1, 1999, based on the recommendation of one commenter.

Comment: We received a number of comments recommending that we periodically recompute the PPS rates using the most recent data. Reasons commonly mentioned include that rebasing would allow the PPS to recognize changes over time in the intensity and scope of services provided in SNFs, and that it would provide an opportunity for re-standardization of the

payment rates using actual resident assessment (MDS) data.

Conversely, we received comments that recommended against rebasing payment rates periodically. These commenters were concerned that because the PPS provides incentives for SNFs to provide services more efficiently and eliminate distinct parts (that would tend to lower average SNF costs, as determined from Medicare cost reports), the impact of rebasing the rates would be unfair, since it would tend to penalize providers for being efficient.

Response: While we are not able to predict the absolute impact on SNF costs of the incentive for SNFs to provide services more efficiently or their continued desire to maintain distinct parts under PPS, we have no doubt that the PPS will result in some downward pressure on costs. Anecdotal evidence up to this point certainly supports this conclusion.

Section 1888(e)(4)(A) of the Act requires a 1995 base year. Section 1888(e)(5)(A) of the Act specifically provides for the establishment of an SNF market basket index, while section 1888(e)(4)(E) of the Act requires that the SNF PPS rates be updated annually using that index.

As discussed in response to earlier comments, we believe that it is appropriate to recognize changes over time in the Medicare population or care delivery practices in SNFs in the context of case-mix adjustments. Our periodic evaluation of the case-mix classification and indices will provide an opportunity for making refinements to the PPS that recognize changes in the intensity and scope of services provided in SNFs.

Comment: We received several comments regarding certain costs that were not included in the computation of the Federal rate. Specifically, the commenters expressed concern that all SNFs receiving "new" provider exemptions from the routine cost limits and all allowable costs associated with atypical services exceptions to the cost limits have not been included in the data used for computation of the Federal rates.

The commenters suggested that it is unfair to exclude the cost associated with those providers that are providing atypical levels of care. Further, they noted that these are the same providers that would have a high case-mix in the new payment rates and, therefore, should be included. Virtually all of these commenters suggested that the rates are distorted due to the exclusion of many providers and costs of furnishing atypical services.

Response: The statute is very specific regarding the exclusion of providers that have received "new" provider exemptions from the calculation of the Federal rates. Section 1888(e)(4)(A) of the Act requires that cost data from SNFs "that were subject to (and not exempted from) the per diem limits" be used in computing the payment rates. Similarly, the statute specifically requires the exclusion of allowable costs associated with exceptions granted in the FY 1995 base year. Section 1888(e)(4)(A)(i) requires the use of the allowable costs of SNF services "excluding exceptions payments" in calculating the payment rates.

Comment: Several commenters were concerned that we eliminated certain cost reports from the calculation of the Federal rates on the basis of their duration. Cost reports in excess of 13 months or less than 10 months in duration were eliminated from the rate computations. In addition, concerns were expressed over the use of a geometric outlier elimination process to remove SNF costs from the data.

Response: As we indicated in the interim final rule, we used only those cost reports for periods of at least 10 months but not more than 13 months. We excluded those periods that fell outside these parameters on the basis that those cost reports may not be reflective of a normal cost reporting period and, therefore, may tend to distort the rate computation. For example, providers entering or exiting the Medicare program could have abnormally high or low costs due to fluctuations in occupancy. This approach does not affect a large number of cost reports and is consistent with our rate setting methodology in other areas of Medicare.

Similarly, we believe the application of a geometric outlier elimination process for the SNF costs used to calculate the payment rates is an appropriate analytical approach consistent with rate setting for payment systems in other areas of Medicare. We believe that three standard deviations from the geometric mean of the log value for each cost component is a fair level of tolerance that focuses on the truly aberrant cost values. In addition, this process involved the removal of both high cost and low cost aberrant values, resulting in a more equitable and more meaningful computation of the rate components.

We would also add that we used all FY 1995 cost reports that were available at the time of the development of the interim final rule and associated payment rates. While some cost reports may not have been available at that

time, we constructed the rates based upon the best available data and are confident it was more than adequate for construction of the rates. Finally, a small number of cost reports were eliminated from the computation of the rates due to faulty or missing data on critical items.

Comment: Several commenters expressed concern with our methodology related to the use of a MEDPAR analog in the standardization of the Federal payment rates. They questioned whether the MEDPAR data were sufficiently accurate for the purpose of developing payment rates and referred to the 28 percent difference, reported in the interim final rule (63 FR 26260), between the therapy index calculated from actual MDS assessments and the MEDPAR analog-generated index. They noted additional limitations of the analog, such as the lack of functional status information and recommended that we use actual MDS data, when available, to re-standardize the payment rates, possibly in conjunction with a rebasing of the cost data.

Response: As noted in the interim final rule, an adequate national sample of MDS data for use in standardizing the Federal payment rates does not yet exist. In the absence of these data, we believe the MEDPAR analog, adjusted by the case-mix adjustment factor, provides an appropriate estimate of case-mix for the purpose of rate standardization. Based on our comparison of actual MDS and MEDPAR data, we concluded that limitations of the MEDPAR case-mix analog had no effect on the nursing component of the rate. Whatever inaccuracy existed in the MEDPAR analog data, the effect was limited to the therapy component and tended to increase, not decrease, the payment rate. The fact that the available MDS data yielded a therapy index value 29 percent higher than the MEDPAR analog data for the same cases demonstrates that use of the MEDPAR data alone would have made the therapy component inappropriately high. That is the reason that the correction factor was applied to the therapy component.

Comment: A few commenters expressed concern about the adjustment we made to the cost report data in developing the Federal rates, to account for providers with cost reports that were not settled. One commenter indicated that all SNFs should not be penalized by this adjustment. It was also suggested that the rates be redone in the future to account for the actual change between the as-submitted cost reports and the settled ones. In addition, one comment

addressed the methodological application of the adjustment in the computation of the rates, suggesting an alternative where the adjustment is applied to total Medicare routine costs as opposed to only costs subject to the routine limit.

Response: As we indicated in the interim final rule, the adjustment made pursuant to section 1888(e)(4)(A)(i) of the Act was applied to unsettled cost reports and was based on the average ratio for all providers in 1995, between their as-submitted and settled cost report. This adjustment is only applied to the cost report data of providers whose cost report was not settled as of the time we computed the rates. It is an actuarial adjustment required under the law that affects how the average SNF costs are determined and does not penalize other providers with settled reports.

As we indicated in the interim final rule, these adjustment factors were validated using data from three previous years, that showed this ratio remains fairly constant. To update and change the rates in the future based on revised cost reports is impractical. Revisions are constantly being made to cost reports (for many years) and our validation exercise indicates the ratios are accurate.

Finally, we have decided to incorporate the methodological alternative described above and will adjust the unadjusted nursing case-mix component of the urban and rural Federal rates by +\$.32 and +\$.24, respectively. In addition, we will adjust the unadjusted non-case-mix component of the urban and rural Federal rate by +\$.25 and +\$.21, respectively. We believe this refinement in the application of the adjustment factor may result in a more accurate estimate of the routine costs of SNFs. This adjustment will be prospective and will be effective at the next scheduled update of the SNF PPS rates on October 1, 1999. That is the earliest point at which we can implement changes to the standard claims processing systems.

Comment: We received one comment asking why the issue of payments for low-volume SNFs was not addressed in the interim final rule.

Response: The new Part A PPS established in section 1888(e) of the Act applies to all SNFs, and does not include any special treatment for low-volume SNFs. Section 1888(d) of the Act provided for a separate, optional payment system for SNFs with less than 1500 days (that is, low-volume SNFs) in their preceding cost reporting period. However, according to current law, this special payment system for low-volume

SNFs is only in effect for cost reporting periods beginning before July 1, 1998.

Comment: Numerous comments were received from hospital-based facilities and their representatives indicating that the rates are too low and do not recognize the additional overhead incurred in a hospital-based facility. The commenters pointed out that the Federal rate uses a mean of the average for all freestanding providers and the average for all freestanding and hospital-based providers. This computation double counts freestanding providers, thus lowering the rates. Some commenters suggested the rates should be redone, or an add-on or separate rate for freestanding versus hospital-based providers be established, similar to what was done for routine cost limits.

Response: As many of the commenters have already recognized, the computation as described above is clearly mandated in the formula set out in section 1888(e)(4) of the Act.

Comment: We received several comments regarding the wage index that is used to standardize and adjust the rates. The commenters suggested that the hospital wage index might not adequately represent wages paid in SNFs. Many of the commenters pointed out that SNF wages and hours are excluded from the hospital wage index computation, yet we are applying it to SNF payments. Most commenters want the wage index updated periodically and often to reflect the most recent changes in wages. One commenter suggested that we make other changes to the method for how the wage index is calculated by including costs that are now excluded, such as physician salaries, and excluding items like interns' and residents' salaries. There were also a few commenters who suggested that any move to a wage index based on SNF wage data be done slowly to ensure it is done accurately. Most commenters hope to see a wage index based on SNF data soon. In addition, many commenters want us to use a later wage index to reflect the recent mandated changes in the minimum wages rates paid to some employees.

Response: As we indicated in the interim final rule, we are using the hospital wage data since the SNF wage data have not been completed. We used the latest completed hospital wage index that was available at the time of publication. It is our intent to use the latest wage index data that are complete and available when we publish rates or updates to the rates in the future.

We have been unable to evaluate a wage index based on SNF wage data, as not all SNF providers reported data via the worksheet S-3. Now that we have a

full year of wage data for both freestanding and hospital-based facilities, we will begin to evaluate and analyze the wage and hourly data from the SNF and hospital-based SNF cost reports. We will analyze and develop these data to evaluate their accuracy and validity. It is our intent, if the data are accurate, eventually to use and publish a wage index based on SNF wage data. However, it has been our experience in the past that when new wage data are used, they can result in enormous and erratic shifts in the wage indexes; many providers could be adversely affected while others experience a windfall. Therefore, before we use any SNF wage data, we will perform numerous edits to ensure quality. In addition, we will ask for public comments once the wage index data are available. Since we have not yet developed a wage index based on SNF wage data, we do not know the impact of excluding or including any particular cost centers.

As discussed above and in the interim final rule, until an appropriate wage index based on SNF data is available, we will use the latest available hospital wage index data in making annual updates to the payment rates. We believe that SNFs and hospitals compete in the same labor market areas and, therefore, absent specific SNF wage data, we continue to believe that the hospital wage data accurately reflect the relative wage costs between labor areas. In making these annual updates, section 1888(e)(4)(G)(ii) of the Act requires that the application of this wage index be made in a manner that does not result in aggregate payments which are greater or less than would otherwise be made in the absence of the wage adjustment. For the initial period of the SNF PPS, the adjustment required by this section was accounted for through the standardization of the cost data that formed the basis for the per diem rate components. By means of standardization, each rate component was adjusted for wage index and case-mix differences so that aggregate payments were unaffected by the presence of these payment adjusters.

Since, for the second PPS year (Federal rates effective October 1, 1999), we plan to update the wage index applicable to SNF payments using the most recent hospital wage data, it is necessary to ensure that the aggregate payments in the second year are neither greater nor less than they would be if we continued to use the wage index from the initial year. This requirement, established pursuant to section 1888(e)(4)(F)(ii) of the Act, will be met by multiplying each of the per diem rate components by the ratio of the volume

weighted mean wage adjustment factor (using the wage index from the initial year) to the volume weighted mean wage adjustment factor, using the wage index for the fiscal year beginning October 1, 1999. The same volume weights are used in both the numerator and denominator and will be derived from 1997 MedPAR data. The wage adjustment factor used in this calculation is defined as the labor share of the rate component multiplied by the wage index plus the non-labor share.

Comment: We received two comments suggesting that the rates should have an add-on to account for the additional cost of completing resident assessments and the administrative costs associated with implementing this new payment system and other unfunded mandates.

Response: We recognize that the increased frequency of assessment may result in additional costs for SNFs. However, as we indicated in response to an earlier comment, the Congress mandated both the basic formula and the fiscal year cost data that we are to use in developing the rates. To the extent that any of these assessment costs are included in the base year data, they are reflected in the rates. We would note that, as we indicated in the interim final rules discussion of the Paperwork Reduction Act, it was determined that the increased assessments required and the time to transmit them has a minimal impact on each individual facility. We recognize that providers will incur additional costs associated with more frequent assessments but we believe our current rate scheme is consistent with the law.

Comment: Several commenters suggested that capital should not be part of the rate, suggesting that it be an add-on or pass-through to recognize those facilities that were committed to large capital expenditures incurred after 1995.

Response: In accordance with section 1888(e)(2)(B) of the Act, the calculation of the Federal rates included the capital costs. We realize that committed capital expenditures after 1995 may create some hardship on some providers. However, we believe that the present rate scheme, which includes capital, is consistent with the language and intent of the statute. Further, we believe that the capital costs included in the rates are adequate to cover capital costs that would be incurred for providers over time.

Comment: We received numerous requests, particularly from rural hospital-based facilities, suggesting that we allow providers to reclassify to a nearby adjacent urban area to receive the urban wage index or the rates

applicable to the adjoining urban area, especially in circumstances where the hospital has been reclassified because it is in a county that was defined as urban under section 1886(d)(8)(B) of the Act (sometimes referred to as a "Lugar" county) or as a result of geographic reclassifications based on decisions of the Medicare Geographical Classification Review Board (MGCRB) or the Secretary under section 1886(d)(10) of the Act for purposes of the hospital PPS. These commenters suggested that the SNFs are competing in the same market as hospitals. One commenter suggested that a board similar to the MGCRB be established to consider an SNF's request to be reclassified.

Response: While we have broad authority to develop an SNF wage index, we continue to believe that the reclassifications permitted for hospitals under sections 1886(d)(8)(B) and 1886(d)(10) of the Act are specific to hospitals. The Congress could have chosen to extend this provision to SNFs under section 1888(e) of the Act, but it did not. In addition, it has been our longstanding policy not to allow or recognize reclassification for SNFs for payment under the routine cost limits. Since we hope eventually to develop a wage index specific to SNFs, the possible effect of reclassification on the wage index is unclear and might have unintended consequences.

Comment: Two comments were received asking that we consider an adjustment for the non-labor portion for Alaska and Hawaii providers, similar to what is done for routine cost limits for SNFs. These commenters suggested that these areas experience a much higher cost than those providers in the continental United States and, therefore, are entitled to this adjustment.

Response: The hospital inpatient PPS does have an adjustment similar to that requested by these commenters; however, it was mandated by the statute governing the hospital PPS. By contrast, the Congress did not provide for such an adjustment in the legislation for the SNF PPS. Costs incurred by Alaska and Hawaii providers are, of course, included in the base year computation.

Comment: One comment we received suggested that SNFs that were subject to the low-volume rates should have been eliminated from the calculation of the Federal rates. Furthermore, the commenter added that these providers should be exempt from PPS and continue to be paid under the low-volume rates.

Response: Section 1888(e)(4)(A) of the Act specifically included low-volume

facilities in the SNF PPS rate calculation.

C. Federal Rates—Part B Add-on

In describing the data to be used in developing the Federal rates, section 1888(e)(4)(A)(ii) of the Act provides for including an estimate of the amounts payable under Part B for covered SNF services furnished during FY 1995 to individuals who were residents of a facility and receiving Part A covered services. This estimate is also known as the "Part B add-on." In this section of the preamble we are providing an expanded discussion of the development of the add-on for Part B services which is included in the Federal rates.

Comment: We received a number of comments questioning the accuracy of our estimate of Medicare Part B allowable charges associated with patients in Medicare Part A stays during the FY 1995 base year used for determining both the Federal and facility-specific payment rates. Certain commenters cited evidence of missing bills and charges associated with individual providers for particular types of services (for example, laboratory services or rehabilitation therapy). In addition, several commenters suggested that we allow for an appeals process related to the Part B estimate associated with facility-specific rates.

Response: We took great care in both the methodological design and construction of the data sources necessary for the development of this estimate. We are aware of several independent industry efforts to review this methodology which found no defects in the design. In this final rule, we are providing the following, more detailed discussion of the methodology used for the development of the Part B estimate with the hope that doing so will clarify our process of determining this estimate and respond to questions and concerns.

The facility-specific payment rate used for the transition is computed using the allowable costs of SNF services for cost reporting periods beginning in FY 1995 (cost reporting periods beginning on or after October 1, 1994, and before October 1, 1995). Included in the facility-specific per diem rate is an estimate of the amount payable under Part B for covered SNF services furnished during cost reporting periods beginning in FY 1995 to individuals who were residents of the facility and receiving Part A covered services.

These estimates were developed using allowed charges (including coinsurance and deductibles) from all Medicare Part

B claims actually submitted (other than those specifically excluded from the consolidated billing requirements, such as physician services) associated with SNF residents in a Part A stay during cost reporting periods that began in FY 1995. Applying the methodology described below, we provided the fiscal intermediaries (FIs) in May of 1998 with the total aggregate amount payable under Part B. In addition, at the request of the nursing home industry, we included a detailing of certain components of that amount for informational purposes.

At that time, we instructed the FIs that only the item listed as "Total Part B Add-on Amount" should be incorporated in the calculation of the facility-specific rates. We noted that, while the total Part B amount was an accurate estimate based on the universe of Part B claims, the assignment of allowed charges into the different service components was only an approximation due to the level of specificity of the codes and the variation in supplier billing and coding practices. The following description details the methodology used to determine the Part B add-on amounts:

1. Identify Cost Report Period

For each SNF, determined appropriate FY 1995 cost report period. Used all FY 1995 cost reports on file as of January 30, 1998. If no FY 1995 cost report was available, estimated a FY 1995 period from the latest cost report available.

2. Create List of Dates for SNF Stays for Each Beneficiary

For each SNF, identified all Part A SNF claims with the discharge date on the claim falling within the cost report period. For each beneficiary, identified the dates of each stay during the cost report period.

3. Identify All Non-Physician Part B Claims

Obtained all Part B physician, supplier, DME claims for 1994, 1995, and 1996. Omitted all professional services, defined as any service associated with a physician specialty code. Obtained all Part B outpatient department facility claims for 1994, 1995, and 1996.

4. Match List of Part A SNF Stays to Part B Claims

By beneficiary, matched list of Part A SNF stays to Part B claims. Kept all non-physician services or facility claims falling on or between dates of admit and discharge for each SNF stay.

5. Drop Claims for DME

For non-physician Part B claims, that is, not facility claims, reviewed all alphanumeric HCPCS and identified and dropped obvious DME codes, for example, wheelchairs, canes, transcutaneous electrical nerve stimulation (TENS), glucose monitors, commodes, walkers, bath and toilet aids, lifts, and oxygen equipment. Because coverage under the Part B DME benefit is not allowed for beneficiaries in an SNF stay, we believe that these codes probably occurred on either the day of admission or the day of discharge or were associated with erroneous payments.

6. Adjust Outpatient Claims to Reflect Costs

Adjusted total charges on Part B outpatient facility bills to reflect total Medicare payments using a payment to charge ratio calculated from FY 95 outpatient cost reports. If no FY 95 cost report was available, used ratio from FY 94 or, if necessary, FY 93 cost report. If a FY 93 cost report was not available, used the payment amount associated with the claim.

7. Drop Outpatient Bills

Removed claims with home health and dialysis provider numbers. Dropped Part B outpatient facility claims where the SNF provider number matched the hospital outpatient provider number. Dropped bills with at least one of the following revenue centers: surgery, emergency room (ER), ambulatory surgical center (ASC), cardiac catheterization, computerized axial tomography (CT) scan, and magnetic resonance imaging (MRI). These outpatient hospital services are excluded from the consolidated billing requirements.

8. Calculate Totals

Calculated total allowed charges for all non-physician Part B claims. Calculated total payments for Part B outpatient facility claims.

9. Create Descriptive Categories Within Totals

At request of certain members of the industry, created general categories to describe the distribution of dollars among types of services. Categories are not exact due to the lack of precision in categories for HCPCS ranges, local codes, and the structure of facility claims. For example, dollars for laboratory services could appear in (a) the "laboratory" category for non-physician Part B, (b) the "other" category for non-physician Part B if the code was local, or (c) the outpatient

department's (OPD) "other" category for laboratory tests conducted by an outpatient facility.

Created categories for non-physician Part B claims using HCPCS and CPT ranges. Often, broad HCPCS categories capture some unrelated codes. In addition, temporary local codes had to be placed into the "other" category.

The structure of the outpatient facility claims prevents associating a code with a specific dollar amount. Created outpatient therapy category by combining all claims from CORF hospitals and any claim with only one physical therapy (PT), occupational therapy (OT), or speech-language pathology (SLP) code. Left all remaining bills in OPD category.

As discussed in the above description of our methodology, a number of factors prevented us from disaggregating the total Part B allowable charges precisely into distinct high level categories (for example, laboratory services). However, we decided to attempt to provide an approximate breakout by category to provide SNFs some notion of what their Part B service mix may have looked like in the FY 1995 base year.

While we did note in the listing of Part B add-ons provided to FIs that the categorization of charges was only an approximation, this qualification may not have always been understood by providers. We regret any confusion caused by this breakout. We would note that our purpose in developing the total estimate of Part B allowable charges did not go beyond providing an accurate account of the total allowed charges to be included in the PPS rates, and we believe our estimate accomplished this. However, even if our purpose had been to map every charge and HCPCS code precisely to some broad category, once again, the data and structure of Medicare's billing system would not have permitted it.

Beyond issues related to the categorization of Part B charges, we received no comments that contained substantiated evidence of systematic defects in the methodology or data. We would note that section 1888(e)(8)(B) of the Act limits administrative review of this estimate.

Comment: We received numerous comments indicating that we should publish, or otherwise make available to the public and the industry, the complete and itemized data that were included in the computation of the rates. Of particular concern was the percentage of the nursing case-mix component of the rate that is attributable to nursing services and non-therapy ancillary costs. Some commenters suggested that they were

unable to replicate the rates we published with the data currently available.

Response: Much of the data necessary to compute the rates have been available for some time, including the 1995 SNF cost reports and the MEDPAR files. We have also put data and information related to the computation of the case-mix indices on our SNF PPS website, at: <www.hcfa.gov/medicare/snfpps.htm>. A public use file containing the most significant data items relating to the calculation of the unadjusted Federal rates can also be found on the website. The standardization and case-mix correction factors are included with the public use data.

It is our understanding from conversations with a number of users of the data that the public use file, along with the data that were already available, has been quite helpful in understanding the calculation of the rates. In addition, we have honored several requests under the Freedom of Information Act for data associated with the rate calculations, and have provided further information through data release agreements.

Regarding the percentage of the nursing case-mix component of the rate that is attributable to nursing services and social services and non-therapy ancillary costs, we agreed with earlier comments to the interim final rule that the public would benefit by knowing the percentages for nursing and social services and non-therapy ancillary services included in the rate. Accordingly, on November 27, 1998, we published a notice in the **Federal Register** (63 FR 65561) to reopen comments to the interim final rule. We also provided the public with a percentage breakdown of the nursing case-mix component of the rates to the extent feasible.

