DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 409, 410, 411, 413, 424, and 484

[HCFA–1059–F]

RIN 0938–AJ24

Medicare Program; Prospective Payment System for Home Health Agencies

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

ACTION: Final rule.

SUMMARY: This final rule establishes requirements for the new prospective payment system for home health agencies as required by section 4603 of the Balanced Budget Act of 1997, as amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. The requirements include the implementation of a prospective payment system for home health agencies, consolidated billing requirements, and a number of other related changes. The prospective payment system described in this rule replaces the retrospective reasonable-cost-based system currently used by Medicare for the payment of home health services under Part A and Part B.

EFFECTIVE DATE: These regulations are effective October 1, 2000.

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

ADL	Activities of Daily Living
BBA	Balanced Budget Act of 1997
BBRA	Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999
COPs	Conditions of participation

DME	Durable medical equipment
FIs	Fiscal intermediaries
FFY	Federal fiscal year
FMR	Focused medical review
FY	Fiscal year
HHA	Home health agency
HIC	Health insurance claim
HHRGs	Home Health Resource Groups
IADL	Instrumental Activities of Daily Living
IPS	Interim payment system
LUPA	Low-utilization payment adjustment
MS	Medical social services
MSA	Metropolitan Statistical Area
NCSB	Neurological, cognitive, sensory, and behavioral variables
OASIS	Outcome and Assessment Information Set
OBQI	Outcome based quality improvement
OCESAA	Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999
OSCAR	On-line Survey and Certification System
OT	Occupational therapy
PEP	Partial episode payment
PPS	Prospective payment system
PT	Physical therapy
RHHI	Regional Home Health Intermediary
RUGs	Resource Utilization Groups
SCIC	Significant Change in Condition
SN	Skilled nursing service
SP	Speech-language pathology

I. Background

A. Current System for Payment of Home Health Agencies

The Balanced Budget Act of 1997 (BBA), Public Law 105 33, enacted on August 5, 1997, significantly changed the way we pay for Medicare home health services. Until the implementation of a home health prospective payment system (PPS), home health agencies (HHAs) receive payment under a cost-based reimbursement system, referred to as the interim payment system and generally established by section 4602 of the BBA. The interim payment system imposes two sets of cost limits for HHAs. Section 4206(a) of the BBA reduced the home health per-visit cost limits from 112 percent of the mean labor-related and nonlabor-related, per-visit costs for freestanding agencies to 105 percent of the median. In addition, HHA costs are subjected to an aggregate per-beneficiary cost limitation. For those providers with a 12-month cost reporting period ending in Federal fiscal year (FFY) 1994, the per-beneficiary cost limitation is based on a blend of costs (75 percent on 98 percent of the agency-specific costs and 25 percent on 98 percent of the standardized regional average of the costs for the agency's census region). For new providers and those providers without a 12-month cost-reporting period ending in FFY 1994, the per-beneficiary limitation is the national median of the per-beneficiary limits for HHAs. Under the interim payment system, HHAs are paid the lesser of (1) actual reasonable costs; (2) the per-visit limits; or (3) the per-beneficiary limits. Effective October 1, 1997, the interim payment system exists until prospective payment for HHAs is implemented.

On October 21, 1998, the Omnibus Consolidated and Emergency Supplemental Appropriations Act for FY 1999 (OCESAA), Public Law 105–277, was signed into law. Section 5101 of OCESAA amended section 1861(v)(1)(L) of the Social Security Act (the Act) by providing for adjustments to the per-beneficiary and per-visit limitations for cost-reporting periods beginning on or after October 1, 1998. We had published a notice with comment period establishing the cost limitations for cost reporting periods beginning on or after October 1, 1998 in the **Federal Register** that was entitled ''Medicare Program; Schedules of Per-Visit and Per-Beneficiary Limitations on Home Health Agency Costs for Cost Reporting Periods Beginning On or After October 1, 1998'' on August 11, 1998 (63 FR 42912). OCESAA made the following adjustments to these limitations:

Providers with a 12-month cost reporting period ending during FY 1994, whose per-beneficiary limitations were less than the national median, which is to be set at 100 percent for comparison purposes, will get their current per-beneficiary limitation plus ⅓ of the difference between their rate and the adjusted national median per-beneficiary limitation. New providers and providers without a 12-month cost-reporting period ending in FFY 1994 whose first cost-reporting period begins before October 1, 1998 will receive 100 percent of the national median per-beneficiary limitation.