Comment: We received a number of comments concerning our discussion in the interim final rule related to OIG's proposal to adjust the Federal rates to account for costs in the 1995 base year cost data that result from medically unnecessary services or improper payments. These comments strongly recommended that we not proceed with such an adjustment, citing the already significant downward impact on the Federal rates of the BBA budgetary savings, the inadequate statistical basis for pursuing such an adjustment, and insufficient statutory authority for proceeding with an actuarial adjustment of this type to the rates.

Response: We are concerned about the application of an adjustment that would have a downward impact on the Federal rates in light of the substantial reduction

already incorporated into the calculation under the BBA requirements. According to the impact analysis contained in the interim final rule, this reduction is 17 percent on average. However, there is a substantial body of evidence, in the form of OIG and GAO studies, that at least suggests there were inappropriate services or improper payments associated with SNF services during the 1995 base year. Consequently, it could reasonably be argued that exclusion of the costs of these services from the cost base used to compute the Federal payment rates is appropriate.

However, we believe that in considering the level of budgetary savings to incorporate into the statutory formula for establishing the Federal rates, the Congress took into account the existing cost base and aggregate SNF payment levels to determine an appropriate level of budgetary savings. Our policy with regard to this issue will be not to proceed with such an adjustment in the absence of specific statutory direction from the Congress.

D. Facility-specific Rates-Transition

Section 1888(e)(2) of the Act provides, for most facilities, a phased transition from facility-specific payment rates (which reflect the individual facility's historical cost experience) to the Federal rates. During such a facility's first three cost reporting periods under the SNF PPS, it receives a blended payment rate, in which the Federal portion initially represents 25 percent of the facility's total payment rate, and then increases by 25 percent increments in each succeeding period until the facility is paid at the full Federal rate.

In this section of the preamble, we are providing responses to comments on a number of issues related to the PPS transition period and the calculation of the facility-specific rates. These include issues related to the eligibility of certain SNFs for the transition. In addition, this section includes policy changes related to the calculation of the Federal rates for certain SNFs with short cost reporting periods and the eligibility for the transition of SNFs with cost reporting periods beginning in FY 1994 but including the entire FY 1995 period.

Comment: We received several comments suggesting that we should define a new SNF as one that first furnished patient care on or after October 1, 1995, rather than one that first received payment on or after October 1, 1995, as our present policy dictates.

Response: We understand that there are many concerns regarding the issue of eligibility for the PPS transition.

However, we believe current policy is consistent with the statute. Section 1888(e)(2)(E) of the Act specifically refers to the date an SNF first received payment from Medicare on or after October 1, 1995, as the threshold date. However, it is important to understand that the threshold for determining eligibility for the transition period affects providers in different ways, creating both winners and losers. Thus, while many providers may want to receive PPS transition payments, many other providers would rather be paid on the basis of the full Federal rate. We do not see the benefit of a policy change that creates losers under the system from winners and vice versa.

Comment: We received a number of comments recommending that we modify our policy with regard to the PPS transition, to allow existing SNFs to elect to bypass the transition and be paid 100 percent of the Federal rate if they had experienced significant shifts in case-mix or significant capital expenditures after the 1995 base year used for determining the facility-specific rate. One commenter included a detailed assessment of this proposed policy, including an estimate of the aggregate costs to the Medicare program of its adoption.

Response: We understand the concern of SNFs that have operated under the Medicare program since 1995 or earlier and yet find themselves disadvantaged by the PPS transition due to changes in their care delivery model or significant capital expenditures that occurred after the 1995 base year used for computing the facility-specific rate. However, we believe our present policy to be reasonable and consistent with the plain language of the statute. Section 1888(e)(2)(E)(ii) of the Act sets forth the requirements concerning whether a facility receives payment under the PPS transition or solely according to the Federal rates. This section provides that for SNFs that "first received Medicare payment for services under this title on or after October 1, 1995, payment for such services shall be made under this subsection as if all services were furnished after the transition period." In our view, this language establishes clear criteria related to provider eligibility for the transition and the appropriate basis for Medicare payment. Accordingly, we have established a policy which relies on the date an SNF first received payment (interim or otherwise) from Medicare to determine the basis of their payment.

Comment: We received one comment asking us to reconsider our policy regarding eligibility for the transition for providers that do not have a cost

reporting period beginning in FY 1995, but whose period contains the entire 1995 FY. Examples of these cost reporting periods include a 13-month cost reporting period beginning September 1, 1994, and ending on September 30, 1995 or reporting periods with a floating beginning date (that is, tied to a specific day of the week) of September 27, 1994.

Response: In Transmittal 405 of the Provider Reimbursement Manual (PRM, HCFA Pub. 15-1), we had initially required these providers to be paid at the Federal rate without a transition period, since these providers did not have a cost reporting period beginning in FY 1995 (the statutory basis for computing the facility-specific transition rate). However, we have reconsidered our policy, because these providers did receive their first payment from Medicare before October 1, 1995. These providers will now be eligible for the transition period.

In addition, any provider that has been paid the full Federal rate based on our original policy contained in Transmittal 405 of the Provider Reimbursement Manual will be held harmless, since they have already transitioned to the PPS. In short, this means that providers with a cost reporting period beginning date in 1994 and whose period contains the full 1995 fiscal year (that is, the 12 months beginning October 1, 1994, through September 30, 1995), will be able to elect either a PPS transition based payment or the full Federal rate. Whichever rate the provider chooses must be used for all the years of the transition period.

Comment: We received a number of comments regarding our policy on changes of ownership and mergers as they relate to a provider's eligibility for the PPS transition.

Response: As discussed earlier in this section, SNFs that first received payment from Medicare on or after October 1, 1995 receive payment based on the Federal rate only while SNFs that first received payment from Medicare prior to October 1, 1995 are paid according to the transition rate and are precluded from receiving payment solely based on the Federal rate. In addition, our policy, as stated broadly in transmittal 405 of the Provider Reimbursement Manual, requires that, for purposes of determining a provider's eligibility for the transition, Medicare makes its determination based on the date of first Medicare payment (interim or otherwise) under the present provider number.

For example, when an SNF undergoes a change in ownership, such as a merger

or a consolidation, the payment is determined by the payment history of the surviving entity as indicated by the surviving SNF's provider number. This conforms with longstanding reimbursement policy and payment principles as applied under the former reasonable cost payment system and provides administrative simplicity in addressing complex transactions among SNFs, hospitals, and other entities.

Comment: We received several comments recommending that we adopt a policy where SNFs would be allowed to elect to bypass the transition period and receive payment based on the full Federal rate.

Response: Similar to our response to an earlier comment, we understand how the transition payment methodology may disadvantage certain providers. However, section 1888(e)(1) and (2)(E) of the Act specifically addresses the issue of which providers are paid the full Federal rate and which ones must receive transition payments. As we discussed, the statute requires that SNFs that received their first payment under Medicare before October 1, 1995, are to be paid based on the transition payment methodology described in the interim final rule.

Comment: We received a number of comments related to the Part B add-on and the methodology for computing facility-specific rates for SNFs that participated in the Multistate Nursing Home Case-Mix and Quality Demonstration (NHCMQD) in 1997. Under the interim final rule, these facilities did not receive a Part B add-on as part of their facility-specific rate. The commenters argued that a Part B add-on is appropriate for these SNFs. Several commenters provided detailed arguments asserting that a Part B add-on for these providers is legally supportable under the statute.

Response: It appears to us that a Part B add-on to the facility-specific rate for providers participating in the NHCMQD in 1997 could well be an appropriate payment policy in light of the historical circumstances.

During the NHCMQD, many Medicare Part A patients in these SNFs received certain ancillary items or services provided by suppliers who then billed Medicare directly under Part B. However, we find that the statutory language at section 1888(e)(3)(B) of the Act, that provides the formula for computing facility-specific rates for NHCMQD providers, does not support this policy outcome.

Accordingly, we are maintaining the policy, set forth in the interim final rule, of not including a Part B add-on in the calculation of facility-specific rates for

SNFs participating in the NHCMQD in 1997. We believe this policy is consistent with the statute. The statute treats NHCMQD providers differently from other facilities. For most facilities, the statute directs the Secretary to use a 1995 base year and provides for a Part B "add-on"; for NHCMQD facilities, the statute directs the Secretary to use a later base year (1997) and does not provide for a Part B "add-on." Although a Part B add-on for NHCMQD facilities might be appropriate as a conceptual matter, the statute does not provide for a Part B add-on and we do not believe the lack of a Part B add-on leads to an absurd result.

In our effort to ensure the appropriateness of the payment methodology set forth in the interim final rule, we have decided to make a modification to one aspect of the calculation of the facility specific rates. This change only affects the methodology for determining the inflation factor applied in the calculation of the facility specific rates for certain providers with short cost reporting periods (that is, less than 12 months).

There were three different types of short periods discussed in the interim final rule:

- a. A short period in the base year,
- b. A short period in the initial period, and
- c. A short period between the base year and the initial period.

The interim final rule included separate instructions on how to determine which factor to use for an SNF having a short period. There was, however, no discussion of how to determine which factor to use if a SNF had more than one short period. For example, an SNF could have a short period in the base year and a short period between the base year and the initial period of the PPS.

We now believe that the instructions for item c should not be applied to SNFs which have both a short period in the base year and a short period between the base year and the initial period. If an SNF has a short period in the base year and a short period between the base year and the initial period, the instructions in section (a) should be applied using the short period in the base year.

E. MDS Assessments

Under the SNF PPS, the Federal rate incorporates adjustments to account for case-mix, using a resident classification system that accounts for the relative resource utilization of different patient types. This classification system, RUG-III, assigns beneficiaries into one of 44

groups, using assessment data from the MDS that the SNF completes according to an assessment schedule specifically designed for Medicare payment.

In the interim final rule, we discussed issues relating to the use of the RUG-III classification system under the SNF PPS, including scheduling and other requirements pertaining to the MDS, use of the RUG-III "grouper" software, and the use of an Other Medicare Required Assessment (OMRA) in certain situations following the discontinuation of rehabilitation therapy services.

In this section of the preamble, we are providing responses to comments on a number of issues related to the use of the OMRA, grace days, and the Health Insurance Prospective Payment System (HIPPS) codes used to bill Medicare Part A covered SNF stays. We also address comments and questions about the midnight rule and its effect on the MDS schedule, and provide clarification regarding counting therapy minutes on the MDS, as well as the requirements for the therapy plan of treatment. In addition, we are responding to comments concerning recognition of respiratory therapy and recreational therapy in the payment rates and on the MDS.

Comment: We received numerous suggestions of ways to improve the MDS instrument, the assessment schedule, and the classification system. These comments included suggestions both to increase and decrease the frequency of required MDS assessments, to improve the MDS staging of pressure ulcers, ideas for modifications to individual RUG-III groups, and commenters' requests that we be more directive in our rules about how facilities are to spend the payments they receive from Medicare.

Response: We appreciate all of the suggestions and will consider them in our future work in these areas. The comments were very specific and too numerous to address in this context. Rather, the subject matter and degree of specificity of some of these suggested changes would be more appropriately addressed through manual issuances.

It is also worth noting that at this time, the SNF PPS has been in effect in most facilities for less than 12 months. In the future, when providers have achieved greater stability and familiarity with the system, and we have additional data to guide our decisions, we can consider making additional refinements such as those suggested by the commenters.

1. Billing Issues

Comment: There were several questions submitted with the comments

regarding the HIPPS codes used for billing SNF PPS claims. The questions focused on how to use these codes for billing as distinguished from MDS coding instructions.

Response: Although these codes were not mentioned in the interim final rule, we believe that it would be helpful and appropriate to explain here what the HIPPS codes are as distinct from the MDS information. The HIPPS codes are 5-character codes used solely for billing the Medicare FI for the Part A SNF stay. The codes reflect the RUG-III group into which the beneficiary classified and the reason for the assessment used for determining the classification. The HIPPS code does not appear anywhere on the MDS. The reason for assessment reflected in the HIPPS code is based on information coded in items A8a and A8b of the MDS, but is not a duplication of the data reported on the MDS. Rather, a conversion must be made from the information on the MDS to the reason for assessment identifier that comprises the last two digits of the HIPPS code.

For instructions for billing on the Unified Billing Form 92 (UB-92), see Transmittal 405 of the Provider Reimbursement Manual (PRM, HCFA Pub. 15-1, 7/98) published on our website. These instructions are sent to our FIs and are also available through them.

Further, in the context of billing procedures, we would also like to use this opportunity to clarify our policy on Periodic Interim Payments (PIP). Since the inception of the Medicare program, SNFs reimbursed on the basis of reasonable costs received interim payments during their cost reporting year for the cost of Part A services provided to Medicare beneficiaries. For many years, SNFs have also been permitted to receive PIP—interim payments paid in equal biweekly amounts—for these services if they met the requirements in § 413.64(h) and received intermediary approval. Since July 1987, the statutory authority for PIP for qualifying SNFs has been in section 1815(e)(2) of the Act. Section 1815(e)(1) of the Act was added to include certain requirements, in addition to the requirements in § 413.64(h), specifically applicable to hospitals receiving prospective payments under section 1886(d) of the Act in order for the hospitals to receive PIP. Section 1815(e)(2) of the Act clarified that the additional requirements applicable to those hospitals were not applicable to other types of providers, including SNFs, entitled to PIP. Accordingly, the regulations at § 413.64(h) were revised to provide for the continuing availability of PIP after July 1987 for

these other types of providers, including for Part A services provided by SNFs.

Interim payments, including PIP, provide cost reimbursed providers with estimated payments during the cost reporting year pending submittal and subsequent settlement of a Medicare cost report. A provider can submit its cost report to the intermediary as late as the last day of the fifth month after the end of the cost reporting period. Following submittal, the intermediary's determination of Medicare cost reimbursement to the provider for services provided to beneficiaries during the year cannot be made until the cost report is reviewed, sometimes including audit of the provider's records. Because determination of Medicare reimbursement takes place after the end of the cost reporting year, interim payments are needed during the year until this final payment can be determined.

Because a cost report is not required to calculate prospective payments, interim payments are not necessary to a provider for services paid on the basis of prospective payments. Nevertheless, with the exception of special requirements for hospitals receiving prospective payments under section 1886(d) of the Act, section 1815(e) currently provides for the availability of PIP for certain services, including Part A services provided by SNFs, if the requirements in § 413.64(h) are met. It does not prohibit PIP for SNFs receiving prospective payments.

While the BBA eliminated PIP under the provisions mandating a PPS for home health agencies (HHAs), the Congress made no such requirement under the statutory provisions related to SNF PPS. This may be because, like the preceding SNF payment system, the SNF PPS continues to rely on a daily payment amount, while for the HHA PPS, changes in the unit of payment were contemplated. However, at this time, we see no reason to discontinue administratively our existing policy of allowing PIP for qualified SNFs, though we may choose to evaluate its continuing need in the future.

Therefore, we are permitting the continued availability of PIP for services of SNFs paid under the PPS. For those services, PIP is based on estimated prospective payments for the year rather than on estimated cost reimbursement. An SNF receiving prospective payments, whether or not it received PIP prior to receiving prospective payments, may receive PIP if it meets the requirements in § 413.64(h) and receives approval by its intermediary. Likewise, if an intermediary determines that an SNF which received PIP prior to

receiving prospective payments is no longer entitled to receive PIP, it will remove the SNF from PIP. As provided in § 413.64(h)(5), intermediary approval of PIP is conditioned upon the intermediary's best judgment as to whether payment can be made under the PIP method without undue risk of its resulting in an overpayment to the provider.

An SNF can receive Medicare payment for the bad debts of Medicare beneficiaries if it meets the requirements at § 413.80 and implementing instructions. Payment for these bad debts are not included in the prospective payments but rather are claimed on the Medicare cost report. Also, some SNFs may incur costs for an approved medical education program or may incur other costs that are not included in the prospective payment. Payment for these costs are determined based on the completion of a Medicare cost report. Because final payment for Medicare bad debts and for costs paid outside the prospective payment system is not determined until the cost report is settled, it is appropriate that SNFs which receive prospective payments should receive estimated interim payments during the year for bad debts and for costs paid outside the prospective payment system. Payments for these costs are made in equal biweekly payments in the same manner as PIP. There is no requirement for an SNF to meet in order to receive biweekly payments for these costs because it is the only type of interim payment made for them.

The new regulations providing for PIP for SNFs receiving prospective payments and for biweekly interim payments for costs outside the prospective payment system closely follow the regulations at § 412.116 which provide for PIP for hospitals receiving prospective payments under section 1886(d) of the Act, as adjusted to remove provisions specifically applicable to those hospitals. As with § 412.116 for hospitals and § 413.64 for SNFs under the previous cost-based system, these regulations for SNFs also provide for accelerated payments in certain situations.

2. Corrections

Comment: We received several comments with questions and suggestions regarding the policies governing the correction of MDS errors and billing errors.

Response: The MDS corrections policy is set forth in the State Operations Manual (SOM, HCFA Pub. 7) by HCFA's Center for Medicaid and State Operations. The corrections policy

applies to all users of the MDS and, thus, is beyond the scope of this regulation. We address issues and provide clarification of Medicare policy regarding how to correct or adjust SNF Part A bills to the Medicare program in the Provider Reimbursement Manual.

3. Other Medicare Required Assessment (OMRA)

Comment: There were a number of questions about the OMRA. These included questions about when the OMRA is to be performed and whether it is a full or comprehensive assessment.

Response: An OMRA is required 8 to 10 days after rehabilitation therapy is discontinued for Medicare beneficiaries who have been receiving rehabilitation therapy in the SNF. Specifically, there is confusion regarding whether or not this assessment type is required in certain circumstances. For example, when the beneficiary has no further need for skilled care and has been moved out of the Medicare-certified portion of the institution before the eighth day following the cessation of rehabilitation services or when one or two of three therapy services are discontinued. As stated in our corrections notice to the interim final rule, published in the **Federal Register** on October 5, 1998 (63 FR 53301), the OMRA is not required to be a comprehensive assessment. There are no PPS requirements for comprehensive assessments (that is, those including Resident Assessment Protocols (RAPs)). Comprehensive assessments are only required for clinical reasons, as they have been since implementation of the nursing home reform requirements enacted in the Omnibus Budget Reconciliation Act of 1987 (OBRA 87, Public Law 100-203).

An SNF must perform an OMRA only for those beneficiaries who continue to have skilled care requirements after their rehabilitation therapy services have been discontinued. For those beneficiaries who are not ready for discharge from the facility, and who continue to require a Medicare covered skilled level of care, an OMRA must be performed in order to obtain an accurate classification into one of the non-therapy RUG-III groups.

The assessment reference date of the OMRA must be set on day 8, 9, or 10 after the last day any rehabilitation therapy services were provided. This timing ensures that no therapy minutes will be captured on the OMRA and that the beneficiary's new classification will be into one of the non-therapy RUG-III groups. An OMRA will always result in classification into a non-therapy RUG-III group. For the days between the

cessation of rehabilitation therapy and the assessment reference date of the OMRA, the beneficiary continues to be covered at the therapy RUG-III group level to which he or she was classified before cessation.

We expect that there will be many cases in which the beneficiary will be discharged from the facility shortly after rehabilitation therapy services end. Before PPS, beneficiaries were often discharged from the SNF immediately upon the discontinuation of rehabilitation therapies. Likewise, many SNF residents who received rehabilitation therapy services under Medicare Part A were moved to a non-Medicare level of care following the cessation of therapy services. These same patterns are expected to continue under the PPS.

In circumstances in which the beneficiary is discharged from the facility (or from the Medicare-certified portion of a larger, noncertified institution) before the eighth day following the end of all rehabilitation therapy, there is no expectation by Medicare that an OMRA will be performed. If the beneficiary remains in the Medicare-certified facility through the eighth day following rehabilitation therapy discontinuation, there must be some clinical reason for his or her continuing skilled stay that is supported by documentation in the medical record. We realize that there will be cases in which the beneficiary stays in the SNF for a number of days after rehabilitation therapy ends, in order for the facility staff to verify that his or her status is stable and to assure that the plans for his or her next destination are appropriate and in the best interests of the beneficiary.

By contrast, always waiting to perform the OMRA to verify that the beneficiary is stable and no longer in need of skilled nursing or therapy services is not appropriate. A pattern of OMRA assessments immediately preceding discharge from the facility, or from the Medicare level of care within the facility, would indicate that perhaps the facility is at times using those 8 to 10 days inappropriately. We believe it is unfair to the beneficiary to use any of the 100 Medicare SNF benefit days available in a benefit period unless he or she is actually in need of skilled services. Likewise, it is an inappropriate use of Medicare trust fund dollars for Medicare to pay for SNF days that are not needed by the beneficiary.

The beneficiary should not be kept in a Medicare Part A stay if skilled services are neither needed, nor being provided. We believe that nursing homes' clinical staff should know when there are no

skilled services being provided to a beneficiary. Our guidelines provided in the PRM (Transmittal 405) reinforce the expectation that facilities may, and in fact are expected to, act in the best interest of the beneficiary with regard to use of the beneficiary's limited SNF benefit days, by ending Medicare Part A coverage appropriately. (See also the discussion below regarding circumstances that serve to discontinue a presumption that the SNF level of care requirement is met by a beneficiary who has classified into one of the upper 26 RUG-III groups.)

F. Certification and Recertification

Comment: We received a few comments regarding the statutory requirement for initial certification and periodic recertification as to level of care, as required under section 1814(a)(2) of the Act.

Response: The comments regarding this particular provision are addressed later, in the discussion on coverage and level of care determinations under the SNF PPS. However, we would like to take this opportunity to clarify that the required certification and recertification statements are not the same as any requirements specifically related to the plan of treatment for therapy that is required for purposes of coverage, or to the overall requirement for the multidisciplinary plan of care required by the long-term care facility requirements for participation at section 1819(b)(2) of the Act.

G. MDS Scheduling Requirements

1. Grace Days

Comment: We received several comments asking about the appropriate use of the 3-day grace period provided for the Medicare 5-day assessment. There is some confusion about when use of the grace days could result in the facility being at a high risk for an audit.

Response: Days six, seven, and eight, of the Medicare covered stay, were provided as grace days for setting the assessment reference date for the Medicare 5-day assessment. This assessment is to have an assessment reference date (MDS 2.0 Item A3a) of any day one through eight of the Medicare Part A stay. Days one through five are optimal but days six through eight are also acceptable, and for some residents may actually be more appropriate; for example, to allow maximum flexibility for nurses to determine when to set the assessment reference date for the beneficiary's MDS, and thereby lessen the burden of the increased frequency of assessments that accompanied the PPS. Thus, the

resident can be assessed using any one of these first eight days as the assessment reference date for the Medicare-required 5-day assessment.

However, we discourage the routine use of grace days for assessing every Medicare admission. We plan to identify patterns of inappropriate use as we gain a better understanding of what facilities' practice patterns are. When a facility routinely uses a grace day as the assessment reference date for the 5-day assessment, it loses the cushion that these days provide against performing the MDS later than day eight and, thus, risks being faced with payment at the default rate.

At this time our main interest is to encourage facilities to perform assessments timely and to recognize the grace days as a cushion and to use them as such, rather than as deadlines for setting each beneficiary's assessment reference date. The grace days are also provided to offset any incentive that facilities may have to initiate therapy services before the beneficiary is able to tolerate that level of activity.