New providers whose first cost-reporting periods begin during FFY 1999 will receive 75 percent of the national median per-beneficiary limitation as published in the August 11, 1998 notice. In the case of a new provider or a provider that did not have a 12-month cost-reporting period beginning during FFY 1994 that filed an application for HHA provider status before October 15, 1998 or that was approved as a branch of its parent agency before that date and becomes a subunit of the parent agency or a separate freestanding agency on or after that date, the per-beneficiary limitation will be set at 100 percent of the median. The per-visit limitation effective for cost-reporting periods beginning on or after October 1, 1998 is set at 106 percent of the median instead of 105 percent of the median, as previously required in the BBA.

There was contingency language for the home health PPS provided in the BBA that was also amended by section 5101 of OCESAA. The language provided that if the Secretary, for any reason, does not establish and implement the PPS for home health services by October 1, 2000, the Secretary will provide for a reduction by 15 percent to the per-visit cost limits and per-beneficiary limits, as those limits would otherwise be in effect on September 30, 2000. Section 302 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Public Law 106–113, enacted on November 29, 1999, however, subsequently removed the contingency language governing the 15 percent reduction to the IPS cost limits for FFY 2001. It also increased the per-beneficiary limit for those providers with limits below the national median.

B. Requirements of the Balanced Budget Act of 1997, the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999, and the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 for the Development of a Prospective Payment System for Home Health Agencies

Section 4603(a) of the BBA provides the authority for the development of a PPS for all Medicare-covered home health services paid on a reasonable cost basis that will ultimately be based on units of payment by adding section 1895 to the Act entitled ''Prospective Payment For Home Health Services.''

Section 5101(c) of OCESAA amends section 1895(a) of the Act by removing the transition into the PPS by cost-reporting periods and requiring all HHAs to be paid under PPS effective upon the implementation date of the system. Section 1895(a) of the Act now states ''Notwithstanding section 1861(v), the Secretary shall provide, for portions of cost reporting periods occurring on or after October 1, 2000, for payments for home health services in accordance with a prospective payment system established by the Secretary under this section.''

Section 1895(b)(1) of the Act requires the Secretary to establish a PPS for all costs of home health services. Under this system all services covered and paid for on a reasonable cost basis under the Medicare home health benefit as of

the date of enactment of the BBA, including medical supplies, will be paid on the basis of a prospective payment amount. The Secretary may provide for a transition of not longer than 4 years during which a portion of the prospective payment may be agency-specific as long as the blend does not exceed budget-neutrality targets.

Section 1895(b)(2) of the Act requires the Secretary in defining a prospective payment amount to consider an appropriate unit of service and the number, type, and duration of visits furnished within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

Section 1895(b)(3)(A)(i) of the Act requires that (1) the computation of a standard prospective payment amount include all costs of home health services covered and paid for on a reasonable-cost basis and be initially based on the most recent audited cost report data available to the Secretary, and (2) the prospective payment amounts be standardized to eliminate the effects of case-mix and wage levels among HHAs.

Section 5101(c) of OCESAA modifies the effective date of the budget-neutrality targets for HHA PPS by amending section 1895(b)(3)(A)(ii) of the Act. Section 1895(b)(3)(A)(ii) of the Act, as amended, requires that the standard prospective payment limitation amounts be budget neutral to what would be expended under the current interim payment system with the limits reduced by 15 percent at the inception of the PPS on October 1, 2000. Section 302 of the BBRA, delayed the application of the 15 percent reduction in the budget neutrality target for PPS until one year after PPS implementation. The law further requires the Secretary to report within 6 months of implementation of PPS on the need for the 15 percent reduction.

Section 5101(d)(2) of OCESAA also modifies the statutory provisions dealing with the home health market basket percentage increase. For fiscal years 2002 or 2003, sections 1895(b)(3)(B)(i) and (b)(3)(B)(ii) of the Act, as so modified, require that the standard prospective payment amounts be increased by a factor equal to the home health market basket minus 1.1 percentage points. In addition, for any subsequent fiscal years, the statute requires the rates to be increased by the applicable home health market basket index change. Section 306 of the BBRA amended the statute to provide a technical correction clarifying the applicable market basket increase for PPS in each of FYs 2002 and 2003. The technical correction clarifies that the update in home health PPS in FY 2002 and FY 2003 will be the home health market basket minus 1.1 percent.

Section 1895(b)(3)(C) of the Act requires the Secretary to reduce the prospective payment amounts if the Secretary accounts for an addition or adjustment to the payment amount made in the case of outlier payments. The reduction must be in a proportion such that the aggregate reduction in the prospective payment amounts for the given period equals the aggregate increase in payments resulting from the application of outlier payments.

Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix adjustment factor that explains a significant amount of the variation in cost among different units of services. Similarly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services in a geographic area compared to the national average applicable level. These wage-adjustment factors may be the factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act.

Section 1895(b)(5) of the Act gives the Secretary the option to grant additions or adjustments to the payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Total outlier payments in a given fiscal year cannot exceed 5 percent of total payments projected or estimated.

Section 1895(b)(6) of the Act provides for the proration of prospective payment amounts between the HHAs involved in the case of a patient electing to transfer or receive services from another HHA within the period covered by the prospective payment amount.

Section 1895(d) of the Act limits review of certain aspects of the HHA PPS. Specifically, there is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the following: the establishment of the transition period under 1895(b)(1) of the Act, the definition and application of payment units under section 1895(b)(2) of the Act, the computation of initial standard prospective amounts under 1895(b)(3)(A) of the Act (including the reduction described in section 1895(b)(3)(A)(ii) of the Act), the establishment of the adjustment for outliers under 1895(b)(3)(C) of the Act, the establishment of case-mix and area wage adjustments under 1895(b)(4) of the Act, and the establishment of any adjustments for outliers under 1895(b)(5) of the Act.

Section 4603(b) of the BBA amends section 1815(e)(2) of the Act by eliminating periodic interim payments for HHAs effective October 1, 2000.

Section 4603(c) of the BBA sets forth the following conforming amendments:

- Section 1814(b)(1) of the Act is amended to indicate that payments under Part A will also be made under section 1895 of the Act;
- Section 1833(a)(2)(A) of the Act is amended to require that home health services, other than a covered osteoporosis drug, are paid under HHA PPS;
- Section 1833(a)(2) is amended by adding a new subparagraph (G) regarding payment of Part B services at section 1861(s)(10)(A) of the Act; and
- Section 1842(b)(6)(F) is added to the Act and section 1832(a)(1) of the Act is amended to include a reference to section 1842(b)(6)(F), both governing the consolidated billing requirements.

Section 4603(d) of the BBA was amended by section 5101(c)(2) of OCESAA by changing the effective date language for the HHA PPS and the other changes made by section 4603 of the BBA. Section 4603(d) now provides that: ''Except as otherwise provided, the amendments made by this section shall apply to portions of cost reporting periods occurring on or after October 1, 2000.'' This change requires all HHAs to be paid under HHA PPS effective October 1, 2000 regardless of the current cost-reporting period.

Section 4603(e) of the BBA sets forth the contingency language for HHA PPS noting that if the Secretary, for any reason, does not establish and implement HHA PPS on October 1, 2000, the per-visit cost limits and per-beneficiary limits under the interim payment system will be reduced by 15 percent. Section 302(a) of the BBRA of 1999 eliminated the interim payment system contingency language by striking this section from the statute.

Section 305 of the BBRA refined the consolidated billing requirements under PPS. The new law excludes durable medical equipment (DME) from the home health consolidated billing requirements.