Our discussion in the interim final rule about the possibility of audits was intended to address the possible practice of routinely using grace days for Medicare assessments. We were cognizant that the routine use of a grace day for the 5-day assessment would pose a temptation to back-date the assessment fraudulently when day eight was missed. We believed that any facility that routinely used grace days for the required assessments was liable to have assessments billed at the default rate; and that the absence of default rate billings in the facility's claims might indicate that some misrepresentation of the assessment reference dates had occurred.

Unlike the routine use of grace days described above, we do expect that many beneficiaries who classify into the rehabilitation category will have 5-day assessment reference dates that fall on grace days. There are many cases in which the beneficiary is not physically able to begin therapy services until he or she has been in the facility for a few days. Thus, for a beneficiary who does not begin receiving rehabilitation therapy until the fifth, sixth, or seventh day of his or her SNF stay, the assessment reference date may be set for one of the grace days in order to capture an adequate number of days and minutes in section P of the current version of the MDS to qualify the resident for classification into one of the rehabilitation therapy RUG-III groups.

Another reason for the provision of three grace days for the 5-day assessment was to make it possible for

beneficiaries to classify into the two highest RUG-III rehabilitation sub-categories. Classification into the Ultra High and Very High Rehabilitation sub-categories is not possible unless the beneficiary receives the sub-category's minimum level of services during the first seven days of the stay.

We also intended to minimize the incentive to facilities to provide too high a level of rehabilitation therapy to newly admitted beneficiaries. Having these extra few days allows time for those beneficiaries who need it, to stabilize from the acute care setting and be prepared for the beginning of rehabilitation in the SNF. We expect facilities will not compromise any beneficiary's health by beginning rehabilitation therapy prematurely or at a level that is too rigorous for the individual's status. In summary, use of grace days is acceptable and permitted for patients with any condition. However, a facility that uses grace days routinely may be subject to audit to determine that assessment reference dates are accurately reflected.

Comment: One commenter requested that we modify the statement at section II.B.7 of the interim final rule that states SNFs "must submit the Resident Assessment Protocols (RAPs) with either the 5-day or the 14-day assessment" to indicate that the SNFs must submit the completed RAP Summary Form, section V of the MDS with either the 5-day or 14-day assessment.

Response: This may be a helpful clarification for providers; however, we want to be certain that providers fully understand this requirement. We will take this opportunity to make clear that the RAPs are not a PPS requirement. The requirements for completion of section V and the care planning responsibilities of facility clinical staff are unchanged by the PPS. We included the clinical requirement for RAPs in the interim final rule in an effort to help providers to understand how the Medicare required SNF PPS assessments coordinate with the required clinical assessments.

The requirement for RAPs is entirely outside of the SNF PPS. In fact, if the clinical initial admission assessment (item AA8a of the MDS 2.0 = "01") was performed before the beneficiary started his Medicare covered SNF stay, neither the Medicare required 5-day, nor the Medicare 14-day assessment is required to have a completed section V. There are no care planning requirements associated with any full MDS assessment performed solely for the purpose of complying with the Medicare assessment schedule for a Part

A Medicare beneficiary's SNF stay. The Medicare PPS requirements are separate from the clinical requirements.

However, we have designed the Medicare requirements so that an SNF can coordinate the scheduling of assessments to avoid duplication of effort.

2. Completion and Locking

For Medicare payment, we are requiring that any assessment, including the 5-day, must be "completed" (that is, signed by all members of the care team) within 14 days of the assessment reference date (MDS item A3a). That is, the completion date at MDS item R2b, must be a date that is within 14 days of the date at A3a. Then the assessment must be "locked" within seven days of the date at R2b, and transmitted to the State in which the SNF operates within 31 days of the final lock date (State Operations Manual, HCFA Pub. 7).

However, there are other considerations to keep in mind. There is still the clinical requirement that an Initial Admission Assessment must be "completed" by the 14th day of the nursing home stay. This means that for a Medicare beneficiary who is newly admitted to the SNF for a covered Part A stay, the SNF must complete a comprehensive MDS by day 14, regardless of the assessment reference dates on the Medicare-required 5 day and 14 day assessments.

As has been the case since the OBRA 1987 requirements were implemented, a comprehensive assessment (Initial Admission Assessment) is due to be completed by the 14th day of the SNF stay. In addition, for Medicare beneficiaries in the SNF for a covered Part A stay, a 5-day assessment must be performed, with an assessment reference date on any day one through eight of the Medicare Part A covered stay, and must be completed within 14 days of the assessment reference date. Also, by the end of the second week in the Medicare Part A covered stay, the Medicare 14-day assessment must be performed. This assessment must have an assessment reference date of any day 11 through 19 (including the 5-day grace period provided for this assessment).

Given these requirements during the first weeks of the SNF stay, and considering that Medicare Part A coverage often begins on the day of admission, we believe that in many cases nursing homes will opt to complete a single assessment to satisfy the requirements for both the 5-day (or 14-day) assessment and the Initial Admission Assessment. In this example, the Medicare 5-day assessment, with an assessment reference date of any day,

one through eight of the stay, will be a comprehensive assessment and will have to be completed within 14 days of the start of the SNF stay. The day of admission is counted as day one. The assessment must comply with the requirements for the Initial Admission Assessment. That is, it must be a comprehensive assessment, including the RAPs.

When the Medicare 5-day assessment is also used to fulfill the requirement for the Initial Admission Assessment, the Medicare 14-day assessment may be performed using any day 11 through 14 of the stay as the assessment reference date (MDS item A3a) and, in addition, the SNF may use the five available grace days (through day 19), if necessary. The Medicare 14-day assessment must then be completed (dated at item R2b) 14 days after the assessment reference date, locked in seven days, and so forth. Keep in mind that there are no grace days for completion of the Initial Admission Assessment. As always, the Initial Admission Assessment must be completed by day 14. Another factor to consider in timing completion and locking of assessments is that bills may only be sent for assessments that have been locked.

3. Discharge and Leave of Absence

Comment: One commenter asked for a definition of "leave of absence" as distinguished from a "discharge."

Response: Although this is not a distinction that is specific to the PPS, we would like to define these terms in the context of clarifying another somewhat misunderstood aspect of Medicare coverage, the so-called "midnight rule" and the clinical requirements for Discharge forms and Re-Entry Tracking forms. We received questions from other commenters on how to handle cases in which the beneficiary is out of the facility at the time of census-taking, midnight. These activities are all interrelated and have generated many questions during the initial phase of PPS implementation. There are a number of reasons why a beneficiary may leave the SNF for a "leave of absence." These include a temporary home visit, a temporary therapeutic leave, or a hospital observational stay of less than 24 hours in which the beneficiary is not formally admitted to the hospital and is not discharged from the SNF. In each of these situations, there is no requirement for the SNF to complete a Discharge or a Re-Entry Tracking form.

When a beneficiary goes to an acute care hospital emergency room (ER) during his or her SNF stay and is in the ER at midnight, there is an additional

aspect with regard to Medicare payment. According to Medicare rules, the day preceding the midnight on which the beneficiary was absent from the facility becomes a day for which the SNF may not bill Part A of Medicare. This is known as the "midnight rule." However, for clinical purposes, as long as the beneficiary returns to the facility in less than 24 hours, was not admitted to the hospital, and was not discharged from the SNF, this time in the ER is considered a "leave of absence" and requires no discharge form.

Likewise, from the perspective of Medicare payment under PPS, there is no requirement for any additional assessment. The day preceding the midnight is not a covered Part A day and, therefore, the Medicare assessment "clock" is altered by skipping that day in calculating when the next Medicare assessment is due. From a clinical standpoint, the leave of absence does not affect the "clock" for the clinical assessments.

For example, if the beneficiary is due for his 30-day assessment on March 30 (day 30 of his Medicare covered stay), but he spends midnight of March 27 in the ER, day 30 of his Medicare Part A covered stay now falls on March 31, as March 27 does not count as one of the beneficiary's 100 days of Medicare SNF care. In other words, the count of days in the Medicare covered stay changes when there is a noncovered day because the facility cannot count that day as one of the beneficiary's benefit days. Given the flexibility of the assessment windows for the Medicare assessments, altering the count of days as described here should have no more than a negligible effect on assessment scheduling for facilities.

Of course, a beneficiary who is required to be in the ER at midnight may well have experienced a significant change in clinical status. In that case, the facility must comply with the clinical requirement to complete a Significant Change in Status Assessment when the beneficiary returns to the SNF. The Medicare payment requirements and the midnight rule have no bearing on this requirement for completion of a Significant Change in Status Assessment.

Alternatively, if the beneficiary is in the ER for more than 24 hours, or is actually admitted to the hospital or discharged from the SNF, a Discharge Tracking form is required. In addition, when the beneficiary returns to the SNF, a Re-Entry Tracking form is required, and a Return/Readmission Assessment (MDS 2.0 item A8b-5) must be performed to restart the Medicare assessment schedule. The Return/

Readmission Assessment fulfills the requirement for a Medicare 5-day assessment in this situation, and the next required assessment would be the Medicare 14-day assessment.

Finally, with regard to MDS scheduling requirements, we are taking this opportunity to clarify the regulations text at § 413.343(b), which specifies the assessment schedule required under the SNF PPS. The current language requires the performance of such assessments on the 5th, 14th, 30th, 60th, and 90th days "following admission." However, as indicated in the preceding discussion, it is not the admission date per se that determines the start of the Medicare assessment schedule, but rather, the commencement of Medicare-covered care in the SNF. Although Medicare-covered posthospital SNF care often does begin immediately upon a beneficiary's admission to the SNF, the existing language fails to address those situations in which such care does not commence until sometime after the day of admission. The Medicare required assessment schedule is based only on those days in the Medicare Part A covered stay and, thus, cannot be scheduled based on the day of admission per se. Therefore, we are revising the language in the regulations text to take into account the possibility that a beneficiary's "posthospital SNF care" (that is, SNF care that is covered under Medicare Part A) may begin subsequent to the day of his or her actual admission to the facility. The Medicare required assessments are to be performed so that, using the first day of posthospital SNF care as day 1, there is a full MDS assessment on the 5th day, the 14th day, the 30th day, the 60th day and the 90th day of the SNF stay.

H. Other Medicare MDS Requirements

In the interim final rule, we stated that collection of medication information using a revised version of section U of the MDS would be required under PPS, beginning October 1, 1999. The criteria we established for this process anticipated that a refined section U would be developed to facilitate streamlined data collection, maximize data accuracy, and minimize burden to facilities. We have, to date, made considerable progress in our work on the section U refinements. However, due to systems constraints resulting from the need to achieve Year 2000 (Y2K) compliance (see the further discussion of the Y2K issue below in the context of the partial delay in SNF consolidated billing implementation), we will not be able to implement the refined version of section U until after

the first months of the year 2000 have passed. Therefore, we have determined that the most straightforward and least burdensome approach is to defer section U implementation until October 1, 2000.

I. Medical Review

Comment: We received several comments requesting that we publish the medical review criteria to be used now that PPS is in place. Also, there were requests that we institute consistent medical review policies across FIs.

Response: We are currently formalizing the medical review criteria that will be used in the review of SNF PPS bills. Certainly, one of the primary goals of the new policy is to provide reviewers with guidelines that will facilitate consistent national medical review policy, one of the initial goals of implementing the PPS. We recently published a PM (PM transmittal No. A-99-20, May 1999) to instruct medical reviewers in the new process. One aspect of the reviews of SNF PPS bills to be performed by the FIs focuses on the MDS information and its consistency with the documentation in the rest of the medical record. In addition, the review process focuses on identification of instances in which inappropriate services were provided or in which the beneficiary did not meet the requirements for Medicare Part A coverage in an SNF.

Comment: There were questions about how the MDS information might be matched to claims data to facilitate monitoring or auditing of SNF reporting practices.

Response: The process for matching the bill to the MDS takes place at HCFA. We use the bill data forwarded to us by the FIs to match to the appropriate MDS from the HCFA MDS Repository. From these matched or unmatched files, we generate various reports for use by HCFA and the FIs in their audit functions.

Comment: We received a comment requesting that we instruct FIs to give demand bills a high priority within the review process and to process these submissions no later than 30 days from the date of the request.

Response: The policy governing how demand bills will be processed under the SNF PPS will be determined by considering the FIs' overall workloads, of which the SNF PPS represents only a small portion.

Comment: A commenter requested that we generate and disseminate to the nursing home industry and to the payers, the full process of transmission of clinical Medicare Part A information and claims submission requirements,

including documentation requirements needed by the fiscal intermediary for late assessment reference dates.

Response: The requirements for the transmission of all MDS assessments can be found in the **Federal Register** published on December 23, 1997 (62 FR 67174). There are no separate requirements for Medicare Part A information. The facility must submit the MDS to the State in which it operates and the State transmits it to us. In contrast, the SNF submits claims to the FI, as they did before PPS. Each claim is transmitted to us by the FI after it has been paid, and we match the claim to the appropriate MDS. The FI may request any information it deems to be necessary to verify the level of services billed by the facility.

Comment: We received one comment suggesting that we should exempt from post-payment review or on-site audit, any 5-day assessment with an assessment reference date on one of the grace days that results in the beneficiary's classification into a Low Rehabilitation group.

Response: This comment reflects a misunderstanding of our policy regarding grace days. As explained above in this final rule, the grace days are available for use, without penalty. The reference to audits in the interim final rule was not intended to preclude any appropriate use of the grace days. Therefore, although the comment indicates that beneficiaries who classify into one of the low rehabilitation groups should be exempt from review (presumably because of the requirement for six days of nursing rehabilitation services in order to qualify for this RUG-III group), there is no reason for us to consider excluding any type of Medicare SNF claims from post-payment review.

Comment: Several commenters cited the BBA mandate that we must implement a quality monitoring system. Section 4432(c) of the BBA requires the Secretary to establish a medical review process to examine the effects of the SNF and PPS related provisions on the quality of SNF services furnished to Medicare beneficiaries, with particular emphasis on the quality of non-routine covered services and Medicare-covered physician services.

Response: The quality of care provided to beneficiaries is paramount in our view. We will use our existing survey and enforcement activities (along with the new techniques and data that are now becoming available with the advent of prospective payment) to ensure the quality of SNF services provided to Medicare beneficiaries.

In addition to the more traditional medical review process we are establishing, as described above, we have also begun work toward the establishment of a quality medical review process that is specifically designed to fulfill the BBA mandate. We have developed an SNF PPS Quality Medical Review Pilot project that uses MDS and other data to monitor and target quality and program integrity problems. This monitoring will be accomplished by testing a more integrated and cooperative approach to medical review of SNF services using several pilot states to partner Peer Review Organizations (PROs), FIs, State Survey Agencies, and Medicaid agencies to assess, monitor, and improve the quality of Medicare SNF services under the PPS.

We are implementing a two-tier strategy using the PRO Special Project process. This strategy is expected to strengthen program integrity and quality review in SNFs, promote SNF quality improvement, deter fraud and abuse, and enhance beneficiary protection. The first tier is a statistical analysis PRO (StatPRO), that is testing a data driven approach which analyzes MDS data to flag potential quality of care and program integrity problems. The MDS data set will be linked with other HCFA data sets (such as, Medicare Part A and B claims, OSCAR-Online Survey Certification and Reporting System, HCIS-HCFA Customer Information System, FI payment, and program integrity data) to identify patterns and trends in care. The second tier of the project pilot tests a data based approach using StatPRO and other data to examine State trends and variations in SNF data and patient care through the collaboration of quality medical review (QMR) teams composed of the PRO, FI, and State survey agency in two States (NC and CO) and in three States (AZ, MA, and MD) the Medicaid Agency is added. The QMR pilots will field test an integrated model where they will work together to better understand each other's program integrity and quality review roles, develop collaborative approaches within their regulatory authority, test a targeted clinical data driven intervention strategy, target beneficiary protection, and deterrence of fraud and abuse. Finally, we will use the vast data resources available from the national MDS data repository to support our quality initiatives.

J. Rehabilitation Therapy Services and PPS

Comment: Many commenters questioned when rehabilitation therapy may begin in the SNF stay.

Response: Although rehabilitation therapy may begin as early as day one of the Medicare Part A SNF stay, we note that all of the rehabilitation therapy services (PT, OT, and SLP) must meet each of the following criteria in order to be coded in the MDS as minutes of rehabilitation therapy:

- The service must be ordered by a physician.
- The therapy intervention must relate directly and specifically to an active written treatment regimen established by the physician after any needed consultation with the qualified rehabilitation therapy professional and must be reasonable and necessary to the treatment of the beneficiary's illness or injury (section 230 of the Medicare Skilled Nursing Facility Manual, HCFA Pub. 12).
- An appropriately licensed or certified individual must provide or directly supervise the therapeutic service and coordinate the intervention with nursing services.

Even though these three criteria are not new with PPS, the establishment of a new payment system has heightened interest in understanding and satisfying these standards. For instance, in addition to the commenters' question about when rehabilitation therapy services can begin, we have received many questions during the first year of PPS implementation regarding standards for supervision of rehabilitation therapy assistants and aides, and many questions regarding the physician signature requirements for the rehabilitation therapy plan of treatment. Accordingly, we will take this opportunity to provide further clarification of those issues. The rehabilitation therapy service must be ordered by a physician. The Medicare policy regarding the requirement for the physician signature on the therapy plan of treatment has not changed. As is stated in the SNF Manual, rehabilitation therapy services provided to a beneficiary in a SNF must be directly and specifically related to an active written treatment plan established by the physician after any needed consultation with a qualified therapist. Implementation of the PPS did nothing to alter this guideline. We will, however, take this opportunity to clarify what is required for coverage of rehabilitation therapy.

As stated in the language in the SNF Manual cited in the preceding paragraph, Medicare requires the physician to make decisions regarding the amount and intensity of rehabilitation therapy services provided to Medicare beneficiaries in SNFs after consulting with the professional

therapist. This requirement is based on our commitment to ensuring quality care for Medicare beneficiaries, and also reflects the requirements for participation (at section 1819(b)(6)(A) of the Act), which specify that the medical care of every SNF resident must be provided under the supervision of a physician. Our policy has not changed, and we are taking this opportunity to clarify that policy. The physician's responsibility in the development of a rehabilitation therapy plan of treatment ensures that the services to be provided will not exceed the beneficiary's abilities as constrained by his clinical status. In addition, we believe that the physician's clinical judgement is an important aspect in preventing injuries that can result from the provision of inappropriate rehabilitation therapy. For example, the rehabilitation plan of treatment for a beneficiary with a hip fracture should be developed with an awareness of his or her limitations due to severe osteoporosis and emphysema. Unless the beneficiary's entire clinical condition is taken into account, there is a significant risk of injury and of a compromised medical status.

We expect that the same care will be taken by the physician and SNF staff to document physician responsibility for developing the therapy plan of treatment, including precautions, that is reasonably expected to be taken for any other element of the medical record. We realize, however, that in the SNF setting there may not be a physician on the premises every day. Therefore, Medicare allows the professional therapist to develop a suggested plan of treatment and to begin providing services based on that plan prior to obtaining the physician's signature on the plan. We continue to require that the plan of treatment must be a physician's responsibility after any needed consultation with a qualified therapist, and that the requirement for physician verification of the suggested plan of treatment will be obtained within a reasonable amount of time. However, a physician signature must be obtained before the facility bills Medicare for payment for the rehabilitation therapy services provided to the beneficiary based on the plan of treatment he or she has approved. In this way, the facility can be sure that the level of therapy for which it bills Medicare is the level the physician deems to be medically necessary. We expect that the type and intensity of therapy billed will always match the type and intensity of therapy on the signed therapy plan of treatment.

We understand that many physicians use the fax to participate actively in the review of written plans of care and so

believe that it is appropriate to accept physicians' faxed signatures for the plan of treatment. As always, whenever the plan of treatment is altered in any way, the modification must be made in writing. If the physician is not the person making the modification, the therapist who is making the change must notify the physician timely, and the physician must sign the change within a reasonable amount of time.

In addition to the issues discussed above, we would like to clarify the requirements for the rehabilitation therapist's initial evaluation of a Medicare beneficiary in a SNF stay and the requirements for licensed therapist supervision of therapy assistants and therapy aides when they provide therapy services to Medicare beneficiaries. The initial evaluation, performed by the licensed therapist and necessary for the development of the plan of treatment, must be performed during the beneficiary's SNF stay. It is not acceptable to use an evaluation that was performed for instance, in the acute care hospital or the rehabilitation hospital setting as the evaluation of the beneficiary in the SNF, because the beneficiary's status must be evaluated as he or she presents in the SNF setting. The evaluation, and the resultant plan of treatment, developed in the acute care hospital or rehabilitation hospital is relevant to the specific type of setting and is not interchangeable with an evaluation and plan of treatment developed for the beneficiary in the SNF setting. The time that it takes for the therapist to perform this evaluation may not be recorded as minutes of therapy received by the beneficiary.

An appropriately licensed or certified individual must provide or supervise the therapeutic service and coordinate the intervention with nursing services. As stated above, Medicare expects that services will be provided by, or supervised by, appropriately licensed or certified professionals.

Physical and occupational therapy assistants may provide rehabilitation therapy services under the supervision of the professional therapist. A rehabilitation therapy assistant must be under the general supervision of a professional therapist who is accessible while the assistant is providing services to the beneficiary. The therapy assistant cannot supervise a therapy aide. It is up to the professional therapist to ensure that the assistant is capable of performing therapy services without the more stringent "line-of-sight" level of supervision required by therapy aides.

A therapy aide must be supervised personally by the professional therapist in such a way that the therapist has

visual contact with the aide at all times. Therapy aides are not to perform any services without "line-of-sight" supervision. Similarly, a therapy aide must never be responsible for provision of group therapy services, as this is well beyond the scope of services that they are qualified to provide.

A therapy student who is participating in field experience must also be under the "line-of-sight" level of supervision of the professional therapist. Even though these students may become licensed therapists within months of the field training portion of their school program, they are not licensed or certified for practice in an unsupervised status. Further, none of the minutes of therapy services provided by the students may be recorded on the MDS as minutes of therapy received by the beneficiary. Medicare recognizes the costs associated with approved educational activities as a pass-through (see § 413.85).

Comment: Many commenters had questions about the correct counting and recording in the MDS of minutes of rehabilitation therapy.

Response: Section P of the current version of the MDS contains the items that capture the amount of time each nursing home resident spends receiving rehabilitation therapy. Thus, it is in section P that the clinician records the number of days and minutes of rehabilitation therapy (PT, OT, ST) received by the individual beneficiary during the past seven days, or since admission to the SNF, whichever is shorter.

The directions for completion of section P instruct the assessor to look back over the "last 7 calendar days," counting only post admission days and minutes of therapy, when counting the days and minutes of rehabilitation therapy received by the beneficiary. The number of minutes recorded here must be the actual number received by the beneficiary. Seven calendar days are, by definition, consecutive days.

In the case of a Medicare 5-day assessment, however, the nurse assessor will choose as the assessment reference date (MDS item A3a), any day one through eight of the covered stay, and will look back over the prior seven calendar days (or over the days since admission if there are fewer than seven days since admission) to count the number of days upon which more than 15 minutes of therapy were received and the number of minutes that were received by the beneficiary during those days. It is irrelevant if there is a break in therapy (for example, for a weekend or holiday) during that time. For example, if day five of the stay is chosen

as the assessment reference date, the assessor would look back to admission to count the patient's PT, OT, and ST time. If the beneficiary received PT for 50 minutes on both the second and fifth days of the Part A covered stay, that would be recorded as two days of PT and 100 total minutes of PT. The actual number (not rounded) of minutes must be recorded on the MDS. Minutes cannot be rounded to multiples of 10 or 15.

The rehabilitation therapy time reported on the MDS is a record of the time the beneficiary spent receiving therapy services, not a record of the therapist's time. As stated in the August 1996 publication, Long Term Care Resident Assessment *Instrument Questions and Answers, Version 2.0*, the beneficiary's "therapy time starts when he begins the first treatment activity or task and ends when he finishes with the last apparatus and the treatment is ended."

Set-up time is included, as is time under the therapist's or therapy assistant's direct supervision. PT, OT, and ST provided outside the building may be counted and recorded on the MDS, as long as the staff who provide therapy are qualified to provide the service. In the State Operations Manual (SOM, HCFA Pub. 7) Transmittal #272, pp. R64, "The therapy treatment may occur inside or outside the facility." This includes the time it takes for the therapist to take the beneficiary to his or her home for a home visit before discharge as long as the therapist uses the time in the car to teach or discuss the beneficiary's treatment or treatment goals, and for family conferences when the beneficiary is also present.

Whether the time spent evaluating the beneficiary is counted depends on whether it is the formal initial evaluation or an evaluation performed after the course of therapy has begun. The time it takes to perform the formal initial evaluation and develop the treatment goals and the plan of treatment may not be counted as minutes of therapy received by the beneficiary. However, a reevaluation—that is, a hands-on examination of the beneficiary and not simply an update to the documentation and revision of the care plan—that is performed once a therapy regimen is underway (for example, evaluating goal achievement as part of the therapy session) may be counted as minutes of therapy received.

This policy was established because we do not wish to provide an incentive for facilities to perform initial evaluations for therapy services for patients who have no need of those specialized services. However, we

believe that the initial evaluation is an appropriate cost of doing business. Therefore, the cost of the initial assessment is included in the payment rates for all Medicare beneficiaries in covered Part A SNF stays.

For beneficiaries who do not classify into one of the Rehabilitation RUG-III groups, the therapy non-case-mix component is part of the daily rate. The amount, \$0.91, is reflected in the rate for all of the non-therapy RUG-III groups.

The Long Term Care Resident Assessment Instrument Questions and Answers Version 2.0, clarifies how to account for therapy provided to an individual within a group setting. It states that if the group has four or fewer participants per supervising therapist (or therapy assistant under general supervision by the therapist) then it is appropriate to report the full time as therapy for each patient. The example used is that of a therapist working with three patients for 45 minutes on training to return to the community. Each patient's MDS would reflect receipt of 45 minutes of therapy for this session.

Although we recognize that receiving PT, OT, or ST as part of a group has clinical merit in select situations, we do not believe that services received within a group setting should account for more than 25 percent of the Medicare resident's therapy regimen during the SNF stay. For this reason, no more than 25 percent of the minutes reported in the MDS may be provided within a group setting. This limit is to be applied for each therapy discipline; that is, only 25 percent of the PT minutes reported in the MDS may be minutes received in a group setting and, similarly, only 25 percent of the OT, or the ST minutes reported may be minutes received in a group setting.

To summarize, the minutes of therapy provided by at least one supervising therapist (or therapy assistant under general supervision by the therapist) within a group of four or fewer participants, may be fully counted, provided that those minutes account for no more than 25 percent of the resident's weekly therapy in that discipline, as reported in the MDS. The supervising therapist may not be supervising any individuals other than the four or fewer individuals who are in the group at the time of the therapy session. Naturally, provision of group therapy time in excess of the 25 percent threshold is allowable, but those minutes may not be counted in section P of the MDS for purposes of RUG-III classification for Medicare Part A beneficiaries.

Under section 1814(a)(2)(B) of the Act, a covered SNF level of care is

defined in terms of those services that necessitate the involvement of skilled personnel, are needed and received on a daily basis and, as a practical matter, can be provided only in an SNF on an inpatient basis. Additionally, the requirements for participation at section 1819(b)(4)(A) of the Act require an SNF to furnish the full range of nursing and specialized rehabilitative services needed to attain or maintain each resident's highest practicable state of well-being, in accordance with the comprehensive plan of care. This means that there are to be no limits placed on the services to be provided to the beneficiary due to the facilities interpretations of how many minutes are "allowed" by the given RUG-III group.

The RUG-III classification system uses minimum levels of minutes per week as qualifiers for classification into the rehabilitation therapy groups. These minutes are minimums and are not to be used as upper limits for service provision. Similarly, there are instances in which beneficiaries in the so-called "clinical categories," Extensive Services, Special Care and Clinically Complex, will need some limited amounts of rehabilitation therapy services, which they should receive, even though they may not require a level that would qualify them for one of the rehabilitation groups. The SNF PPS is based on averages, and a facility that continues to provide services as they are needed by its beneficiaries should receive payments that, in the aggregate, are adequate to pay for those services. Any policy of holding therapy to the bare minimum, regardless of beneficiary need, is inconsistent with the statutory requirements discussed above, and will result in poor outcomes, longer lengths of stay, and a degradation in the facility's quality of care.

Section T of the current version of the MDS must be included with each Medicare PPS assessment, but in the case of a Medicare five day assessment, the clinician captures minutes of therapy that are anticipated for the beneficiary during the first two weeks of the nursing home stay. This makes it possible for the beneficiary to classify into the appropriate RUG-III rehabilitation group based on the anticipated receipt of rehabilitation therapy, even though the assessment is done during the first few days of the SNF stay.

Section T of the current version of the MDS contains three items, T1b, T1c and T1d, in which the assessor is to record "ordered therapies." The T1b item asks, "Has physician ordered any of the following therapies to begin in FIRST 14

days of stay—PT, OT, or speech pathology service?" If the answer to this question is yes, then the number of expected minutes and days is completed in items T1c and T1d of the current version of the MDS. If the answer is no, then there is nothing to report in T1c or T1d.

If the physician orders therapy for 10 days, the projected number of days in section T will be 10 rather than 14; likewise, if the physician does not order a limited number of days, the projection will be based on the entire two weeks, assuming the beneficiary's continued stay and receipt of services.

The RUG-III grouper takes into consideration both the days and minutes already received by the beneficiary, as reported in section P of the current version of the MDS, and the days and minutes expected to be received in the first two weeks of the stay. The number of days and minutes expected, as reported in section T, should include those already received.

For example, the beneficiary received an hour of OT on both the fourth and fifth days (a Monday and Tuesday) of the SNF stay. The prescribed regimen calls for the beneficiary to receive an hour of OT daily, Monday through Friday, during the first two weeks in the SNF. The assessment reference date was set for the fifth day of the stay; two days and 120 minutes were reported as having been received in section P of the MDS, and 10 days and 600 minutes were reported as anticipated in section T. The 10 days and 600 minutes recorded in section T include the 2 days and 120 minutes already received, in addition to the upcoming three days and 180 minutes expected to be received in the first week, and the five days and 300 minutes of therapy in the second week.

We realize that reporting therapy time that has not yet been provided is a significant change for providers, but it is in compliance with the grouper logic and allows the facility to provide the most accurate representation of the services to be provided to the beneficiary during the first assessment period.

K. RUG-III Groups

Comment: We received a few comments stating that the "limits" on therapy minutes imposed by the RUG-III groups were too low, and that more than 720 minutes should be allowed for beneficiaries in the highest RUG-III groups.

Response: The RUG-III system does not impose limits on the services a resident may receive; rather, it is used to determine how much Medicare pays for the services that the resident

receives. The minutes used to classify beneficiaries into RUG-III groups are in no way to be taken as upper limits. The 720-minute threshold for the Ultra High sub-category is a minimum for purposes of classifying residents. In fact, during the demonstration, there were beneficiaries who were receiving more than 1,000 minutes per week, and we expect that there will be similar instances during the national implementation. All of the groups were created based on a continuum of minutes being provided, including Ultra High. Just as we expect to see beneficiaries in the High Rehabilitation sub-category receiving 450 minutes per week, we expect that as many minutes as are needed will be provided to beneficiaries in the Ultra High groups.

Comment: We received a comment requesting that we explain how the RUG-III grouper works. The commenter believed that we failed to explain fully in the interim final rule the grouping logic that restricts classification into the Rehabilitation Ultra High and Very High sub-categories to beneficiaries who have a full week of therapy recorded in section P of the MDS.

Response: The grouper software uses the minutes and days recorded in sections P and T together to classify beneficiaries into the RUG-III rehabilitation groups. However, in order for a beneficiary to classify into the upper two sub-categories, Ultra High and Very High, he or she must have received at least one full week (five days) of therapy at the level that would qualify for these groups.

For example, suppose a beneficiary is admitted on Monday, May 1 and begins PT and OT on May 4. The beneficiary receives 90 minutes of PT and 60 minutes of OT on the 4th, 5th, 6th, 7th, and 8th of May. The assessment reference date for the Medicare 5-day assessment is Monday, May 8. The beneficiary will classify into the Ultra High sub-category based on having received more than 720 minutes of therapy across at least two disciplines during the past seven days, as recorded in section P of the MDS. If, on the other hand, the beneficiary received this level of therapy on only four of the first seven days in the SNF, he or she would classify into the High Rehabilitation sub-category since this is the highest level of classification that is possible when a minimum of 500 minutes and five days of therapy have not been provided.

We have posted a tool on our web site that allows the user to follow the grouper logic manually. It walks through each step of the grouping logic

and we believe it is a useful learning tool. The website address is: <www.hcfa.gov/medicare/hsqb/mds20/>.

Comment: There were a few comments regarding the use of the combination of physician visits and order changes to qualify beneficiaries for the Clinically Complex RUG-III category. One of the commenters argued that these criteria are unacceptable because an SNF represents not a medical model but rather a nursing model; as such, the physician's involvement and participation may be limited, or may result from consultation sought by the facility's nursing staff due to changes in a resident's condition or the need for specific services. Another commenter inquired about the specific definition being used to define a "physician order change."

Response: These comments are representative of concerns that have been expressed during the initial implementation of the SNF PPS. While we are aware that many facilities operate using a nursing model as opposed to a medical model of care delivery, the commenter's further observation on why the nursing staff would consult with the physician provides the explanation for why physician order changes and visits are qualifiers for the RUG-III groups.

The RUG-III system uses clinical events, conditions, and services as indicators of severity. The results of the research that is the basis of the RUG-III system showed that an increased frequency of physician visits and order changes are indicators of a beneficiary's clinical instability. As in the commenter's example, the nursing staff may consult with the physician due to changes in the beneficiary's condition that require medical intervention or the need for specific services that require a physician order.

We would also like to make clear what constitutes an order change. The specific issues that have been raised include whether an order to continue a specified treatment is a new order and, therefore, counts as an order change; whether a sliding scale medication order counts as a new order every time the clinician administers one of the different dosages specified in the scale; whether orders written to clarify a previous order count; and, whether all doctor's visits count in the number of physician visits item.

A physician's order to continue or renew some specified treatment or regimen would not be considered to be an order change, nor would an order written solely to clarify an earlier order.

As stated in the Long Term Care RAI User's Manual, the definition of an order change does not include admission orders, return admission orders, or renewal orders without changes. Similarly, a sliding scale dosage schedule that is written to cover different dosages depending on lab values, does not count as an order change simply because a different dose is administered based on the sliding scale guidelines. "Physician visits" are also defined in the *Long Term Care RAI User's Manual*. The physician is defined to include an "MD, osteopath, podiatrist, or dentist who is either the primary physician or consultant. Also include an authorized physician assistant or nurse practitioner working in collaboration with the physician." The visit is defined as a partial or full exam at the facility or in the physician's office.

L. Nurse Staffing and the Staff Time Measurement Studies

Comment: We received a variety of questions related to the staff time measurement (STM) studies performed in 1995 and 1997 that were used to set the case-mix indices. These included questions about what portion of the nurses' time was accounted for in the study, whether all nursing minutes (resident specific and non-specific) were used, whether medication aide time was counted, and what nurse staffing mix was used. Also, the suggestion was made that we should conduct another STM study after the PPS has been in place for a year.

Response: Before addressing the specific comments, we are taking this opportunity to provide a brief background explanation of the STM studies. As stated in the interim final rule, we conducted the STM studies in 12 States across 154 SNFs and 3,900 residents. The 1997 STM was performed to supplement the 1995 study to secure additional STM data from SNFs identified as providing both high quality care and more than an average level of rehabilitation therapy to patients on their Medicare-certified nursing units, and to include a broad geographic distribution of providers.

The STM data collection accounted for all nursing staff time during the 48-hour collection period. This time included that of the registered nurses (RNs), licensed practical nurses (LPNs), aides (certified nursing assistants (CNAs)), and medication aides. The resident-specific component counted all nursing time of 30 seconds or more spent in an activity directly attributable to a specific resident. The non-resident specific component included all time

not directly related to a specific resident, such as meetings, nursing unit administration, and staff meal times. Also, if the nursing staff member worked past the end of the shift, that time was counted as well.

The therapy staff time was collected over a 7-day period. All time that the therapist, therapy assistant, and therapy aides spent working in the certified nursing unit was accounted for and was apportioned between resident specific and non-resident specific, following the same methodology as was used in the nursing time allocation. All of these collected time data were used in the development of the indices.

The staffing levels and the nurse staffing mix on the units selected for the study met the OBRA 87 staffing requirements and provided more than 110 minutes of daily resident specific nurse staff time. Both freestanding and hospital-based facilities were used in the study. Salaries were adjusted based on the American Health Care Association's 1995 study of national nursing home salaries.

The nurse staffing mix found on the certified nursing units in the study were determined per unit, based on the mix of residents on the nursing unit at the time of the data collection. Based on a case-mix of 0.92, the average time across the two staff time studies was: 1.2 hours per resident, per day of RN time; 0.7 hours per resident, per day of LPN time; 2.6 hours per resident, per day of CNA time (including medication aides). This adds up to 4.6 hours per resident, per day of nursing time.

An important point to understand about the nursing time is how it affects the rates. The nursing time associated with any one group in the RUG-III hierarchy does not represent the nursing minutes that must be provided (and that will be paid for by Medicare) to each of those beneficiaries. Rather, the minutes are a distributional value—an average for the RUG-III group—and were an important factor in the development of the case-mix indices. The weight for each of the 44 RUG-III groups represents the average resources (including, of course, nursing) required to care for beneficiaries who classify to that group relative to the average resources required to care for beneficiaries in all of the other RUG-III groups. The RUG-III group with a value of 1.0 is identified and the weights for the other groups are calculated once that has been done. The value of 1.0 indicates that the average resources required to care for beneficiaries in that group are the average compared to all of the other groups. Accordingly, the resource requirements to care for

beneficiaries in the other 43 RUG-III groups are either higher or lower than for the group with the weight of 1.0. Depending on the distribution of beneficiaries across the RUG-III groups, the group with the relative value of 1.0 will vary. It is important to bear this concept in mind, in order to avoid the misconception that a RUG-III group with a relative weight that changes from one year to the next has staffing requirements that have changed from the original staff time measurement study. The RUG-III system does not impose any new staffing requirements. The data are available from the HCFA PPS website address:

<www.hcfa.gov/medicare/snfpps.htm>

Comment: One commenter requested that we explain why the Behavior Category is so low in the RUG-III hierarchy, even though beneficiaries who classify into that group require intensive amounts of staffing resources.

Response: The reason for this is that the RUG-III hierarchy is in large part based on minutes of licensed nursing time and on the clinical conditions that require the attention of licensed staff. This is a result of early research findings that indicated that beneficiaries who have the clinical characteristics that would classify them into the medically complex categories, like Extensive Care, generally require much more RN and LPN time than do beneficiaries who classify into the groups in the lower end of the clinical scale. Similarly, beneficiaries who classify into groups lower in the hierarchy generally require less licensed nurse time but, as stated by the commenter, may require intensive amounts of staffing resources.

Beneficiaries in the Behavior Category may not need much licensed nurse time, but instead may require a large amount of certified nurse assistant (CNA) time. Much of the care required in these lower-end RUG-III groups is of the type provided by CNAs, such as assistance with activities of daily living (ADLs) and other types of maintenance care. In general, the need for CNA time is reflected in the beneficiaries' ADL sum scores, whereas the need for licensed nurse time is predicted by clinical complexity as reflected by the level in the hierarchy. Thus, beneficiaries who classify into the Extensive Services category where the ADL sum score is at least 7, have highly complex clinical needs and require high levels of both licensed nurse (RN/LPN) and CNA time. Beneficiaries in the lower-weighted RUG-III groups may also require skilled nursing care, but generally not as much as required in the higher groups.

Comment: Several commenters had concerns that the STM was collected

over too short a period, that too few facilities were used and that not enough of them were hospital-based facilities, and that too few of the facilities used were located in metropolitan statistical areas (MSAs) with populations in excess of 500,000 people.

Response: We are confident that the methodology used for the STM studies was valid and appropriate for the task. Three STM studies were conducted. The first was in 1990, followed by another in 1995, and the last in 1997. The staff time studies were conducted in 13 States, in units of more than 300 nursing homes, representing care provided to about 12,000 residents. The States included were California, Colorado, Florida, Kansas, Maine, Maryland, Mississippi, Nebraska, New York, Ohio, South Dakota, Texas, and Washington. These States are geographically representative and include rural areas, as well as MSAs with populations in excess of 500,000.

Within each of these States, the selection of SNFs was guided by the research design that called for a sample that would adequately represent units that provide high quality, high-acuity care. The facilities in the combined 1995 and 1997 study sample were 55 percent for-profit facilities, 45 percent non-profit, 22 percent hospital-based facilities; 36 percent of the facilities had a head trauma unit, a ventilator unit, a special rehabilitation therapy unit, or a dialysis unit, or had been recommended as a high intensity unit by the Technical Expert Panel. Although the amount of time spent collecting data on any particular unit was short, the studies were conducted during different years and each year's study was performed over a period of months. In this way, the study was reflective of practice in the facilities in the aggregate, if not precisely representative of any particular facility over time.

Comment: One commenter argued that the staffing patterns (using 1995 as the base year) used in developing the rate structure lock SNFs into historic staffing patterns. Another commenter asserted that since there is no language in the regulation requiring SNFs to use a certain proportion of the rate on direct care services, they will not do so, and suggested that we adopt the staffing recommendations of the Institute for Geriatric Nursing of the John A. Hartford Foundation.

Response: As indicated earlier, the RUG-III system does not impose staffing requirements. We do not believe that our use of the 1995 base year locks facilities into any particular level of nurse staffing, either directly or indirectly. As stated above, the staffing

levels in the staff time studies were based on the unit's case-mix at the time. The study used units that had a mix of payor types. Nationally, of the 14,000 Medicare certified facilities, fewer than 4,000 have an average daily census of more than 10 Medicare beneficiaries. We do not believe that it is appropriate to require staffing standards based on the needs of such a small portion of the facility's population, but this is an issue that is outside of this regulation's scope. We will carefully review and consider the findings of the National Academy of Sciences report (the report cited by the commenter is part of this larger effort) when it becomes available.

Comment: One commenter suggested that we include speech language pathology assistant times when we perform our next staff time measurement study. The commenter recommended that we include the times for these care providers in our update of the RUG-III case-mix indices.

Response: While we are not prepared to address the issue of when to conduct another staff time measurement study within the context of this final rule, we would note that services of speech language pathology assistants are not recognized for separate coverage under Medicare. In order for this class of providers to be eligible for Medicare payment, they must first achieve licensure or some other standard credential recognized at the national level. To date, these assistants have not obtained this standing.

Comment: We received a number of comments regarding the treatment of respiratory therapy services under the RUG-III. Several commenters expressed concern that facilities would be using inappropriately trained nurses rather than appropriately trained personnel to provide respiratory therapy services.

Response: We share the commenters' concern with regard to the quality of care. As stated in the SNF Manual at section 230.10.B.1, Medicare requires that respiratory services must be provided by respiratory therapists or technicians, physical therapists, nurses, or other qualified personnel. We currently have no evidence that unqualified personnel are administering respiratory treatments, but note that the State surveyors monitor long-term care facilities for such lapses in quality. The rules governing the provision of respiratory treatment were not altered by the implementation of PPS but certainly, in light of the PPS and its associated incentives, we are determined to monitor closely the provision of SNF care, including respiratory treatments. A key provision in implementing the new payment

system is to safeguard quality of care for nursing home residents, and this issue warrants particular attention for our quality and enforcement initiative.

Comment: Several commenters raised concerns with the manner in which respiratory therapy is recognized in the SNF PPS.

Response: As discussed earlier in this preamble in the context of the Federal PPS rates, the treatment of respiratory therapy services in the SNF PPS was the result of careful consideration and extensive analysis. The RUG-III case-mix classification system, which forms the basis for the payment rates, does not include respiratory therapy in the same category as the rehabilitation therapies (occupational, speech, and physical therapy).

The primary reason for this was the difference in treatment patterns between respiratory therapy and the rehabilitation therapies. A secondary reason is that the costs of respiratory therapy services are not always separately identifiable on SNF cost reports, since trained nurses are qualified to provide these services, and often do so. However, we note that all costs from the base year data associated with respiratory therapy were captured in the computation of the payment rates, and the provision of respiratory therapy, as indicated on the resident assessment, can result in a higher payment in the non-rehabilitation RUG-III groups.

We believe that the SNF PPS accounts for respiratory therapy appropriately, and we do not believe that the RUG-III classification system will discourage the provision of needed respiratory rehabilitation. However, as discussed earlier, we are engaged in research to determine the potential for making refinements to the current case-mix model to improve accuracy of the payments. Ancillary services, such as pharmacy and respiratory therapy, will be one focus of the research.

Comment: One commenter noted that Medicare beneficiaries with more than \$1,000 in paid respiratory therapy claims account for only 18 percent of all Medicare beneficiaries who received respiratory therapy services in 1996, and that the top four diagnoses (excluding a generic category of "other diseases of the lung")—chronic bronchitis, chronic airway obstruction, pneumonia due to solids or liquids, and pneumonia—average between \$75 and \$100 per day in respiratory services. The commenter added that this amount far exceeds the payment amounts associated with the 42 RUG-III categories that do not have respiratory adjustments, and that this warrants the development of an outlier policy to

insure adequate care for these beneficiaries.

Response: Please refer to the preamble discussion on the Federal rates, in which we discuss "outlier" situations.

Comment: One commenter suggested that any future revisions to the MDS 2.0 should include an expansion of data collection fields to capture critical respiratory therapy diagnoses and medication requirements, and that certain data items in the current MDS related to respiratory care should be considered in revising the RUG-III classifications, so that patient acuity and payment will be appropriately recognized.

Response: These are important issues to consider as we revise the MDS and implement new versions in the future; however, we will not be making any changes to the MDS in this final rule.

Comment: Several commenters raised issues in connection with recreational therapy. Some indicated that the definitions and language within section T should accurately reflect and comply with the recreational therapy profession's standards and practices. To provide an accurate picture of the resident's rehabilitation needs, sections T1c and T1d should include recreational therapy within the mix of comprehensive rehabilitation services.