C. Summary of the Proposed Rule

We published a proposed rule in the **Federal Register** on October 28, 1999 at (64 FR 58134) that set forth proposed

requirements that would establish the new prospective payment system for home health agencies as required by the Balanced Budget Act (BBA) of 1997, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA), of 1999, and the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA). The PPS would replace the retrospective reasonable cost-based system currently used by Medicare for the payment of home health services under Part A and Part B.

1. Transition to PPS

The statute provides authority for a transition period of no longer than 4 years to PPS. We proposed a full transition to the PPS. The overwhelming majority of the industry seems eager to move to PPS. However, some individual home health agencies (HHAs) will object to PPS because they currently enjoy a competitive advantage with high cost limits under the interim payment system. Furthermore, the statute now requires that we pay all providers under PPS on October 1, 2000 rather than phasing in by cost reporting period.

2. Unit of Payment (60-Day Episode)

We proposed a 60-day episode as the basic unit of payment under the HHA PPS. Evidence from the Phase II per-episode HHA PPS demonstration illustrated that the length of a 60-day episode captured a majority of the patients. Moreover, the 60-day episode would coordinate with the 60-day physician recertification of the plan of care and with the 60-day reassessment of the patient using the Outcomes and Assessment Information Set (OASIS). This would encourage physicians' involvement in the plan of care.

3. Split Percentage Payment Approach to the 60-Day Episode Payment (Periodic Interim Payments Statutorily Eliminated With PPS)

Because the PPS system must maintain a cash flow to agencies accustomed to billing on 30-day cycles or receiving periodic interim payments, we proposed a split percentage billing for each 60-day episode. Under this system, an agency would receive a partial episode payment (50 percent) as soon as it notifies us of an admission and a final percentage (50 percent) payment at the close of the 60-day episode.

4. Partial Episode Payment Adjustment (PEP Adjustment)

The partial episode payment adjustment (PEP adjustment) provides a simplified approach to the episode definition and accounts for key intervening events in a patient's care defined as:

—A beneficiary elected transfer, or

—A discharge and return to the same HHA that would warrant a new clock for purposes of payment, OASIS assessment, and physician certification of the new plan of care. When a new 60-day episode begins, the original 60-day episode payment is proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care before the intervening event. The proportional payment is the PEP adjustment.

The proposed PEP adjustment is based on the span of days including the start-of-care date/first billable service date through and including the last billable service date under the original plan of care before the intervening event. The PEP adjustment is calculated by using the span of days (first billable service date through and including the last billable service date) under the original plan of care as a proportion of 60. The proportion is multiplied by the original case-mix and wage-adjusted 60-day episode payment.

We also proposed to close out the initial episode payment with a PEP adjustment and restart the 60-day episode clock under an existing episode due to a beneficiary elected transfer. We are concerned that these transfer situations could be subject to manipulation. Therefore, we proposed that we will not apply the PEP adjustment if the transfer is between organizations of common ownership.

In addition, the discharge and return to the same HHA during the 60-day episode period is only recognized when a beneficiary reached the treatment goals in the original plan of care. The original plan of care must be terminated with no anticipated need for additional home health services for the balance of the 60-day period. The discharge cannot be a result of a significant change in condition. In order for the situation to be defined as a PEP adjustment due to discharge and return to the same HHA during the 60-day episode, the discharge must be a termination of the complete course of treatment in the original plan of care. We would not recognize any PEP adjustment in an attempt to circumvent the payment made under the significant change in condition payment adjustment discussed below.

5. Significant Change in Condition Adjustment (SCIC Adjustment)

We proposed that the third intervening event over a course of a 60-day episode of home health care that could trigger a change in payment level to be a significant change in the patient's condition. We proposed the significant change in condition payment adjustment (SCIC adjustment) as the proportional payment adjustment reflecting the time both before and after the patient experienced a significant change in condition during the 60-day episode. The proposed SCIC adjustment occurs when a beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. In order to receive a new case-mix assignment for purposes of SCIC payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in treatment approach in the patient's plan of care.