Response: Recreational therapy has long been among the services that Medicare has recognized as related to patient care in SNFs; however, it is not a therapy specifically identified for coverage in the statute. For this reason, recreational therapy services are not included in the RUG-III system in the same way as the rehabilitation therapies.

Comment: One commenter expressed a belief that the RUG-III system fails to reflect the importance of interdisciplinary comprehensive rehabilitation services. The commenter argued that recreational therapy is identified as a viable and recognized treatment option within all rehabilitation treatment settings, and noted that within the present RUG-III version, Recreation Therapy treatment minutes are not used in identifying the RUG-III rehabilitation classification.

Response: To the extent recreational therapy services were furnished in the SNF PPS base year, they are reflected in the SNF PPS payments. Thus, the SNF PPS reflects the provision of recreational therapy services to Medicare beneficiaries. Accordingly, we find no evidence to support the notion that the RUG-III classification system in any way prevents Medicare beneficiaries from receiving recreational therapy services.

M. SNF Coverage and Level of Care Determinations

One of the prerequisites for coverage under the "extended care" (that is, Part A SNF) benefit is the beneficiary's need for and receipt of an SNF level of care. In the preamble to the interim final rule (63 FR 26283-85), we designated the upper 26 of the 44 RUG-III groups as representing an SNF level of care. We specified that a beneficiary's assignment to one of the upper 26 RUG-III groups as the result of a resident assessment would automatically classify the beneficiary as meeting the SNF level of care definition. Beneficiaries assigned to one of the lower 18 RUG-III groups would not automatically classify as either meeting or not meeting the level of care definition, but would instead receive an individual determination under the longstanding level of care criteria in regulations at Part 409, subpart D.

As discussed below, in this final rule we are clarifying the role played by a beneficiary's RUG-III assignment in the process of making SNF level of care determinations, and we are also restoring portions of the regulations text that appeared previously in § 409.33(a) on management and evaluation, observation and assessment, and patient education, which were deleted by the interim final rule.

Comment: We received numerous comments regarding the procedures for making SNF level of care determinations under the SNF PPS. Several commenters were under the impression that, in view of the prospective nature of the SNF PPS, and the interim final rule's designation of the upper 26 RUG-III groups as representing an SNF level of care, a resident assessment that triggers assignment to one of the upper 26 groups would result in automatic coverage that continues for the entire duration of the period to which that assessment applies, regardless of any changes in condition or services provided that might occur subsequent to the completion of the assessment itself. This impression was reinforced, in their view, by a table (Table 2.D) on the Medicare Assessment Schedule, which appeared in the preamble of the interim final rule (63 FR 26267), and which included a column entitled "Number of Days Authorized for Coverage and Payment." These commenters also asserted that making coverage determinations for a predetermined block of time was the approach that had been adopted under the NHCMQD, which served as the forerunner of the SNF PPS.

Response: In order to understand the actual effect of an assignment to one of the upper 26 RUG-III groups in making level of care determinations under the SNF PPS, it is also necessary to consider how SNF coverage determinations were made before the inception of the PPS. Before the SNF PPS, when a beneficiary met the "posthospital" requirements for SNF coverage (that is, the timely initiation of SNF care following the beneficiary's discharge from a qualifying hospital stay), an individual level of care determination was made, using the longstanding criteria that appear in regulations at §§ 409.31 through 409.35, and manual instructions in the Medicare Intermediary Manual, Part 3 (MIM-3, HCFA Pub. 13-3), sections 3132ff and the Skilled Nursing Facility Manual, sections 214ff.

As discussed in the interim final rule, this determination entailed a retrospective review by the Medicare FI, which focused primarily on a beneficiary's need for and receipt of specific, individual skilled services. Along with the posthospital and level of care requirements, the SNF services also had to meet additional requirements that apply to Medicare coverage generally; for example, the overall requirement that a service must be reasonable and necessary to diagnose or treat the beneficiary's condition (section 1862(a)(1) of the Act). Under this system of retrospective review, it was possible for an FI to issue a denial of coverage that was retroactive all the way back to—and even including—the day of SNF admission itself. As noted in the interim final rule, this situation made it extremely difficult for an SNF to predict with any degree of certainty that a particular admission ultimately would, in fact, be covered.

In the interim final rule, we designated a beneficiary's correct assignment to one of the upper 26 RUG-III groups as representing an SNF level of care in an effort to bring more predictability and certainty to the process of making coverage determinations. However, this designation was made specifically with respect to the SNF level of care requirement itself, and was never intended to supersede any of the other existing criteria for coverage under the SNF benefit, such as the posthospital requirements, or the overall requirement for services to be reasonable and necessary to diagnose or treat the beneficiary's condition. Thus, under this approach, when the initial Medicare (that is, 5-day) required assessment results in a beneficiary being correctly assigned to one of the upper 26 RUG-III groups, this effectively creates

a presumption of coverage for the period from admission up to, and including, the assessment reference date for that assessment, and the coverage that arises from this presumption remains in effect for as long thereafter as it continues to be supported by the actual facts of the beneficiary's condition and care needs. Relative to the situation that existed before the SNF PPS, we believe that this approach provides the SNF with far greater confidence in coverage at the outset of a resident's stay, and enables the SNF, once coverage is established, to continue to bill for the resident's care for as long as the resident's actual care needs continue to support coverage.

The use of this presumption at the outset of a resident's SNF stay is supported by the SNF benefit's basic nature as a posthospital benefit, which is a major factor in determining the typical course of an SNF stay. In its July 1998 testimony before the House Ways and Means Committee (GAO/T-HEHS-98-214), the GAO noted that SNF residents tend to be relatively unstable and require fairly intensive skilled care during the period immediately following admission from the prior hospitalization, but that this tendency typically diminishes as they get further on in the SNF stay. The GAO indicated that a policy which continues to "deem" coverage for these individuals after they have clearly reached the point where they no longer need a skilled level of care would represent an unwarranted expansion in the SNF benefit.

We concur with the GAO's conclusion and, in view of the misunderstanding expressed by commenters on this point, we believe it is appropriate to clarify in this final rule that the initial presumption of coverage that arises from a beneficiary's Medicare-required 5-day assessment and his or her resulting RUG-III assignment encompasses the period from admission through the assessment reference date for the initial 5-day assessment, and is not intended to create an opportunity for continued payment beyond the point where SNF care is no longer reasonable and necessary; accordingly, the continuation of coverage, once established by the RUG-III presumption, would depend upon the subsequent course of the resident's actual condition and care needs.

We also wish to clarify that this presumption does not arise in connection with any of the subsequent assessments, but applies specifically to the period ending with the assessment reference date for the initial Medicare-required 5-day assessment that occurs shortly after the beneficiary's admission

from the prior hospital stay. Accordingly, we are amending the regulations text at § 409.30 to clarify that this presumption is valid up to and including the assessment reference date (that is, the last day of the observation period, which must occur no later than the eighth day of posthospital SNF care) for the initial Medicare-required 5-day assessment.

As the preceding discussion indicates, the course that SNF stays characteristically take over time means, in effect, that the basis for making any type of presumption with regard to coverage would tend to become progressively less conclusive as a resident moves farther into the SNF stay, and would be at its most conclusive at the very outset of the stay, during the period immediately following the resident's admission from the prior hospitalization. Accordingly, in situations in which a resident's condition upon admission is such as to warrant assignment to one of the upper 26 RUG-III groups, we regard this very tendency of SNF stays to be at their most intensive and unstable immediately following admission as justifying a presumption of coverage at the very outset of the SNF stay, during the period leading up to the assessment reference date for the initial Medicare-required 5-day assessment. This initial portion of the SNF stay provides the opportunity for the facility to initiate skilled nursing and rehabilitation services, and to begin its complete assessment of the beneficiary's clinical characteristics and care needs.

In addition, we believe that the use of the coverage presumption during these first few days of a resident's stay may provide the additional benefit of enabling medical review resources to be deployed for maximum effectiveness: by combining the clinical criteria that are captured in the upper 26 RUG-III groups with the tendency (as discussed above) for the initial portion of an SNF stay to be the most intensive and unstable, the presumption should provide a more reliable way of identifying at the outset those residents who do, in fact, require a covered SNF level of care. This, in turn, will enable medical reviewers to focus their resources elsewhere, on other residents or other portions of the SNF stay that are far more likely to involve the provision of noncovered care.

The underlying principle at work in the use of this administrative presumption at the outset of a covered stay is the fact that the RUG-III groups themselves are expressions of a certain level of services—skilled nursing care and skilled rehabilitation services, the

need for which represents the SNF level of care described in the statute at section 1814(a)(2)(B) of the Act. We, therefore, believe that in situations in which a beneficiary's initial, Medicare-required 5-day assessment results in an accurate assignment to one of the highest 26 of the 44 RUG-III groups, this assignment (in combination with the proximity to the prior qualifying hospital stay) makes it appropriate to presume that the beneficiary meets the SNF level of care definition at the outset of the stay. However, as is the case with all such administrative presumptions, this presumption is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of the Act). Accordingly, the presumption would not apply, for example, in those situations in which a resident's assignment to one of the upper 26 RUG-III groups is itself based on the receipt of services that are subsequently determined to be not reasonable and necessary.

The role of this presumption in determining coverage is, in some ways, similar to that performed by a physician who correctly certifies that a beneficiary requires a covered level of care, in that both activities serve to identify a beneficiary's initial need for covered care. In this context, it is worth noting that the interim final rule amended the physician certification regulations to reflect the use of the RUG-III system specifically with regard to the initial certification (§ 424.20(a)(1)(ii)), but not the subsequent recertifications (§ 424.20(c)).

Further, we note that the process of providing appropriate resident care in SNFs (which consists of a continuous loop of resident assessment, care planning, implementing specific interventions, and assessing the resident's response to and continued need for the interventions) serves to keep the SNF apprised, on an ongoing basis, of any changes in the resident's care needs. Thus, once the SNF determines that skilled care is no longer required, it must acknowledge this change in condition at that point and issue the appropriate written notice of noncoverage to the beneficiary.

Under existing program policy, in situations involving a provider that has acted in good faith but has nonetheless had a claim for Medicare coverage denied, a separate statutory provision on limitation of liability at section 1879 of the Act might permit payment to be

made on an exception basis. This provision specifically refers to denials based on the general exclusion from coverage for care that is not reasonable and necessary (section 1862(a)(1) of the Act), as well as the exclusion for custodial care (section 1862(a)(9) of the Act). Taken together, these provisions indicate that any presumption about the need for covered care at the outset of the SNF stay is rebuttable by one of these general coverage exclusions—and might be remediable by the limitation of liability provision.

We do not agree with the commenters who argued that the prospective nature of the SNF PPS should result in coverage being granted prospectively for a predetermined block of time (that is, for the entire duration of the assessment period). Rather, the SNF PPS is prospective in the sense of paying a predetermined rate that represents—in the aggregate—the cost of SNF care that would typically be associated with a beneficiary who classifies to a particular RUG-III group. However, we note that a basic feature of the SNF PPS (and one that fundamentally distinguishes it from, for example, its inpatient hospital counterpart) is that it makes payment on a per day rather than a per episode basis. This means that while there may, in practice, be some variation in resource intensity from one resident to another within a particular RUG-III group (and even from one day to another within a particular resident's stay), the SNF PPS per diem payments, when taken in the aggregate, appropriately reflect the overall intensity of resources associated with that particular RUG-III group. Further, the per diem basis for payment recognizes that in practice, the levels and types of services required and the duration of the actual need for a covered SNF level of care may vary somewhat from one resident to another.

The preamble discussion of the case-mix system in the interim final rule (63 FR) 26261) notes that in the nursing home setting, “* * * no adequate models have been found for using length of stay or episode cost to explain resource use. Thus, the RUG-III nursing home case-mix system explains patient resource use on a daily basis.” Accordingly, the framework set forth in the interim final rule supports the concept that the continuation of SNF coverage (once it has been initiated by the RUG-III presumption) must be supported by the resident's actual condition and care needs, and is not guaranteed for some predetermined block of time. To determine otherwise would effectively create a perverse incentive for SNFs to extend the length

of Medicare stays beyond the point where the provision of skilled care ceases to be reasonable and necessary. Additionally, with regard to dually-entitled residents, an SNF might have an additional incentive to prolong the period during which it receives Medicare per diem payments, in order to delay the change to a Medicaid payment that, in some States, is lower.

Further, with regard to the comments on the NHCMQD, we note that in contrast to the SNF PPS itself, we intentionally refrained from conducting medical review under the demonstration, in order to observe facility practices and care patterns in its absence. The resulting facility activity under the demonstration did not appear to diverge significantly from prior experience. With regard to duration of coverage, it would appear that the primary factor in determining the cessation of coverage under the demonstration was not the resident assessment cycle but, rather, the interest of beneficiaries and their families in keeping the length of SNF stays as short as possible—in order to avoid or minimize their financial liability for the daily SNF coinsurance that begins on the 21st day of Part A coverage, and to have the beneficiary return home at the earliest possible moment (under the demonstration, patients were only in the SNF long enough to have an average of 2.5 Medicare-required assessments). Based on the demonstration experience, as well as the nature of the coverage presumption itself (that is, its validity up to the assessment reference date for the initial Medicare-required 5-day assessment), this presumption clearly is not designed to guarantee payment for

the entire duration of the assessment period.

Nevertheless, consistent with the averaging function of the PPS, the payment rate, once established, is guaranteed for as long as the beneficiary's care needs continue to fall within the range of covered care, even if the specific acuity of the beneficiary's care needs within this range decreases; thus, the SNF can continue to receive the higher payment rate for such a beneficiary's covered care up to the next assessment. Conversely, it is possible that a resident's acuity may decrease to the point where it actually falls below a covered level of care, even though it has not changed sufficiently to trigger a Significant Change in Status Assessment. At that point, the ongoing coverage is ended by Medicare's statutory coverage exclusion of custodial care at section 1862(a)(9) of the Act, which provides that "* * * [n]otwithstanding any other provision of this title, no payment may be made for any expenses incurred for items or services * * * where such expenses are for custodial care" (emphasis added), and the SNF would be required to issue a notice of noncoverage. Under the implementing regulations at 42 CFR 411.15(g), this exclusion is invoked whenever a beneficiary receives care that does not meet the requirements for coverage as SNF care as set forth in §§ 409.31 through 409.35. The qualifying language in the statute means that the custodial care exclusion from coverage takes precedence over other provisions of the program—including any presumptions made with regard to coverage. Thus, under the SNF PPS, the introduction of the coverage

presumption based on a beneficiary's RUG-III group assignment was intended to streamline and simplify the initial level of care determination (which, along with the posthospital requirements, governs access to coverage under the extended care benefit). However, once this presumption has served to establish a beneficiary's initial access to coverage under the extended care benefit, it does not in any way supplant or invalidate the remainder of the basic and longstanding process for determining the duration of that coverage. While we believe that the use of this coverage presumption at the outset of the SNF stay represents a significant advancement toward achieving greater simplicity, predictability, and consistency in the coverage process, we will continue to monitor coverage determinations under the SNF PPS with a view toward the possibility of making further refinements and improvements in the future.

Finally, with regard to Table 2.D (Medicare Assessment Schedule), which appeared in the preamble to the interim final rule (63 FR 26267), we note that the heading to column four, Number of Days Authorized for Coverage and Payment, refers to the *maximum* period of coverage between assessments, but was not intended to prescribe coverage of a predetermined block of time consisting of a minimum number of days. In order to resolve any confusion that publication of this table may inadvertently have caused, we are now republishing the table below, with that particular column omitted.

TABLE 2.D.—MEDICARE ASSESSMENT SCHEDULE

| Medicare MDS assessment type | Reason for assessment (AA8b code) | Assessment reference date | Applicable medicare payment days |
|------------------------------|-----------------------------------|---------------------------|----------------------------------|
| 5 day | 1 | Days 1—8* | 1 through 14. |
| 14 day | 7 | Days 11—14** | 15 through 30. |
| 30 day | 2 | Days 21—29 | 31 through 60. |
| 60 day | 3 | Days 50—59 | 61 through 90. |
| 90 day | 4 | Days 80—89 | 91 through 100. |

* If a patient expires or transfers to another facility before day 8, the facility will still need to prepare an MDS as completely as possible for the RUG-III classification and Medicare payment purposes. Otherwise the days will be paid at the default rate.

** RAPs follow Federal rules.

Comment: One commenter questioned the appropriateness of using a resident's assignment to one of the upper 26 RUG-III groups as a determinant of a skilled level of care in situations in which the RUG-III assignment is based solely on events that occurred during the "look-back" period (for example, IV medications within the past 14 days).

The commenter noted that this could result in a resident being covered even though the qualifying skilled services that triggered the RUG-III assignment have themselves been discontinued before admission to the SNF, and the resident is no longer actually receiving any skilled care whatsoever by the time of the assessment itself.

Response: We note that the use of the "look-back" period in making RUG-III assignments is essentially a clinical proxy that is designed to serve as an indicator of situations that involve a high probability of the need for skilled care. Thus, our expectation is that the occurrence of one of the specified events during the "look-back" period,

when taken in combination with the characteristic tendency (as discussed above) for an SNF resident's condition to be at its most unstable and intensive state at the outset of the SNF stay, should make this a reliable indicator of the need for skilled care upon SNF admission in virtually all instances. In particular, residents in such situations may need the types of services formerly listed in § 409.33(a) of the regulations, that are discussed more fully below. If it should become evident in actual practice that this is not the case, it may become appropriate at that point to reassess the validity of the RUG-III system's use of the "look back" period in making assignments.

Comment: In the interim final rule, we invited comments on the feasibility of dispensing with the level of care criteria in existing regulations, in favor of utilizing the RUG-III framework as the exclusive means for making level of care determinations. One commenter expressed support for this approach; however, many others supported the continuation of individual level of care determinations under the existing criteria for beneficiaries assigned to one of the lower 18 RUG-III groups. A few of these commenters suggested that we might reassess this approach after the PPS has been in operation for a few years; at that point, they suggested, it might be possible to identify specific clusters of services within the lower 18 RUG-III groups that could serve as reliable indicators of skilled care, and to incorporate those indicators into the upper 26 RUG-III groups.

Response: As requested by most of the commenters, we are retaining in the regulations the existing criteria with certain modifications, as discussed elsewhere in this preamble. To the extent that our continuing experience in implementing the SNF PPS may indicate at some future point that further revisions in these criteria are warranted, we will consider making appropriate refinements to them at that time.

Comment: We received a number of comments concerning certain incremental adjustments that we made to the existing level of care criteria in the interim final rule. We made these revisions in order to achieve greater consistency with the general approach adopted under the SNF PPS with the use of the RUG-III groups, and also to reflect the significant advances in the state of long-term care practices that have occurred during the quarter century since the current SNF level of care regulations were first promulgated. Specifically, in view of changes in medical practice over time, we deleted

the previous references to hypodermoclysis and subcutaneous injections as examples of skilled nursing services. We retained enteral feeding as an example of a skilled nursing service, but adopted specific qualifying criteria from the RUG-III framework (that is, that the enteral feeding must comprise at least 26 percent of daily calorie requirements and at least 501 milliliters of fluid per day). Further, we deleted the categories previously listed in § 409.33(a) of "management and evaluation of a care plan," "observation and assessment", and "patient education" as examples of skilled services, in the belief that these categories were already effectively captured by the clinical proxies that have been incorporated into the upper 26 RUG-III groups.

Additionally, in the preamble to the interim final rule (63 FR 26284), we indicated that it might well be desirable to delete the insertion, irrigation, and replacement of urinary catheters as an example of a skilled service, in order to avoid providing a perverse incentive for their inappropriate use. However, we also invited comments on the desirability of retaining this example specifically with regard to suprapubic catheters.

Of the comments we received on these changes, the largest number supported retaining suprapubic catheters as an example of a skilled nursing service, noting that this procedure is a major vector for infection that can be fatal if improperly performed, and that requires a greater amount of skilled care than Foley catheters. One commenter favored deleting even suprapubic catheters from the examples of skilled nursing services, while another favored retaining all types of catheters in the examples. Several commenters advocated reinstating observation and assessment, management and evaluation, and patient education as explicit examples of skilled services in the SNF level of care regulations (or, alternatively, amending the regulations governing the home health benefit at § 409.42(c)(1), which currently cross-refer to the SNF regulations, to include them). A few commenters suggested retaining subcutaneous injections as an example of a skilled nursing service specifically with regard to those residents who, due to cognitive impairments such as those associated with dementia, are unable to self-administer the injections, and another favored retaining hypodermoclysis.

Response: As noted above, our reason for deleting the explicit references in the regulations to management and

evaluation, observation and assessment, and patient education was not that they no longer represented appropriate examples of skilled care, but rather, because we believed that these separate references were no longer necessary in view of the clinical indicators that have been incorporated into the upper 26 RUG-III groups. However, in order to avoid possible confusion on this point, we are accepting the commenters' suggestion to reinstate these categories as specific examples in the SNF level of care regulations.

Further, while we continue to believe that it is inappropriate to cite the use of a urinary catheter as an example of a skilled service in most instances, we agree with the reasons advanced by the commenters who favored specifically retaining suprapubic catheters in the list of examples of skilled nursing services; accordingly, we are modifying the example regarding catheters to refer exclusively to this particular type of catheter. However, for the reasons discussed previously in the preamble to the interim final rule, we are not reinstating hypodermoclysis or subcutaneous injections as examples of skilled nursing services. Regarding the latter, we do not believe that the presence of a cognitive impairment in the person who receives the injection would significantly affect the skills required on the part of another person who actually administers it.

Finally, we are taking this opportunity to correct a technical inaccuracy that appears in the regulations at § 411.15(g), defining the term "custodial care," as well as in the introductory material for § 409.30. An earlier version of the custodial care definition (which appeared at § 405.310(g)) correctly described this term in the SNF context as any care that does not meet the SNF level of care criteria, which at that time appeared in § 405.126 through § 405.128. When the SNF level of care criteria were redesignated as § 409.31 through § 409.35 (48 FR 12534, March 25, 1983), a conforming change was subsequently made to the cross-reference in the custodial care regulations (50 FR 33031, August 16, 1985).

However, in addition to the level of care regulations at redesignated § 409.31 through § 409.35, this conforming change inadvertently revised the cross-reference erroneously to include the SNF benefit's posthospital requirements at redesignated § 409.30. Since the posthospital requirements are not an element of the custodial care definition, we are deleting that portion of the citation from the cross-reference, which is revised to refer correctly to the SNF

level of care criteria at § 409.31 through § 409.35. Similarly, we are revising the cross-reference in the second sentence of the introductory material in § 409.30 (regarding the use of the RUG-III groups in making level of care determinations) to refer solely to the level of care requirements in § 409.31, and not to the posthospital requirements set forth in the remainder of § 409.30 itself.

Comment: Some comments reflected certain longstanding misconceptions regarding the SNF level of care definition, in terms of a beneficiary's need for and receipt of skilled services on a daily basis which, as a practical matter, can be furnished only in an SNF on an inpatient basis. One recurring misconception with regard to the "daily basis" requirement (which some of the commenters expressed as well) is that Medicare coverage guidelines provide for specific breaks in skilled therapy services for the observance of a prescribed list of national holidays. Another longstanding misconception shared by some commenters is that the cessation of therapy for so much as a single day due, for example, to the beneficiary's temporary illness or fatigue, would mandate an automatic discontinuance of coverage. The recurring misconception with regard to the "practical matter" requirement is that a beneficiary's ability to have even an occasional, brief absence from the SNF in order to attend, for example, a holiday meal with family or friends, would result in the loss of Medicare coverage. As explained below, these interpretations of Medicare SNF coverage requirements are incorrect.

Response: We note that the commenters' misunderstandings reflect certain recurring misconceptions about the SNF level of care criteria that long predate the SNF PPS. With regard to the "practical matter" requirement, it is true that a beneficiary's ability to have frequent or prolonged absences from the facility may raise a question as to whether the beneficiary, as a practical matter, can only receive the care that he or she needs on an inpatient basis in the SNF. However, this is not the case when a beneficiary is capable of having only occasional, brief absences from the facility. As section 214.6.C. of the Medicare SNF Manual indicates:

An SNF should * * * not interpret the "practical matter" criterion so strictly that it results in the automatic denial of coverage for patients who have been meeting all of the SNF level of care requirements but who have occasion to be away from the SNF for a brief period of time. While most beneficiaries requiring an SNF level of care find that they are unable to leave the facility for even the briefest of time, the fact that a patient is

granted an outside pass, or short leave of absence, for the purpose of attending a special religious service, holiday meal or family occasion, for going on a ride or for a trial visit home, is not by itself evidence that the individual no longer needs to be in an SNF to receive required skilled care. Very often special arrangements, not feasible on a daily basis, have had to be made to allow for absence from the facility.

Thus, the requirement for daily skilled services should not be applied so strictly that it would not be met merely because there is a brief, isolated absence from the facility in a situation where discharge from the facility would not be practical. It is also worth noting that, in addition to the coverage guidelines discussed above, the Medicare certification requirements for SNFs, at § 483.15(d), provide that each resident has the right to participate in social, religious, and community activities that do not interfere with the rights of other residents in the facility. Similarly, with regard to the "daily basis" requirement, the Medicare program does not specify in regulations or guidelines an official list of holidays or other specific occasions that a facility may observe as breaks in rehabilitation services, but recognizes that the resident's own condition dictates the amount of service that is appropriate. Accordingly, the facility itself must judge whether a brief, temporary pause in the delivery of therapy services would adversely affect the resident's condition.

Comment: A commenter asked whether the certification and recertification statements for posthospital skilled nursing facility services required under section 1814(a)(2) of the Act must be performed only by a physician, or can be performed by an authorized facility staff member. Another requested that we authorize a physician assistant to perform certification and recertification statements (as nurse practitioners and clinical nurse specialists already are under current law). One commenter noted that the SNF benefit's requirement for a physician to certify (and periodically recertify) that a beneficiary needs an SNF level of care was waived under the NHCMQD, and argued that this requirement is a needless burden that should be permanently eliminated.

Response: Section 1814(a)(2) of the Act requires that a physician (or a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility, but who is working in collaboration with a physician) initially certifies, and periodically recertifies, the need for a skilled level of care.

However, this provision does not currently authorize facility staff members or physician assistants to perform this function. Section 424.20 sets forth the timing of the required certifications as follows: the initial certification must occur at the time of admission or as soon thereafter as is reasonable and practicable; the first recertification is required no later than the 14th day of posthospital SNF care; and, subsequent recertifications are required at least every 30 days after the first recertification.

Comment: One commenter noted that the upper 26 groups of RUG-III are designated as representing a covered SNF level of care only in the preamble to the interim final rule, and suggested that this designation should also be made explicit in the regulations text itself.

Response: The reason that we declined to specify particular RUG-III groups in the regulations text itself was not to expand or contract coverage relative to the types of conditions that the upper 26 RUG-III groups currently identify, but rather, to allow for the possibility that the RUG-III groups themselves might be reconfigured in the future. This gives us the necessary flexibility to designate (in the routine annual update of Federal prospective rates described in regulations at § 413.345) those reconfigured RUG-III groups that would correspond to the upper 26 groups under the current RUG-III configuration, without having to go through the full rulemaking process in order to make specific revisions in the regulations text itself. (Of course, any such reconfiguration in the RUG-III groups would itself be effected through rulemaking.)

N. SNF Consolidated Billing

The consolidated billing requirement (established by section 4432(b) of the BBA) places with the SNF itself the Medicare billing responsibility for virtually the entire package of services furnished to a resident of an SNF. In the interim final rule, we addressed both the scope of services and the definition of an SNF "resident" that apply for purposes of this provision. As discussed below, this final rule provides additional clarification on implementation timeframes for this provision and on the scope of services to which this provision applies, including the role played by the SNF care planning process.

Comment: We received many comments regarding timeframes for implementation of the SNF consolidated billing provision, particularly with respect to those SNF residents who are

not in a covered Part A stay. Many expressed support for a delay in the implementation of this aspect of the provision, and requested that advance notification be given before implementing it.

Response: Section 4432(d) of the BBA provides that, unlike the effective date for the PPS itself (which is tied to the start of the individual SNF's first cost reporting period that begins on or after July 1, 1998), the consolidated billing provision applies to items and services furnished on or after July 1, 1998. In April 1998, we published PM transmittal number AB-98-18, which contained operational instructions for Medicare contractors on consolidated billing implementation.

As noted in the preamble to the interim final rule, in order to accommodate individual SNFs that lacked the capability to perform consolidated billing as of the July 1, 1998, effective date, the PM provided for a "transition period," under which such a facility would be required to begin consolidating its bills for items and services furnished on or after the earlier of either (1) January 1, 1999 or, (2) the facility's PPS start date.

However, this instruction was subsequently superseded by PM transmittal number AB-98-35 (July 1998), which eliminated the transition period described in PM transmittal number AB-98-18, and provided instead that an SNF must consolidate its bills as of its PPS start date, for those of its residents who are in a covered Part A stay. For those SNF residents who are not in a covered Part A stay (for example, who have exhausted their available days of coverage under the Part A SNF benefit, or who do not meet that benefit's posthospital or level of care requirements), the PM postponed implementation of consolidated billing indefinitely. This was necessitated by systems modification delays in connection with achieving Y2K compliance.

The Y2K problem arose because computer programming, which has commonly employed only two digits to record the year in the date for transactions and other entries, will not be able to distinguish the year 2000 from the year 1900 without reprogramming. This problem must be corrected on a timely basis in order to avoid the potential for significant disruption of the automated systems that are essential to administering the entire Medicare program. (For a more detailed discussion of Medicare and the Y2K problem, please refer to the preamble for the proposed rule on the outpatient hospital PPS, 63 FR 47605,

September 8, 1998.) Making the necessary systems renovations to correct this problem is an extensive and complex process that must be given priority over other systems modifications.

Accordingly, consolidated billing implementation with regard to those SNF residents who are in noncovered stays is being postponed at present, because it will require systems modifications that are far more extensive than those needed for the SNF PPS under Part A—modifications of a magnitude that simply cannot be accomplished until the current actions to achieve Y2K compliance have been completed. We plan to publish a notice of the anticipated implementation date for this aspect of consolidated billing in the **Federal Register** at least 90 days in advance.

Comment: Numerous commenters recommended a wide variety of items and services that they believe should be categorically excluded from the SNF consolidated billing requirement and paid separately from the PPS. Some examples included: laboratory services, intravenous medications, medications for patients with acquired immune deficiency syndrome (AIDS), and various types of practitioner services. Some of these commenters noted our discussion in the preamble to the interim final rule regarding a technical amendment to section 1833(h)(5)(A) of the Act (which would specifically authorize SNFs to receive Part B payment for laboratory tests that they do not themselves either perform or supervise), and advocated deferring the application of consolidated billing to those services until after the actual enactment of this legislation. Other commenters argued that since the consolidated billing legislation specifically excludes several types of practitioner services, the services of certain additional types of practitioners, such as clinical social workers and audiologists, should similarly be excluded. One commenter mistakenly understood the exclusion of "physician services" from consolidated billing to be the result of an administrative decision by us, and expressed support for this decision; another argued that the statute's categorical exclusion of "physician services" from this provision mandates the exclusion not only of a diagnostic test's professional component (representing the physician's interpretation of the diagnostic test), but also of the technical component (representing the test itself).

Response: The only types of services furnished to SNF residents that are categorically excluded from the PPS and

consolidated billing provisions are the ones specified in a short list of statutory exclusions at section 1888(e)(2)(A)(ii) of the Act, for which an outside supplier can still bill Medicare directly and receive a separate payment under Part B. All other services are subject to consolidated billing when furnished to an SNF resident, and are included in the PPS payment that Medicare makes to the SNF for a covered Part A stay. In addition, we note that the issue of an SNF receiving Part B payment for laboratory services under consolidated billing does not arise at present since, as discussed previously, the implementation of SNF consolidated billing is currently on hold for those residents who are not in a covered Part A stay.

Further, we note that although the consolidated billing legislation does exclude the services of psychiatrists and clinical psychologists, it does not exclude the services of clinical social workers. (In this context, it is worth noting that the SNF consolidated billing requirement was modeled on the corresponding Medicare comprehensive billing or "bundling" requirement for inpatient hospital services (section 1862(a)(14) of the Act), which has been in effect for well over a decade and similarly includes clinical social worker services, while excluding the services of certain other types of mental health professionals.) Similarly, section 1888(e)(2)(A)(ii) of the Act does not exclude audiologists; in fact, it is quite explicit in specifying that "speech language therapy" services are always subject to consolidated billing, even when performed by a type of practitioner (such as a physician) whose services would otherwise be categorically excluded from this provision.

We note that the exclusion of physician services themselves from consolidated billing is statutory rather than the result of an administrative decision; further, the implementing regulations at § 411.15(p)(2)(i) define the excluded "physician's services" as those meeting the criteria of § 415.102(a), and the latter provision specifies, in part, that this definition encompasses only those services that are furnished personally by the physician. Thus, under consolidated billing, only the professional component of a diagnostic test (representing the interpretation that the physician performs personally) is billed separately as a physician service, while the technical component represents the diagnostic test itself, which must be billed by the SNF.

Finally, in connection with further defining the bundle of services subject to consolidated billing when furnished to an SNF resident, we are taking this opportunity to make a conforming change in the regulations governing Medicare provider agreements in subpart B of Part 489. The interim final rule amended this subpart by adding a new paragraph (s) to § 489.20 to implement section 1866(a)(1)(H)(ii) of the Act, which makes compliance with the consolidated billing provision a specific requirement under the terms of a SNF's Medicare provider agreement. We are now adding a new paragraph (h) to § 489.21, which explicitly precludes an SNF from charging a resident for any items or services that are subject to the Medicare consolidated billing requirement. (We note that this new provision parallels the longstanding provision in paragraph (f) of § 489.21, which similarly prohibits a hospital from charging its inpatient for any items or services that are subject to the Medicare hospital bundling provision.)

Comment: Several commenters wrote regarding the provision in section 4541 of the BBA, which imposes a \$1500 annual per beneficiary limit on Part B payments for outpatient PT services (including speech-language therapy services) and a similar limit for outpatient OT services, but specifically excepts services furnished by a hospital's outpatient department from each of these annual limits. (This \$1500 Part B payment limit does not affect SNF residents who are in a covered Part A SNF stay, since the therapy services that they receive are bundled to the SNF and included in the PPS payment made under Part A, rather than being billed separately to Part B.)

The commenters objected to the interim final rule's exclusion of beneficiaries who are considered SNF "residents" for consolidated billing purposes from the outpatient hospital exception to the Part B therapy payment limit (63 FR 26299). The commenters argued that this decision results in a reduction of an SNF resident's available Part B therapy benefits in relation to residents of a totally noncertified nursing home (who would, by comparison, get a richer benefit package), thus effectively depriving SNF residents of the "escape hatch" that would otherwise be afforded by the exception of services furnished in the outpatient hospital setting from the \$1500 therapy payment limit.

Another commenter cited the discussion in Program Memorandum transmittal number AB-98-63 (October 1998) of the \$1500 limit on Part B therapy payment, and asked whether

the SNF billing and tracking requirements for Part B therapy services described in the PM indicate that the decision to postpone consolidated billing implementation for residents in noncovered SNF stays has been reversed specifically with regard to therapy services.

Response: As discussed in the preamble to the SNF PPS interim final rule, we decided not to except services furnished to SNF residents in the outpatient hospital setting from the Part B \$1500 therapy payment limit, specifically in order to avoid creating a perverse incentive to have the hospital outpatient department furnish therapy services that the resident could appropriately receive from the SNF itself. We note that section 1819(a)(1) of the Act defines an SNF, in part, as an institution that is primarily engaged in furnishing skilled rehabilitation services to its residents. This means that the provision of therapy services to its residents is an inherent and essential function of this type of facility.

Moreover, the long-term care facility requirements for participation (at section 1819(b)(4)(a)(i) of the Act) specifically require an SNF to provide ". . . specialized rehabilitative services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident . . ." Thus, an SNF that fails to provide medically necessary therapy services simply because a resident had reached the \$1500 annual Part B payment limit for these services would be in violation of this requirement, and would be subject to appropriate enforcement remedies.

In addition, we wish to clarify that the SNF billing and tracking responsibilities described in PM AB-98-63 arise solely in the context of implementing the \$1500 Part B therapy payment limit, which represents an entirely separate BBA provision (and statutory authority) from SNF consolidated billing; as specified in PM AB-98-35 (July 1998), the consolidated billing provision itself currently remains on hold for all services furnished to SNF residents in noncovered stays.

Finally, in addition to the comments on the \$1500 therapy cap provision specifically as it affects SNF residents, several commenters included more general observations about the nature of the provision itself. However, these concerns are beyond the scope of this regulation, and were addressed instead in the June 5, 1998, proposed rule on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 1999 (63 FR 30818), and in the

final rule published on November 2, 1998 (63 FR 58814).

Comment: One commenter noted that the regulation at § 413.335(b) concerning prospective payment for SNFs indicates that the PPS payment represents payment in full for the costs associated with furnishing inpatient SNF services to Medicare beneficiaries, but does not contain language that specifically excepts those types of services (such as physician services) that are categorically excluded by law.

Response: The qualifying language that the commenter requested is, in fact, already contained in the regulations at § 413.1(g)(2), which specify that, for an SNF resident in a covered Part A stay, the PPS determines the amounts paid for services furnished, "other than those described in § 411.15(p)(2) of this chapter." The latter provision lists the services that are categorically excluded from the PPS bundle.

Comment: We received a large number of comments about the treatment of ambulance services under the consolidated billing provision. Some advocated exclusion of all ambulance services from the consolidated billing provision. Others expressed concern that confusion over the circumstances in which these services are subject to consolidated billing could result in payment delays. Several commenters specifically requested clarification on whether emergency and other outpatient trips to a hospital via ambulance are subject to consolidated billing. Others argued that the inclusion of ambulance services under consolidated billing is inconsistent with the negotiated fee schedule provisions for ambulance services in the BBA.

Response: As discussed previously, the only types of services furnished to SNF residents that are categorically excluded from the PPS and consolidated billing provisions are the ones specified in a short list of statutory exclusions at section 1888(e)(2)(A)(ii) of the Act. Since ambulance services do not appear on this statutory excluded list, they are subject to consolidated billing when furnished to an SNF resident and are included in the PPS payment that Medicare makes to the SNF for a covered Part A stay.

The statute specifies that the consolidated billing provision applies only to those services that are furnished to an SNF "resident." Thus, as explained in the preamble to the interim final rule, an ambulance trip is considered to be furnished to an SNF resident (and, thus, subject to consolidated billing) if it occurs during the course of an SNF stay, but not if it occurs at either the very beginning or

end of the stay. (This policy is comparable to the one governing ambulance services furnished in the inpatient hospital setting, which has been subject to a similar comprehensive Medicare billing or "bundling" requirement for well over a decade.) Accordingly, the initial ambulance trip that first brings a beneficiary to an SNF is not subject to consolidated billing because the beneficiary has not yet been admitted to the SNF as a resident at that point. Similarly, the regulations at § 411.15(p)(2)(x) provide that an ambulance trip that conveys a beneficiary from the SNF is not subject to consolidated billing when it occurs in connection with one of the events specified in §§ 411.15(p)(3) (i) through (iv) as ending the beneficiary's SNF "resident" status. The events are—

- A trip for an inpatient admission to a Medicare-participating hospital or critical access hospital (CAH), or to another SNF.
- A trip to the beneficiary's home to receive services from a Medicare-participating home health agency under a plan of care.
- A trip to a Medicare-participating hospital or CAH for the specific purpose of receiving emergency services or certain other intensive outpatient services that are not included in the SNF's comprehensive care plan.
- A formal discharge (or other departure) from the SNF that is not followed within 24 hours by readmission to that or another SNF.

With regard to the third bullet above, § 411.15(p)(3)(iii) of the regulations excludes from consolidated billing those types of outpatient hospital services ". . . that are not furnished pursuant to the [SNF's] comprehensive care plan." This outpatient hospital exclusion (as discussed in greater detail below, in the context of the SNF comprehensive plan of care) applies to a small number of exceptionally intensive services that lie well beyond the scope of care that SNFs would ordinarily furnish (and, thus, beyond the ordinary scope of SNF care plans), as well as emergency services (which, by their nature, cannot be anticipated and planned for in advance). This means that when an outpatient visit to a hospital occurs for the purpose of receiving one of these excluded types of services, the individual receiving the services ceases to be a "resident" of the SNF for consolidated billing purposes and, thus, the associated ambulance transportation to the hospital is also excluded from consolidated billing. We note that this exclusion applies to the return trip from the hospital to the SNF as well, since the beneficiary's status as an SNF "resident" for consolidated

billing purposes (once ended by the receipt of an excluded outpatient hospital service) does not resume until he or she returns to the SNF.

With regard to the concerns about the negotiated fee schedule provisions for ambulance services, section 4531 of the BBA—the same provision that mandates the development of an ambulance fee schedule through a negotiated rulemaking process—also prescribes an interim payment methodology to be used until the ambulance fee schedule takes effect. Under the interim payment methodology, Part B will continue to pay for ambulance services that an SNF furnishes (either directly with its own resources, or under arrangements made with an outside supplier) on a reasonable cost basis, in which the cost per trip is limited to the prior year's reasonable cost per trip, updated by an inflation factor (that is, the consumer price index for all urban consumers (CPI-U) minus one percentage point). We note that the Medicare contractors have already received instructions (PM Number A-97-15 (November 1997) and PM Number A-98-2 (February 1998)) that describe this payment methodology in detail.

Comment: One commenter noted that the regulations at § 410.40(b)(4) require ambulance services furnished to an SNF resident to be furnished by, or under arrangements made by, the SNF itself. The commenter questioned whether this requirement is consistent with our policy of allowing certain ambulance services (such as those furnished in connection with the receipt of excluded outpatient hospital services) to be excluded from consolidated billing.

Response: In discussing services furnished to an SNF resident, § 410.40(b)(4) includes a specific cross-reference to the SNF "resident" definition at § 411.15(p)(3) which, in turn, specifies certain circumstances (such as the receipt of excluded outpatient hospital services) as ending a beneficiary's status as a "resident" of the SNF for consolidated billing purposes.

Comment: One commenter noted that our designation of certain categories of outpatient hospital services as ending (for consolidated billing purposes) a beneficiary's status as an SNF "resident" also has the effect of unbundling ambulance transportation that is associated with the beneficiary's receipt of those services. The commenter then suggested that we should similarly designate a beneficiary's receipt of excluded dialysis services at an offsite location as ending his or her SNF resident status in order to permit the associated

ambulance transportation to be unbundled as well.

Response: We believe that this comment reflects a misunderstanding of the underlying purpose of the outpatient hospital exclusion. This exclusion from consolidated billing does not serve as a mechanism for unbundling ambulance services per se. Rather, as discussed above, this exclusion is intended to encompass those services—specific to the outpatient hospital setting—that are so exceptionally intensive, costly, or emergent as to lie well beyond the ordinary scope of SNF care. The resulting unbundling of ambulance services associated with these excluded outpatient hospital services occurs simply because the bundling of ambulance services is itself tied to a beneficiary's status as an SNF "resident" for consolidated billing purposes, which is suspended by the beneficiary's receipt of these excluded types of outpatient hospital services.

By contrast, the performance of dialysis—even if it occurs offsite in the outpatient hospital setting—is a type of activity that clearly falls well within the normal scope of SNF care. (As discussed below, the effect of the exclusion of dialysis services from the SNF consolidated billing provision is that an SNF is not itself required to furnish—either directly or under arrangements—dialysis services to its residents; however, if an SNF nonetheless elects to furnish these services, they are included within the scope of the Part A extended care benefit, as well as in the PPS per diem payment that Part A makes to the SNF.) Accordingly, while the statute categorically excludes dialysis services themselves from the requirement for SNF consolidated billing, their receipt offsite does not have the effect of ending a beneficiary's status as an SNF resident for purposes of this requirement and, consequently, does not result in unbundling the associated ambulance transportation.

We note, in addition, that the policy regarding ambulance services in the SNF setting is also affected by a final rule on ambulance services coverage that was published in the **Federal Register** on January 25, 1999 (64 FR 3637). Although this rule was published well after the SNF PPS interim final rule, it has raised certain questions and concerns about ambulance trips (and transportation generally) in the SNF context.

In addition to the specific service categories listed in sections 1861(h)(1) through (6) of the Act, the extended care benefit includes coverage of ". . . such other services necessary to the health of the patients as are generally provided

by, or under arrangements made by, skilled nursing facilities" (section 1861(h)(7) of the Act). As explained in the interim final rule on the SNF PPS (63 FR 26302), the medical and other health services specified in section 1861(s) of the Act (which include ambulance services) are considered to be "generally furnished" by SNFs and, therefore, coverable under the Part A extended care benefit (see regulations at § 409.27(a)).

As discussed previously, under the SNF consolidated billing provision, the SNF itself is responsible for billing Medicare for virtually all of the services that a resident receives, except for a short list of excluded service categories specified in the statute at section 1888(e)(2)(A)(ii) of the Act. Since the Congress did not specify ambulance services as one of the excluded categories, such services must be billed to Medicare by the SNF when furnished to an SNF resident. As explained above and in the interim final rule (63 FR 26298), the consolidated billing provision does not apply to an ambulance trip that conveys a beneficiary to the SNF for the initial admission, or from the SNF following a final discharge, but only to ambulance transportation that is furnished during the period that the beneficiary is actually an SNF resident.

Nevertheless, as noted in the interim final rule (63 FR 26296), it is possible for particular service categories (such as preventive or screening services) to be subject to the SNF consolidated billing provision, and yet not be included within the scope of coverage under the Part A SNF benefit. It has been suggested that this is also the case with ambulance services, in view of instructions in the SNF Manual at sections 260.2 and 262 that indicate ambulance services are covered only under Part B. However, we note that these sections appear in a portion of the instructions that deal exclusively with situations involving SNF services covered under Part B when no payment under the Part A SNF benefit is possible (Part A benefits exhausted, no prior qualifying hospital stay, etc.); thus, the reference to "ambulance services" in this context applies specifically to the Part B benefit described in section 1861(s)(7) of the Act.