The SCIC adjustment is calculated in two parts. The first part of the SCIC adjustment reflects the adjustment to the level of payment *before* the significant change in the patient's condition during the 60-day episode. The second part of the SCIC adjustment reflects the adjustment to the level of payment *after* the significant change in the patient's condition occurs during the 60-day episode. The first part of the SCIC adjustment uses the span of days of the first billable service date through the last billable service date before the intervening event of the patient's significant change in condition that warrants a new case-mix assignment for payment. The first part of the SCIC adjustment is determined by taking the span of days before the patient's significant change in condition as a proportion of 60 multiplied by the original episode payment amount. The original episode payment level is proportionally adjusted using the span of time the patient was under the care of the HHA before the significant change in condition that warranted an OASIS assessment, physician change orders indicating the need for a significant change in the course of the treatment plan, and the new case-mix assignment for payment at the end of the 60-day episode.

The second part of the SCIC adjustment reflects the time the patient is under the care of the HHA after the patient experienced the significant change in condition during the 60-day episode that warranted the new case-mix assignment for payment purposes. The second part of the SCIC adjustment is a proportional payment adjustment reflecting the time the patient will be under the care of the HHA after the significant change in condition and

continuing until the end of the 60-day episode. Once the HHA completes the OASIS, obtains the necessary physician change orders reflecting the need for a new course of treatment in the plan of care, and assigns a new case-mix level for payment, the second part of the SCIC adjustment begins. The second part of the SCIC adjustment is determined by taking the span of days (first billable service date through the last billable service date) after the patient experiences the significant change in condition through the balance of the 60-day episode as a proportion of 60 multiplied by the new episode payment level resulting from the significant change. The initial percentage payment provided at the start of the 60-day episode will be adjusted at the end of the episode to reflect the first and second parts of the SCIC adjustment (or any applicable medical review or low utilization payment adjustment (LUPA) discussed below) determined at the final billing for the 60-day episode.

6. Low-Utilization Payment Adjustment (LUPA)

We proposed payments for low-utilization episodes by paying those episodes at a standardized average per-visit amount. Episodes with four or fewer visits would be paid the per-visit amount times the number of visits actually provided during the episode. ''Savings'' from reduced episode payments would be redistributed to all episodes.

7. Case-Mix Methodology

In the proposed rule, we described a home health case-mix system developed under a research contract with Abt Associates, Inc., of Cambridge, Massachusetts. The case-mix system uses selected data elements from the OASIS assessment instrument and an additional data element measuring receipt of therapy services of at least 8 hours (the 8-hour threshold has been defined as 10 visits for purposes of case-mix adjustment of PPS reimbursements). The data elements are organized into three dimensions to capture clinical severity factors, functional severity factors, and services utilization factors influencing case-mix. The process of selecting data elements for each dimension was described in the proposed rule. In the clinical and functional dimensions, each data element is assigned a score value derived from multiple regression analysis of the Abt research data. The score value measures the impact of the data element on total resource use. Scores are also assigned to data elements in the services utilization dimension. To find a patient's case-mix group, the case-mix grouper sums the patient's scores within each of the three dimensions. The resulting sum is used to assign the patient to a severity level on each dimension. There are four clinical severity levels, five functional severity levels, and four services utilization severity levels. Thus there are 80 possible combinations of severity levels across the three dimensions. Each combination defines one of the 80 groups in the case-mix system. For example, a patient with high clinical severity, moderate functional severity, and low services utilization severity is placed in the same group with all other patients whose summed scores place them in the same set of severity levels for the three dimensions.

8. Outlier Payments

Outlier payments are payments made in addition to the 60-day episode payments for episodes that incur unusually large costs. Outlier payments would be made for episodes whose estimated cost exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group, PEP adjustment or total SCIC adjustment would be the episode payment amount, PEP adjustment, or total SCIC adjustment for that group plus a fixed dollar loss amount that is the same for all case-mix groups. The outlier payment would be a proportion of the amount of estimated costs beyond the threshold. Costs would be estimated for each episode by applying standard per-visit amounts to the number of visits by discipline reported on claims. The fixed dollar loss amount and the loss-sharing proportion are chosen so that total outlier payments are estimated to be no more than 5 percent of estimated total payments. There is no need for a long-stay outlier payment because we would not be limiting the number of continuous episode payments in a fiscal year that may be made for Medicare covered home health care to eligible beneficiaries.

9. Consolidated Billing/Bundling

Under the consolidated billing requirement, we would require that the HHA submit all Medicare claims for the home health services included in 1861(m) of the Social Security Act while the beneficiary is under the home health plan of care established by a physician and is eligible for the home health benefit. The proposed rule included an approach that was superseded by changes to the law made by the BBRA.

II. Provisions of Proposed Rule

In the proposed rule that was published on October 28, 1999 (64 FR 54134), we proposed a number of revisions to the regulations in order to implement the prospective payment system, the HHA consolidated billing provision, and conforming statutory changes. We proposed to make conforming changes in 42 CFR parts 409, 424, and 484 to synchronize all timeframes for the plan of care certification, OASIS Recertification (follow-up) assessment, and episode payments to reflect a 60-day period. In addition, we proposed to add a new subpart in part 484 to set forth our new payment system for HHAs. These revisions and others are discussed in detail below.

First, we proposed to revise part 409, subpart E, and discussed the requirements that must be met for Medicare to make payment for home health services. We proposed to make a conforming change in § 409.43 regarding the plan of care requirements. Specifically, we proposed to revise the frequency for review in paragraph (e) of this section by replacing the phrase ''62 days'' with ''60 days unless there is—

- An intervening beneficiary elected transfer;
- A significant change in condition resulting in a new case-mix assignment; or
- A discharge and return to the same HHA during the 60-day episode that warrants a new 60-day episode payment and a new physician certification of the new plan of care.

In addition, we proposed to revise subpart H of this part regarding payments of hospital insurance benefits. We proposed to revise paragraph (a) in § 409.100, which discusses payment for services, to specify the conditions under which Medicare may pay hospital insurance benefits for home health services. We proposed to provide introductory text to paragraph (a) and to redesignate the current paragraph (a) as paragraph (a)(1). Proposed paragraph (a)(2) of this section would require that Medicare may pay hospital insurance benefits for the home health services specified at section 1861(m) of the Act, when furnished to an individual who at the time the item or service is furnished is under a plan of care of an HHA, to the HHA (without regard to whether the item or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

We proposed to make similar changes in part 410, subpart I, which deals with payment of benefits under Part B. We

proposed to add a new paragraph (b)(19) to § 410.150 to specify the conditions under which Medicare Part B pays for home health services. Specifically, proposed paragraph (b)(19) specified that Medicare Part B pay a participating HHA, for home health services furnished to an individual who at the time the item or service is furnished is under a plan of care of an HHA (without regard to whether the item or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

We also proposed to revise part 411 subpart A, which discusses excluded services. We proposed to add a new paragraph (q) to § 411.15 to specify the conditions under which HHA services are excluded from coverage. Proposed paragraph (q) specified that a home health service as defined in section 1861(m) of the Act furnished to an individual who is under a plan of care of an HHA is excluded from coverage unless that HHA has submitted a claim for payment for such services.

We also proposed to simplify the authority citation for part 413. In § 413.1 in the introduction to the section on principles of reasonable cost reimbursement, we proposed to add a new paragraph (h) to include the timeframe under which home health services will be paid prospectively. Paragraph (h) under this section specified that the amount paid for home health services as defined in section 1861(m) of the Act that are furnished beginning on or after October 1, 2000 to an eligible beneficiary under a home health plan of care is determined according to the prospectively determined payment rates for HHAs set forth in part 484, subpart E of this chapter. In addition, we proposed to amend § 413.64 concerning payments to providers. Specifically, we proposed to amend paragraph (h)(1) of this section by removing Part A and Part B HHA services from the periodic interim payment method.