By contrast, for situations that do involve payment under the Part A SNF benefit, the applicable SNF Manual instructions in this regard appear at section 230.10.A. These instructions correspond to section 1861(h)(7) of the Act, which includes within the scope of the extended care benefit those services—not otherwise specified in

section 1861(h)—that are generally furnished by (or under arrangements made by) SNFs. As explained in the preamble to the interim final rule (63 FR 26302), this provision is considered to include the full range of medical and other health services described in section 1861(s) of the Act, other than those particular service categories (such as preventive and screening services) that, under the statute, lie specifically beyond the scope of the extended care benefit. The remainder of the medical and other health services described in section 1861(s) of the Act are considered to be "generally furnished" by SNFs and, therefore, within the scope of the extended care benefit when furnished to a resident in a covered Part A stay.

Thus, when an SNF provides or makes arrangements for a resident's transportation by ambulance during the course of a covered Part A stay, such services are not considered Part B ambulance services under the separate Part B benefit at section 1861(s)(7) of the Act, but Part A extended care services that SNFs generally furnish under section 1861(h)(7) of the Act. This is essentially similar to the use of the term "durable medical equipment" (DME), which refers exclusively to the Part B benefit described in section 1861(s)(6) of the Act; however, when an SNF furnishes the same types of items to a resident during the course of a covered Part A stay, they are not covered as DME under the separate Part B benefit, but rather, "as supplies, appliances and equipment" under the Part A extended care benefit at section 1861(h)(5) of the Act. Further, section 1833(d) of the Act prohibits Part B payment for any service that is payable under Part A.

In order to clarify that the Part A SNF benefit covers ambulance transportation under the authority of section 1861(h)(7) of the Act, we are relocating the ambulance provision from § 409.20(a)(8) to a new subparagraph of § 409.27, the section of the regulations that implements this particular portion of the statute. We are also clarifying that the SNF benefit's coverage of ambulance transportation is limited to those circumstances meeting the general medical necessity requirements that would apply to Part B coverage under the separate ambulance services benefit (as set forth in § 410.40(d)(1)) if the services were not covered under Part A—that is, those situations in which a beneficiary's medical condition is such that other means of transportation would be contraindicated.

We note that the ambulance rule's primary objective in revising the extended care benefit regulations was to clarify that the scope of this benefit

specifically includes coverage of transportation via ambulance. In the SNF PPS context, this effectively results in bundling the cost of all ambulance trips made in connection with an individual who has the status of an SNF resident, regardless of whether, prior to the PPS, the SNF undertook to furnish these services itself as "patient transportation" under Part A or, alternatively, allowed an outside supplier to furnish them as "ambulance services" under Part B.

However, the ambulance rule's revision was made in a manner that also raises the issue of coverage of transportation generally, by modes other than ambulance. In the institutional context, the issue of non-ambulance transportation arises mainly in the SNF setting, since this particular institutional setting is one in which a facility may routinely utilize offsite sources of services for its resident during the course of his or her stay, under circumstances that do not necessarily require the use of an ambulance.

Further, we note that unlike transportation via ambulance (which involves a service that is precisely delineated in terms of vehicle type, appropriate destinations, etc., and is recognized as a specific benefit category), the concept of non-ambulance transportation is a more generalized one that denotes the basic function of conveying an individual from one place to another, rather than a particular benefit or mode of conveyance. Under the long-term care facility requirements for participation at § 483.25, an SNF's essential obligation is to provide each resident with those services that are necessary " * * * to attain or maintain the [resident's] highest practicable physical, mental, and psychosocial well-being. * * *" The SNF can meet this obligation either by providing the needed services onsite at the SNF, or by securing them at an offsite location. SNFs that pursue the latter course have historically used a wide variety of means for conveying a resident to receive offsite services. Some of these (like community wheelchair transportation) were available at no cost and others generally involved various non-Medicare funding sources (such as Medicaid, or the resident's own family).

We note that, unlike transportation via ambulance, no separate benefit category has ever existed under Part B of Medicare for coverage of non-ambulance modes of transportation. Thus, prior to the inception of the SNF PPS, non-ambulance transportation for SNF residents occurred in a wide variety of ways that did not generally

involve any Medicare payment under either Part A or Part B. In making the ambulance final rule's revision to the extended care benefit regulations, it was not our intent to create an SNF benefit expansion by establishing a new entitlement under the Medicare program that did not heretofore exist in this setting; nor is it our intent to define as part of the SNF PPS bundle any services for which the Medicare program did not previously assume financial responsibility under either Part A or Part B. Therefore, we are revising § 409.27, as discussed above, to refer specifically to ambulance transportation rather than to transportation generally.

Comment: Several commenters requested clarification regarding the status of dialysis services under consolidated billing. One commenter suggested that Part B should pay for dialysis performed at the hospital outpatient department or, alternatively, when furnished by a freestanding dialysis center on the SNF's premises.

Response: Dialysis is one of the service categories that the BBA specifically excludes from the SNF consolidated billing provision. Most of the other excluded service categories are, by definition, outside the scope of the Part A extended care benefit. For example, an SNF cannot bill Part A for physician services, since section 1861(b)(4) of the Act defines these services as being outside the scope of the inpatient hospital benefit which, in turn, has the effect of excluding them as well from the extended care benefit under section 1861(h) of the Act (see the undesignated clause following section 1861(h)(7) of the Act).

By contrast, dialysis services have always been included within the scope of the Part A extended care benefit under section 1861(h)(7) of the Act that provides for coverage of those services (not specified elsewhere in section 1861(h)) that are generally furnished by, or under arrangements made by, SNFs. Thus, the exclusion of dialysis from the consolidated billing provision means that an SNF is not itself required to furnish or make arrangements for this service. However, even though the SNF is not required to furnish or make arrangements for dialysis during the course of a covered Part A stay, if it nonetheless elects to do so, the dialysis is included within the scope of the Part A extended care benefit, as well as in the PPS per diem payment. Alternatively, since the exclusion of dialysis services from the consolidated billing provision allows the SNF the option of declining to furnish or make arrangements for dialysis services, those services that meet the following

coverage requirements for the Part B dialysis benefit could be furnished and billed to Medicare directly by an outside dialysis supplier.

There are two situations under which dialysis services would be considered a Part B service and billable by an end stage renal disease (ESRD) facility or supplier when provided to an SNF resident. The first is for institutional dialysis services received at a Medicare certified ESRD facility. Institutional dialysis services must be provided by entities that meet the ESRD conditions of coverage that are specified in regulations at part 405, subpart U. These regulations limit outpatient maintenance dialysis services to those services provided "on the premises" of the facility. Thus, it is not possible for Part B institutional dialysis services to be provided at the site of a nursing facility or SNF that does not itself meet the ESRD conditions of coverage. The second situation involves Part B coverage of home dialysis services for residents of nursing facilities or SNFs, as these facilities may qualify as the residents' home for purposes of this benefit.

In order for Medicare payment of home dialysis to be made, the resident must elect to become a home dialysis patient and have completed a training program provided by an approved ESRD facility. Once a patient has completed the training, he or she must elect either Method I, where an ESRD approved facility furnishes the dialysis equipment and supplies, or Method II, where the patient elects a single supplier other than the ESRD facility to furnish all of the dialysis equipment and supplies, other than laboratory services and support services which are provided by a certified ESRD facility. Each home patient must have his or her own supplies and equipment. These cannot be shared with other SNF residents. Also, home dialysis is intended to be self-dialysis performed by the patient or the patient's family. Therefore, Medicare does not cover the services of staff to assist with the home dialysis services.

Comment: Many commenters requested clarification of the relationship between the SNF comprehensive care plan and a beneficiary's status as a "resident" of the SNF for consolidated billing purposes. Section 1862(a)(18) of the Act defines the applicability of the consolidated billing requirement in terms of services that are furnished to an individual who is a "resident" of an SNF. The implementing regulations at § 411.15(p)(3) specify several circumstances that have the effect of

ending a beneficiary's status as an SNF "resident" for consolidated billing purposes.

Section 411.15(p)(3)(iii) specifies as one such circumstance the receipt of those types of outpatient hospital services "... that are not furnished pursuant to the [SNF's] comprehensive care plan." Many commenters expressed confusion about the appropriate interpretation of this provision, along with the erroneous belief that a given outpatient hospital service is subject to the SNF consolidated billing provision only if it is actually specified in the individual care plan of the particular beneficiary to whom the service is furnished. Other commenters suggested additional types of outpatient hospital services for exclusion beyond the specific categories already identified in the preamble to the interim final rule. Still others advocated extending the exclusion to apply to services furnished in nonhospital settings as well (for example, MRIs performed at freestanding imaging centers).

Response: The purpose of citing the SNF's comprehensive care plan in the context of an outpatient hospital visit is to clarify that the SNF retains the overall billing responsibility for essentially the entire package of care furnished during the outpatient visit, other than certain specifically excluded services. As explained in the interim final rule (63 FR 26298), in the outpatient hospital context, this exclusion applies to the small number of exceptionally intensive services that lie well beyond the scope of care that SNFs would ordinarily furnish (and, thus, beyond the ordinary scope of SNF care plans), as well as emergency services (which, by their nature, cannot be anticipated and planned for in advance).

In November 1998, we issued PM transmittal number A-98-37, which provided additional clarification on the outpatient hospital exclusion, as well as a list of the specific HCPCS codes that identify the excluded services. The PM explains that this exclusion is not invoked merely because a particular outpatient hospital service does not appear in the individual SNF care plan of the person receiving the service; rather, the exclusion applies only to those specified categories of services that, by definition, lie well beyond the scope of SNF care plans generally. Currently, only those services that are specifically cited in the PM itself are excluded from consolidated billing on this basis: cardiac catheterization; computerized axial tomography (CT) scans; MRIs, ambulatory surgery involving the use of an operating room;

emergency room services; radiation therapy; angiography; and, lymphatic and venous procedures. However, as indicated in the interim final rule, we continue to consider further refinements in this policy as the new PPS for outpatient hospital services is being developed, and any further refinements would be made through future rulemaking.

In this context, we note that a key concern underlying the development of the consolidated billing exclusion of certain outpatient hospital services specifically involves the need to distinguish those services that comprise the SNF bundle from those that will become part of the outpatient hospital bundle that is currently being developed in connection with the outpatient hospital PPS. Accordingly, we are not extending the outpatient hospital exclusion from consolidated billing to encompass any other, freestanding settings.

Finally, in order to resolve the confusion that commenters expressed regarding the role of the comprehensive care plan, we are revising the parenthetical in § 411.15(p)(3)(iii) to read as follows: “. . . (but only with respect to those services that are beyond the general scope of SNF comprehensive care plans, as required under § 483.20).” This is to clarify that an outpatient hospital service is not excluded from consolidated billing merely because it does not appear in the particular care plan of the individual beneficiary receiving the service; rather, consolidated billing excludes only those types of outpatient hospital services that we specifically identify as being beyond the scope of SNF care plans generally. As indicated above, this exclusion currently encompasses only those particular service categories that we have specifically identified in PM A-98-37; however, as we continue to examine this issue, we may make further modifications in future instructions.

Comment: Many commenters requested further clarification regarding the definition of “emergency” outpatient hospital services in terms of their exclusion from SNF consolidated billing. One commenter argued that it is unreasonable to define an emergency as including only “life or death” situations. Another commenter noted the interim final rule’s description of emergency outpatient hospital services as being beyond the general scope of SNF care plans (since, by their nature, they cannot be anticipated and planned for in advance), and questioned whether this characterization would be appropriate in those instances where

“emergency” situations actually are addressed in a resident’s plan of care (for example, contingency plans that are based on risk factors identified in the resident assessment). Another inquired as to whether the exclusion of emergency services extends to other services that are clearly unrelated to the emergency itself, but that happen to be performed during the individual’s visit to the emergency room.

Response: As noted in the preceding discussion of the relationship between the outpatient hospital exclusion and the comprehensive care plan, PM transmittal number A-98-37 (November 1998) provided additional clarification on the exclusion of certain outpatient hospital services from SNF consolidated billing. As the PM indicates, we are not establishing a special definition of “emergency” services unique to consolidated billing, but instead are incorporating the longstanding definition contained in regulations at § 424.101, “services that are necessary to prevent death or serious impairment of health and, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services.” This definition is not limited to “life or death” situations, since it specifically includes those that present a risk of “serious impairment of health” as well. The PM also explains that emergency services are excluded from consolidated billing by virtue of their designation as being beyond the scope of SNF care plans generally, which would be true regardless of whether the individual care plan of a particular resident may occasionally address contingency plans in the event of a medical emergency. The PM also clarifies that the exclusion from consolidated billing is limited to, “Those services and supplies that are directly related and required to complete the procedure or treat the emergency condition for which the beneficiary came to the hospital, for example, anesthesia when used during ambulatory surgery involving the use of an operating room.” All other services and supplies must be bundled back to the SNF and the hospital must look to the SNF for payment.

Thus, for example, a laboratory test that is required to diagnose the condition that occasioned the emergency visit would be excluded from consolidated billing, and can be billed to Part B by the hospital. By contrast, a routine diagnostic test that is unrelated to the emergency condition itself would not be excluded from consolidated billing merely because it happens to be performed during the

beneficiary’s visit to the emergency room.

Comment: Two commenters noted that the outpatient hospital exclusion of ambulatory surgery from SNF consolidated billing applies specifically to those procedures that involve the use of an operating room, and they requested clarification on whether this exclusion would encompass the insertion and replacement of a percutaneous esophageal gastrostomy (PEG) tube when performed in a hospital’s gastrointestinal (GI) suite or endoscopy suite rather than in an operating room.

Response: The procedure codes that specifically pertain to PEG tubes are 43750 (percutaneous placement of gastrostomy tube) and 43760 (change of gastrostomy tube), both of which come under the general exclusion from SNF consolidated billing for ambulatory surgery involving the use of an operating room. The reason that the instructions in PM A-98-37 restrict the outpatient hospital exclusion for ambulatory surgery to those procedures that involve the use of an operating room is to avoid encompassing procedures that are simple enough to be performed at bedside in the SNF itself. Accordingly, with respect to PEG tube procedures, we regard the use of a GI suite or an endoscopy suite as equivalent to the use of an operating room for purposes of this exclusion.

Comment: We received many comments on various aspects of an SNF’s relationship with its suppliers. In the interim final rule (63 FR 26300), we noted that section 1888(e)(9) of the Act provides that the amount of Part B payment to an SNF shall be determined in accordance with the applicable fee schedule for the particular service. We also noted the concern that if an SNF were to arrange with an outside supplier for the provision of a particular service for less than the applicable fee schedule amount, allowing the SNF to retain the difference could create a perverse incentive for the SNF to provide unnecessary services.

We invited comments on possible ways to address this concern, including pursuing legislation (to limit the SNF’s Part B payment to the lower of the applicable fee schedule amount or the amount that the supplier actually charges the SNF) or, alternatively, to require the SNF to pay its supplier the full fee schedule amount. A few commenters expressed support for limiting the SNF’s Part B payment to the lower of the applicable fee schedule amount or the amount of the supplier’s actual charge to the SNF, but only if the SNF is required to pass this entire

amount (as so limited) on to the supplier. A greater number supported requiring the SNF to pass the full fee schedule amount on to the supplier, regardless of the supplier's actual charge (some of these commenters advocated permitting the SNF to retain a "reasonable" administrative charge).

By far the largest group of commenters, however, argued against imposing any restrictions in this area, noting that transactions between the SNF and its suppliers are a private contractual matter in which we should not intervene. They maintained that the appropriate way to address any abusive practices would be through more vigorous enforcement of existing statutes and regulations (such as medical review procedures), rather than to prescribe the specific terms of payment between the SNF and its suppliers. Other commenters expressed concerns about possible violations of the anti-kickback provisions at section 1128B(b) of the Act, as well as more general concerns about the timeliness and adequacy of the SNF's payment to its suppliers.

Response: We agree that, under current law, an SNF's relationship with its supplier is essentially a private contractual matter, and the terms of the supplier's payment by the SNF must be arrived at through direct negotiations between the two parties themselves. Accordingly, we believe that the most effective way for a supplier to address any concerns that it may have about the adequacy or timeliness of the SNF's payment would be for the supplier to ensure that any terms to which it agrees in such negotiations satisfactorily address those concerns.

We remain concerned, however, over the potential for the provision of unnecessary services, and will continue to evaluate possible legislative and other approaches to addressing this concern. In addition, we note that our discussion of the relationship between an SNF and its suppliers should not be construed as addressing in any manner the potential applicability of the statutory anti-kickback provisions, since matters relating specifically to the enforcement of these provisions lie exclusively within the purview of the Office of the Inspector General.

O. Scope of Extended Care Benefits

Along with the promulgation of regulations specifically describing the SNF PPS itself, the interim final rule also included a number of conforming revisions in other portions of the regulations. One such revision was a reorganization of subpart C of part 409 (describing the scope of covered

services under the Part A SNF benefit), which now tracks more accurately the corresponding portion of the Medicare statute at section 1861(h) of the Act.

Comment: One commenter requested us to clarify that the regulations at § 409.26(a) (coverage of transfer agreement hospital services) provide for separate Part B payment for the medical services of an intern or resident of the SNF's transfer agreement hospital.

Response: The commenter's understanding of the purpose of this provision is incorrect. This section of the regulations implements section 1861(h)(6)(A) of the Act, which describes the scope of services included in the Part A extended care benefit. Accordingly, the medical services of interns and residents described in § 409.26(a) are covered as SNF services under Part A, rather than being covered separately as practitioner services under Part B.

P. Impact Analysis

As required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995, and the Regulatory Flexibility Act (RFA) (Public Law 96-354), the interim final rule included a Regulatory Impact Statement, on which we received numerous comments.

Comment: Many commenters were concerned about the budgetary savings from the SNF PPS as indicated in the interim final rule, as compared with CBO's estimate at the time of the BBA. Many of these commenters felt that this "extra" money should be given back to the SNFs through the calculation of the rates to be used in the PPS.

Response: CBO's estimate of savings of \$9.2 billion over five years only shows the effect on SNFs under Medicare fee for service and does not include the indirect savings due to reduced managed care payments, which are based on average fee for service payments by county. The estimate of 5-year savings shown in the interim final rule (63 FR 26304) of \$12.87 billion includes both the fee-for-service effect and the managed care effect (which, as stated in the interim final rule, is about 25 percent of the total). If savings attributable to managed care are taken out, the result is very close to the \$9.5 billion in savings which CBO had estimated.

Comment: Many commenters were concerned about the behavioral offset which was assumed in the savings estimate. Some argued that there should have been no offset assumed whatsoever, and all believed that the offset that actually was assumed was much too large. In addition, many commenters expressed concern about

the potential for nursing home closures and diminished beneficiary access to needed care.

Response: The "behavioral" offset assumed for the impact analysis is only used as a device to assess impact. It is not used to adjust the payment rates. Along with the possible sources of this offset listed in the interim final rule, there are probably many additional factors which would also have the effect of offsetting the savings from this provision.

We are aware and concerned about the statements being reported about potential closures of nursing homes and the delay in patient discharges from hospitals that are being attributed to the change in payments resulting from implementation of the PPS for SNFs. At this time, however, we do not have sufficient claims or MDS data either to confirm or refute these statements. It will be several months before we can establish a baseline and begin to assess the impact on access and quality. As we accumulate data and learn more about the effects of the new payment system, we will report the results.

Regarding the issue of beneficiary access to care, we note that in terms of the impact analysis itself, if these beneficiaries had to remain in higher cost care as opposed to moving to SNFs, this could affect the budgetary savings to Medicare and, therefore, would be part of this offset factor. The final result is that this behavioral offset factor is only used to determine the total budget effect of a provision. It is not meant to indicate abusive behavior by the providers. The 45 percent factor that was used in our impact analysis is in the typical range for offset factors related to a significant payment system change like the SNF PPS. While little empirical data is currently available to estimate the overall impact of the PPS and consolidated billing on access to care in SNFs, this is an important issue in the context of the payment system, certification requirements and quality monitoring activities.

However, from a broader policy perspective, this issue involves not only the payment characteristics of the PPS itself, but also a number of related requirements regarding provider participation in the Medicare program. Some commenters expressed concern that the payment rates under the SNF PPS may be inadequate and could result in SNFs withholding needed care and services from Medicare beneficiaries, or even denying admission to them. We note that in order to be certified for participation in the Medicare program as an SNF, a nursing home must first meet a set of requirements for

participation designed to protect and promote resident health and safety. These certification standards include the requirement to “* * * provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident * * *” (section 1819(b)(2) of the Act). Thus, an SNF that fails to provide or make the necessary arrangements for the care and services that a resident requires would jeopardize its program certification.

Further, the statutory provision regarding Medicare provider agreements (section 1866(a)(1) of the Act) requires an SNF to accept the Medicare payment for covered SNF services as payment in full. The corresponding regulations at § 489.53(a)(2) specify that one of the grounds for terminating a provider agreement is when the provider “* * * places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care.” In addition, longstanding program guidelines in section 134 of the Medicare SNF Manual (HCFA Pub. 12) indicate that, while a provider may restrict the types of health conditions it accepts or may establish other criteria relating to the admission of patients, if those restrictions apply to Medicare beneficiaries, they must apply in the same manner to all other persons seeking care and treatment by the provider.

Comment: One commenter felt that a 17 percent level of budgetary savings cited in the interim final rule was significant for providers of care.

Response: The 17 percent savings factor is an average based on the Medicare business of a provider. When this factor is converted to a total facility basis, it is estimated to be a 1.7 percent savings on average. This does not meet the threshold of three percent which we have used in the past to determine that an anticipated impact is significant. We do realize that using average values does not totally reflect each individual SNF's effect, which was acknowledged in the impact analysis of the interim final rule. However, for many of the factors included in the calculation, only averages existed. Specific data were not available for each individual facility.

Comment: One commenter stated that the 17 percent savings would be higher once the PPS was fully implemented. This factor only was for the first year of implementation, when most facilities would be paid based on 75 percent of their facility-specific rate and 25 percent of the Federal rate.

Response: We agree with this comment that the estimated savings will be greater in future years. The effect of a system that paid all facilities entirely at the Federal rate as of the first year, instead of having the transition, would be that it would save 21 percent on average instead of 17 percent (see table IX.2). This effect would be felt much more heavily by hospital-based facilities (33 percent savings) as opposed to freestanding facilities (18 percent). This result was not included in the original interim final rule because that rule only deals with setting rates for the first year and not with what will happen when it is fully implemented. The results listed here have the same caveats as those done in the original impact analysis; primarily, that averages have been used and the effects on individual providers may differ. Future impacts will be shown as the rates are developed and published in the future.

Comment: Several commenters stated that the 17 percent reduction may be true on average but specific providers may have much larger reductions (based on geographical characteristics).

Response: As was stated in the interim final rule, we do not know the effect on individual providers. Some providers will have a greater than 17 percent reduction in payments while others will have less than that or even an increase. As more data becomes available through the implementation of this system, we will be able to complete a much more thorough analysis of the effects of this system on many of these smaller groups of characteristics.

Comment: Several commenters asserted that the savings were understated because they did not take into account the added costs of implementing PPS for the facilities.