We also proposed to revise part 424, which explains the conditions for Medicare payment. We proposed to revise § 424.22 regarding the certification requirements as a condition for payment. We proposed to add a new paragraph (a)(1)(v) that would specify that as a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify that the individual is correctly assigned to one of the HHRGs. We proposed to make a conforming change at paragraph (b)(1) of this section regarding the timing of the recertification. Specifically, we proposed to amend § 424.22(b) by replacing the phrase ''at least every 2 months'' with ''at least every 60 days,'' and adding the following sentence: ''Recertification is required at least every 60 days preferably unless there is a beneficiary elected transfer, a significant change in condition resulting in a new case-mix assignment, or a discharge and return to the same HHA during the 60-day episode that warrants a new 60-day episode payment and a new physician certification of the new plan of care.''

We proposed to add a new statutory authority, section 1895 of the Act, to paragraph(a) of § 484.200, ''Basis and scope.'' Section 1895(a) provides for the implementation of a prospective payment system for HHAs for portions of cost-reporting periods occurring on or after October 1, 2000.

We proposed to revise the regulations in 42 CFR part 484, which set forth the conditions that an HHA must meet in order to participate in Medicare. First, we proposed to revise the part heading from ''Conditions Of Participation: Home Health Agencies'' to the more generic heading ''Home Health Services.'' We proposed to make a conforming change in § 484.18(b) by replacing the phrase ''62 days'' with ''60 days'' unless there is—

- A beneficiary elected transfer;
- A significant change in condition resulting in a change in the case-mix assignment; or
- A discharge and return to the same HHA during the 60-day episode.

Also, we proposed to revise § 484.55(d)(1) by replacing ''every second calendar month'' with language that reflects the 60-day episode and possible PEP Adjustment or SCIC Adjustment. We proposed to require that the comprehensive assessment be updated and revised as frequently as the patient's condition warrants but not less frequently than every 60 days beginning with the start-of-care date unless there is—

- A beneficiary elected transfer;
- A significant change in condition resulting in a change in the case-mix assignment; or
- A discharge and return to the same HHA during the 60-day episode.

In addition, we proposed to add and reserve a new subpart D, then add a new subpart E, ''Prospective Payment System for Home Health Agencies.'' This proposed subpart sets forth the regulatory framework of the new prospective payment system. It specifically discussed the development of the payment rates, associated adjustments, and related rules. In § 484.202, ''Definitions,'' we proposed the following definitions for purposes of this new subpart:

As used in this subpart—

Case-mix index means a scale that measures the relative difference in resource intensity among different groups in the clinical model.

Clinical model means a system for classifying Medicare-eligible patients under a home health plan of care into mutually exclusive groups based on clinical, functional, and intensity-of-service criteria. The mutually exclusive groups are defined as Home Health Resource Groups (HHRGs).

Discipline means one of the six home health disciplines covered under the Medicare home health benefit (skilled nursing services, home health aide services, physical therapy services, occupational therapy services, speech-language pathology services, and medical social services).

Market basket index means an index that reflects changes over time in the prices of an appropriate mix of goods and services included in home health services.

In proposed § 484.205 ''Basis of payment,'' we discussed the Medicare payment to providers of services. Proposed § 484.205(a) described the method by which the provider would receive payment. Specifically, § 484.205(a)(1) provided that an HHA receives a national 60-day episode payment of a predetermined rate for a home health service paid on a reasonable cost basis. We determine this national 60-day episode payment under the methodology set forth in § 484.215. Paragraph (a)(2) specified that an HHA may receive a low-utilization payment adjustment (LUPA) of a predetermined per-visit rate. We proposed to determine the LUPA under the methodology set forth in § 484.230. Paragraph (a)(3) of this section provided that an HHA may receive a partial episode payment (PEP) adjustment due to an intervening event during an existing 60-day episode that initiates the start of a new 60-day episode payment and a new patient plan of care. We proposed to determine the PEP Adjustment under the methodology set forth in § 484.235. Paragraph (a)(4) of this section specified that a HHA may receive a significant change in condition (SCIC) Adjustment due to the intervening event defined as a significant change in the patient's condition during an existing 60-day episode. We proposed to determine the SCIC adjustment under a methodology set forth in 484.237.