Response: It is true that the savings estimate shown in the interim final rule in table IX.1 (63 FR 26304) does not include any additional costs due to implementing PPS. This is because these savings are the difference in payments to facilities under the PPS compared to the previous payment system (either based on reasonable cost or the optional low-volume PPS). In developing the impact analysis, the previous system payments would not include the costs of implementing PPS. Likewise, the estimates of the new PPS costs do not include the implementation costs. Therefore, the differences between these costs or the savings do not include any effect of this additional cost. On the other hand, the savings estimates do not reflect the lower costs which result from providing services more efficiently, which is a natural outcome of implementing a PPS.

Comment: One commenter stated that the Congress had only intended to reduce the rate of growth in SNF payments and not actually reduce the level of payments.

Response: The statute prescribes the methodology for calculating the payment rate. The statute specifies the base year and specifies the updates to the base year costs. The legislation which implemented this system called for only allowing a market basket minus 1 percentage point increase going back to 1995. This amounted to a total of about seven percent over the three years. In the meantime, costs on a per diem basis had been increasing at a total of about 40 percent during that same period. Some of that increase is due to an increase in case-mix during that period, but as can easily be seen from these numbers, a very stringent limit had been placed on facilities' rate of growth for the last three years. Payments under this system are higher, on average, when compared to 1995 payments, but when compared to 1996 and 1997 payments, could very well be lower.

In addition, due to the formula expressed in the statute, many hospital-based facilities may face a reduction even in comparison to 1995 payments, because the formula for calculating the Federal rate is more weighted to the freestanding average. Thus, because of the statutory formula, most facilities may see a drop in payments in their first year of PPS as opposed to their last year under the previous payment system.

Comment: One commenter wished to know if we considered the probability of units closing or decertifying because of reimbursement levels. They wanted an estimate of the potential closings of small rural facilities since they are usually the only such units in these communities.

Response: We did consider the chance of some facilities closing due to the implementation of PPS. As stated in the interim final rule, the effect on individual SNFs will depend on their ability to adapt to the incentives resulting from the new system. If a provider decides that it cannot (or will not) adapt to the PPS, then that provider may decide to drop out of the Medicare program. This certainly may be a consequence of this provision but, as shown in the impact analysis of the interim final rule, the effect of these provisions are fairly equitable across urban and rural and hospital-based and freestanding ranges. Of course, individual SNFs may be affected in very different ways and this may prompt a variety of responses, including an election to drop out of the program.

There is no way to estimate the number of facilities that will make the election to leave the Medicare program.

However, as part of the offset factor development, this possibility was considered and, therefore, some of that offset is due to the possibility that beneficiaries may be required to stay in more expensive care settings in the absence of SNF care being available. This was one of the reasons reflected in the impact analysis to the interim final rule that budgetary savings from this provision would be diminished.

Comment: Several commenters expressed concern that suppliers would be significantly affected by the changes made in this system.

Response: The way suppliers do business will to some extent be affected by these provisions. Since the suppliers will now have to negotiate with facilities in order to receive payment for their services, this will be different from the current process for suppliers in situations involving an SNF that had not previously elected to do the Medicare billing for its residents' supplies. However, we do not anticipate that this change will be uniformly significant, even among this subset of suppliers, since its effect will be limited primarily to those particular areas that have an abundance of suppliers competing for the business of a relatively small number of SNFs. By contrast, we believe that in most situations suppliers should be able to negotiate a fair amount of payment from the facilities and, thus, will not be significantly affected economically by these provisions, as discussed further in section VI below.

Comment: One commenter argued that since the interim final rule is a major rule (savings over \$100 million), it appears inconsistent to state that an assessment of costs and benefits pursuant to the Unfunded Mandates Reform Act was not needed since local governments and the private sector would not be incurring costs of over \$100 million. This commenter felt that there would be cost shifting and these entities would be picking up the amount of savings the Federal government was realizing.

Response: The interim final rule implemented major changes in how SNFs will be paid by Medicare. Other payers, being prudent purchasers of health care services, will still be able to negotiate with the providers to reach a fair and equitable payment for services rendered to patients they cover. Because other payers are able to negotiate we believe that if providers attempt to shift costs due to SNF PPS other payers will quickly negotiate what they will pay to avoid being unduly burdened with

additional costs. Therefore, there is a great amount of uncertainty regarding the amounts, if any, that other payers may have to bear due to the payment changes as a result of SNF PPS. In previous cases, what has occurred is that other payers have adjusted their policies after we changed our payment policy.

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may mandate an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more. We believe that this final rule will not mandate expenditures in that amount. We do realize that using average values does not totally reflect each individual SNF's effect, which was acknowledged in the Impact section of the interim final rule, or the segmented aggregate effect on State, local, or tribal governments, and the private sector. However, for many of the factors in the calculation only averages existed, and facility-specific data were not available for each individual facility, not making such segmentation possible.

IV. Provisions of the Final Regulations

This final rule incorporates the provisions of the interim final rule with the following revisions, as discussed previously in this preamble:

- We are amending the regulations text at §§ 409.20 and 409.27 to clarify that transportation by ambulance that meets the general medical necessity requirements set forth in § 410.40(d)(1) is covered under the Part A SNF benefit as services that are generally furnished by (or under arrangements made by) SNFs.

- We are amending the regulations text at § 409.30 (Basic requirements) to clarify that the initial presumption of coverage that arises from a beneficiary's first Medicare assessment and his or her resulting RUG-III assignment is valid as of the assessment reference date (that is, the last day of the observation period) for the initial 5-day assessment. We are also correcting an erroneous cross-reference that appears in the introductory material for § 409.30, as well as in the definition of custodial care at § 411.15(g).

- In § 409.33 (Examples of skilled nursing and rehabilitation services), we are restoring certain portions of the regulations text that the interim final rule deleted, with regard to the overall management and evaluation of the care plan; observation and assessment of the patient's changing condition; and, patient education. We are also clarifying

that the use of insertion, sterile irrigation, and replacement of catheters as an example of a skilled nursing service applies solely with regard to suprapubic catheters.

- In § 411.15(p)(3)(iii) we are revising the parenthetical phrase to clarify that our basis for determining that a particular type of outpatient hospital service is subject to the SNF consolidated billing provision is its inclusion within the customary scope of SNF care plans generally, without regard to whether it appears in the individual care plan of a particular beneficiary.

- We are adding a new § 413.350 that provides for making periodic interim payments under the SNF PPS, and we are making a conforming revision in § 413.64(h)(2)(iii). We are also revising the regulations text at § 413.343(b), in order to clarify the language that describes the required Medicare assessment schedule.

- We are amending § 489.21 by adding a new paragraph (h), which specifically precludes charging an SNF resident for an item or service that is subject to the consolidated billing requirement.

V. Collection of Information Requirements

The information collection requirements associated or referenced in this rule, which are subject to the Paperwork Reduction Act, have been approved by the Office of Management and Budget. The titles, approval numbers and current expiration dates of the collection requirements are as follows: "Medicare Common Claim Form," 0938-0008, 08/31/99; "SNF Resident Assessment MDS Data," 0938-0739, 04/30/99.

VI. Impact Analysis

A. Background

Summary of the Interim Final Rule Regulatory Impact Statement

Section 1888(e) of the Act specifies that the base year for computing the RUG payment rates is FY 1995 (that is, October 1, 1994, through September 30, 1995.) Pursuant to the statute, we incorporated several elements into the SNF PPS such as case-mix methodology, the MDS assessment schedule, a market basket index, a wage index, the urban and rural distinction used in the development or adjustment of the Federal rates, and coverage requirements.

In the interim final rule, we stated that SNF PPS will result in estimated annual savings over five years ranging from \$30 million in the first year to

\$4.28 billion in the fifth year. Savings included both the savings from Medicare fee-for-service and managed care payments. It was projected that 8958 SNFs would experience a decrease in Medicare payments as a result of the SNF PPS. The percentage reduction in payments was estimated to be 17 percent.

However, because Medicare SNF payments account for only approximately 10 percent on average of a SNF's total revenue the revenue reduction of a SNF as a result of the interim final rule was approximately 1.7 percent. These were average figures and we did not (and do not) have data that would allow us to determine if a substantial number of SNFs will experience revenue decreases greater than the estimated average.

As stated in the interim final rule, we did not expect suppliers of services to SNFs to be significantly affected by the consolidated billing provisions. Total Medicare reimbursement to suppliers was estimated in the interim final rule to be about \$4 billion each year. The reimbursement to suppliers for SNF services was estimated to be about \$60 million each year. Therefore, we believed that the consolidated billing provisions related to the services provided to patients in Part A SNF stays would generally have a minimal impact on suppliers.

As stated in the interim final rule the majority of ancillary services are provided directly by SNFs or under

arrangements with suppliers and are, therefore, already billed to Medicare by the SNFs. While there was a possibility that, for those services being consolidated as a result of the statute and the interim final rule, a sizeable number of these suppliers might be reimbursed by SNFs at rates lower than the rates at which they were reimbursed by Medicare under the previous system, we believed that this was highly dependent on the reaction each individual supplier had to the new payment system.

In addition, with regard to consolidated billing related to services provided to SNF patients who are not in a Part A stay, to the extent that these services have been necessary in the past, they will still be required and provided to these patients by suppliers.

Accordingly, it was anticipated that the total impact on suppliers would be minimal. However, determining the effect on individual suppliers was not possible due to a lack of data. Therefore we were not able to determine if the new SNF per diem rates would result in a substantial number of suppliers experiencing significant decreases in their total revenues.

B. Impact of This Final Rule

We have examined the impacts of this final rule as required by Executive Order 12866, section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995, and the Regulatory Flexibility Act (RFA) (Public Law 96-354). Executive

Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually).

The purpose of this final rule is not to initiate significant policy changes with regard to the SNF PPS but, rather, to clarify and make minor modifications in the policies that were established in the SNF PPS interim final rule published on May 12, 1998 (63 FR 26251). Accordingly, we believe that the revisions and clarifications mentioned elsewhere in the preamble (for example, the adjustment to the nursing case-mix component of the urban and Federal rates) will have, at most, only a negligible overall effect upon the regulatory impact estimate specified in the interim final rule. As such, these revisions will not represent an additional burden to the industry.

Columns A-C of Table IX.2 below, published in the interim final rule (63 FR 26304) depicted the number of facilities that were projected to experience a decrease in Medicare SNF payments under the new SNF PPS rates and the percentage change for the type of facility.

TABLE IX.2.—IMPACT ON SNFS BY TYPE

| Type of SNF | Total number of SNFs (A) | Number of SNFs with lower payment (B) | Estimated average percentage reduction in payments for first year transition (C) | Estimated average percentage reduction in payments for fully implemented PPS (D) |
|------------------------------|-----------------------------|--|---|---|
| MSA Freestanding | 5617 | 5585 | 17 | 18 |
| MSA Hospital Based | 683 | 679 | 19 | 34 |
| Non-MSA Freestanding | 2204 | 2189 | 17 | 18 |
| Non-MSA Hospital Based | 533 | 531 | 18 | 30 |
| Total | 9037 | 8984 | 17 | 21 |

Specifically, column (A) of the table depicted the total number of SNFs in the data base for FY 1995 cost reporting periods. Column (B) depicted the number of SNFs whose payment rate for cost reporting periods beginning July 1, 1998 would be lower than the payment they would have received under the former cost-based methodology for cost reporting periods beginning July 1, 1998.

As described in the interim final rule, the payments received under SNF PPS would initially be based on a facility level case-mix score developed using the case-mix indices and the MEDPAR analog. The payments that would have been received under the former (pre-SNF PPS) system were estimated by using the same average inflation factor from the 1995 data for each facility. Column (C) depicts the estimated

reduction in payments on a percentage basis between the two payment methodologies for the first year of transition. New column (D) depicts the estimated reduction in payments on a percentage basis between the two payment methodologies for the fully implemented SNF PPS.

The estimated effect of the fully implemented SNF PPS (if, instead of having the transition, it paid all

facilities entirely at the Federal rate as of the first year) is that it would save 21 percent on average instead of 17 percent. This effect is felt much more heavily by hospital-based facilities (34 percent savings) as opposed to freestanding facilities (18 percent).

As was stated in the interim final rule, the results listed in Table IX.2 should be viewed with caution and as illustrative of broad groupings of SNFs. Averages have been used and the effects on individual SNFs may differ. Future impacts will be shown as the rates are developed and published in the future.

As stated in the interim final rule, in developing the estimate, we assumed each facility would increase costs at the national average rate. This national average increase includes the higher costs of new facilities entering the program. Therefore, this increase might be slightly higher than the true amount for existing facilities. We do, however, expect total payments to SNFs to decrease compared to payments that would have occurred under the former cost-based methodology. The effects of this decrease in payments to any individual SNF will depend on that SNF's ability to operate under the new payment methodology and on the proportion of its revenues that come from the Medicare program.

The RFA requires agencies to analyze options for regulatory relief of small entities. The BBA mandates implementation of SNF PPS. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and governmental agencies. Most SNFs and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less annually. States and tribal governments are not considered to be small entities, nor are intermediaries or carriers.

Under the RFA, an economic impact is significant if the annual total costs or revenues of a substantial number of entities will be increased or decreased by at least 3 percent. Medicare payments generally do not account for a high proportion of SNF revenue (about 10 percent on average) and the estimated average percentage reduction in payments for the fully implemented SNF PPS reduces those payments by approximately 21 percent on average. Therefore, total revenues for SNFs will be reduced by about 2.1 percent. As stated above, we are unable to determine the effects on individual SNFs and therefore are unable to determine if the new SNF per diem rates will result in a substantial number of SNFs experiencing significant decreases in their total revenues.

C. Rural Hospital Impact Statement

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. We are not preparing a rural impact statement since we have determined, and the Secretary certifies, that this rule will not have a significant economic impact on the operations of a substantial number of small rural hospitals.

D. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may mandate an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more. We believe that this final rule will not mandate expenditures in that amount.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR chapter IV is amended as follows:

PART 409—HOSPITAL INSURANCE BENEFITS

A. Part 409 is amended as set forth below:

1. The authority citation for part 409 is revised to read as follows:

Authority: Sections 1102 and 1871 of the Social Security Act (U.S.C. 1302 and 1395hh).

Subpart C—Posthospital SNF Care

2. In § 409.20, remove paragraph (a)(8).

3. In § 409.27, the word “and” is removed from the end of paragraph (a),

the period at the end of paragraph (b) is removed and a semicolon followed by the word “and” is added in its place, and a new paragraph (c) is added, to read as follows:

§ 409.27 Other services generally provided by (or under arrangements made by) SNFs.

* * * * *

(c) Transportation by ambulance that meets the general medical necessity requirements set forth in § 410.40(d)(1) of this chapter.

Subpart D—Requirements for Coverage of Posthospital SNF Care

4. In § 409.30, the second sentence in the introductory text is removed and two sentences are added in its place to read as follows:

§ 409.30 Basic requirements.

* * * A beneficiary in an SNF is also considered to meet the level of care requirements of § 409.31 up to and including the assessment reference date for the 5-day assessment prescribed in § 413.343(b) of this chapter, when assigned to one of the Resource Utilization Groups that is designated (in the annual publication of Federal prospective payment rates described in § 413.345 of this chapter) as representing the required level of care. For the purposes of this section, the assessment reference date is defined in accordance with § 483.315(d) of this chapter, and must occur no later than the eighth day of posthospital SNF care.

* * * * *

5. In § 409.33, paragraphs (a), (b), and (c) are redesignated as paragraphs (b), (c), and (d), respectively; a new paragraph (a) is added; and newly designated paragraph (b)(4) is revised to read as follows:

§ 409.33 Examples of skilled nursing and rehabilitation services.

(a) *Services that could qualify as either skilled nursing or skilled rehabilitation services.* (1) *Overall management and evaluation of care plan.* (i) When overall management and evaluation of care plan constitute skilled services. The development, management, and evaluation of a patient care plan based on the physician's orders constitute skilled services when, because of the patient's physical or mental condition, those activities require the involvement of technical or professional personnel in order to meet the patient's needs, promote recovery, and ensure medical safety. Those activities include the management of a plan involving a variety of personal care services only when, in light of the patient's condition, the aggregate of

those services requires the involvement of technical or professional personnel.

(ii) Example. An aged patient with a history of diabetes mellitus and angina pectoris who is recovering from an open reduction of a fracture of the neck of the femur requires, among other services, careful skin care, appropriate oral medications, a diabetic diet, an exercise program to preserve muscle tone and body condition, and observation to detect signs of deterioration in his or her condition or complications resulting from restricted, but increasing, mobility. Although any of the required services could be performed by a properly instructed person, such a person would not have the ability to understand the relationship between the services and evaluate the ultimate effect of one service on the other. Since the nature of the patient's condition, age, and immobility create a high potential for serious complications, such an understanding is essential to ensure the patient's recovery and safety. Under these circumstances, the management of the plan of care would require the skills of a nurse even though the individual services are not skilled. Skilled planning and management activities are not always specifically identified in the patient's clinical record. Therefore, if the patient's overall condition supports a finding that recovery and safety can be ensured only if the total care is planned, managed, and evaluated by technical or professional personnel, it is appropriate to infer that skilled services are being provided.

(2) Observation and assessment of the patient's changing condition. (i) When observation and assessment constitute skilled services. Observation and assessment constitute skilled services when the skills of a technical or professional person are required to identify and evaluate the patient's need for modification of treatment or for additional medical procedures until his or her condition is stabilized.

(ii) Examples. A patient with congestive heart failure may require continuous close observation to detect signs of decompensation, abnormal fluid balance, or adverse effects resulting from prescribed medication(s) that serve as indicators for adjusting therapeutic measures. Similarly, surgical patients transferred from a hospital to an SNF while in the complicated, unstabilized postoperative period, for example, after hip prosthesis or cataract surgery, may need continued close skilled monitoring for postoperative complications and adverse reaction. Patients who, in addition to their physical problems, exhibit acute psychological symptoms

such as depression, anxiety, or agitation, may also require skilled observation and assessment by technical or professional personnel to ensure their safety or the safety of others, that is, to observe for indications of suicidal or hostile behavior. The need for services of this type must be documented by physicians' orders or nursing or therapy notes.

(3) Patient education services. (i) When patient education services constitute skilled services. Patient education services are skilled services if the use of technical or professional personnel is necessary to teach a patient self-maintenance.

(ii) Examples. A patient who has had a recent leg amputation needs skilled rehabilitation services provided by technical or professional personnel to provide gait training and to teach prosthesis care. Similarly, a patient newly diagnosed with diabetes requires instruction from technical or professional personnel to learn the self-administration of insulin or foot-care precautions.

(b) * * * (4) Insertion and sterile irrigation and replacement of suprapubic catheters; * * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

B. Part 411 is amended as set forth below:

1. The authority citation for part 411 continues to read as follows:

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Exclusions and Exclusion of Particular Services

§ 411.15 [Amended]

2. In § 411.15: a. In paragraph (g), remove the citation “§§ 409.30” and add, in its place “§§ 409.31”. b. Paragraph (p)(3)(iii) is revised to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * * (p) * * * (3) * * * (iii) The beneficiary receives outpatient services from a Medicare-participating hospital or CAH (but only with respect to those services that are beyond the general scope of SNF comprehensive care plans, as required under § 483.20 of this chapter); or * * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

C. Part 413 is amended as set forth below:

1. The heading for part 413 is revised as set forth above.

2. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1861(v)(1)(A), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(v)(1)(A), and 1395hh).

3. In § 413.64, paragraph (h)(2)(iii) is revised to read as follows:

§ 413.64 Payments to providers: Specific rules.

* * * * * (h) * * * (2) * * *

(iii) Part A SNF services furnished in cost reporting periods beginning before July 1, 1998. (For services furnished in subsequent cost reporting periods, see § 413.350 regarding periodic interim payments for skilled nursing facilities).

* * * * *

§ 413.343 [Amended]

4. In § 413.343(b), remove the words “following admission” and add, in their place, the words “of posthospital SNF care”.

5. Add § 413.350 to subpart J to read as follows:

§ 413.350 Periodic interim payments for skilled nursing facilities receiving payment under the skilled nursing facility prospective payment system for Part A services.

(a) General rule. Subject to the exceptions in paragraphs (b) and (c) of this section, SNFs receiving payment under the PPS for Part A services do not receive interim payments during the cost reporting year, and receive payment only following submission of a bill. Paragraph (d) of this section provides for accelerated payments in certain circumstances.

(b) Periodic interim payments. (1) An SNF receiving payment under the prospective payment system may receive periodic interim payments (PIP) for Part A SNF services under the PIP method subject to the provisions of § 413.64(h). To be approved for PIP, the SNF must meet the qualifying requirements in § 413.64(h)(3). Moreover, as provided in § 413.64(h)(5), intermediary approval is conditioned upon the intermediary's best judgment as to whether payment can be made

under the PIP method without undue risk of its resulting in an overpayment to the provider.

(2) *Frequency of payment.* The intermediary estimates an SNF's prospective payments net of estimated beneficiary coinsurance and makes biweekly payments equal to $\frac{1}{26}$ of the total estimated amount of payment for the year. If an SNF has payment experience under the prospective payment system, the intermediary estimates PIP based on that payment experience, adjusted for projected changes supported by substantiated information for the current year. Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6). The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an SNF receives interim payments for less than a full reporting period. These payments are subject to final settlement.

(3) *Termination of PIP.* (i) Request by the SNF. An SNF receiving PIP may convert to receiving prospective payments on a non-PIP basis at any time.

(ii) Removal by the intermediary. An intermediary terminates PIP if the SNF no longer meets the requirements of § 413.64(h).

(c) *Interim payments for Medicare bad debts and for Part A costs not paid under the prospective payment system.* For Medicare bad debts and for costs of an approved education program and other costs paid outside the prospective payment system, the intermediary determines the interim payments by estimating the reimbursable amount for the year based on the previous year's

experience, adjusted for projected changes supported by substantiated information for the current year, and makes biweekly payments equal to $\frac{1}{26}$ of the total estimated amount. Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6). The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an SNF receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Accelerated payments.* (1) *General rule.* Upon request, an accelerated payment may be made to an SNF that is receiving payment under the prospective payment system and is not receiving PIP under paragraph (b) of this section if the SNF is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the SNF.

(ii) Due to an exceptional situation, there is a temporary delay in the SNF's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* An SNF's request for an accelerated payment must be approved by the intermediary and HCFA.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as SNF bills are processed or by direct payment by the SNF.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

D. Part 489 is amended as set forth below:

1. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102, 1819, 1861, 1864(m), 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, and 1395hh).

2. In § 489.21, a new paragraph (h) is added to read as follows:

§ 489.21 Specific limitations on charges.

* * * * *

(h) Items and services (other than those described in § 489.20(s)(1) through (11)) furnished to a resident (as defined in § 411.15(p)(3) of this chapter) of an SNF for which Medicare payment would be made if furnished by the SNF or by other providers or suppliers under arrangements made with them by the SNF. For this purpose, a charge by another provider or supplier for such an item or service is treated as a charge by the SNF for the item or service, and is also prohibited.

(Catalog of Federal Domestic Assistance Program Number 93.773, Medicare—Hospital Insurance; and Program Number 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 14, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: July 22, 1999.

Donna Shalala,

Secretary.

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