Proposed paragraph (b) discussed the 60-day episode payment and circumstances surrounding adjustments to the payment method. This paragraph

proposed that the national 60-day episode payment represents payment in full for all costs associated with furnishing a home health service paid on a reasonable cost basis as of August 5, 1997 (the date of the enactment of the BBA) unless the national 60-day episode payment is subject to a low-utilization payment adjustment as set forth in § 484.230, a partial episode payment adjustment as set forth in § 484.235, a significant change in condition payment adjustment as set forth in 484.237, or an additional outlier payment as set forth in § 484.240. All payments under this system may be subject to a medical review adjustment. We noted that DME provided as a home health service as defined in section 1861(m) of the Act would continue to be paid the fee schedule amount.

In paragraph (c) of this section, we proposed the low-utilization payment adjustment to the 60-day episode payment. We would require that an HHA receive a national 60-day episode payment of a predetermined rate for home health services paid on a reasonable cost basis as of August 5, 1997, unless we determine at the end of the 60-day episode that the HHA furnished minimal services to a patient during the 60-day episode. The low-utilization payment adjustment would be determined under the methodology set forth in § 484.230.

In paragraph (d), we discussed the partial episode payment adjustment. We describe that an HHA receives a national payment of a predetermined rate for home health services paid on a reasonable cost basis as of August 5, 1997, unless there is an intervening event that warrants the initiation of a new 60-day episode payment and a new physician certification of the new plan of care. The initial HHA receives a partial episode payment adjustment reflecting the length of time the patient remained under its care. A partial episode payment adjustment would be determined under the methodology set forth in § 484.235.

In paragraph (e), we discussed the significant change in condition adjustment. We discussed that the HHA receives a national 60-day episode payment of a pre-determined rate for home health services paid on a reasonable cost basis as of August 5, 1997, unless HCFA determines an intervening event defined as a beneficiary experiencing a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. In order to receive a new case-mix assignment for purposes of payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in the treatment approach in the patient's plan of care. The significant change in condition payment adjustment is a proportional payment adjustment reflecting the time both before and after the patient experienced a significant change in condition during the 60-day episode.

In paragraph (f), we discussed how we treat payment for outliers. In this paragraph we would provide that an HHA receives a national 60-day episode payment of a predetermined rate for home health services paid on a reasonable-cost basis as of August 5, 1997, unless the estimated cost of the 60-day episode exceeds a threshold amount. The outlier payment is defined to be a proportion of the estimated costs beyond the threshold. An outlier payment is a payment in addition to the national 60-day episode payment. The total of all outlier payments is limited to 5 percent of total outlays under the HHA PPS. An outlier payment would be determined under the methodology set forth in § 484.240.

In proposed § 484.210, we specified the data used for the calculation of the national prospective 60-day episode payment. These data include the following:

- Medicare cost data on the most recent audited cost report data available.
- Utilization data based on Medicare claims.
- An appropriate wage index to adjust for area wage differences.
- The most recent projections of increases in costs from the HHA market basket index.
- OASIS assessment data and other data that account for the relative resource utilization for different HHA Medicare patient case-mix.

Proposed § 484.215, paragraphs (a) through (e) specified the methodology used for the calculation of the national 60-day episode payment. Proposed paragraph (a) specified that in calculating the initial unadjusted national 60-day episode payment applicable for a service furnished by an HHA using data on the most recent available audited cost reports, we determined each HHA's costs by summing its allowable costs for the period. We then determined the national mean cost per visit.

Proposed paragraph (b) of this section specified that in calculating the initial unadjusted national 60-day episode payment, we determined the national mean utilization for each of the six disciplines using home health claims data.

Proposed paragraph (c) of this section specified that we used the HHA market basket index to adjust the HHA cost data to reflect cost increases occurring between October 1, 1996 through September 30, 2001. For each fiscal year from 2002 or 2003, we would update the cost data by a factor equivalent to the annual market basket index percentage minus 1.1 percentage points.

Proposed paragraph (d) regarding standardization of the data for variation in area wage levels and case-mix specified that we would standardize the cost data described in paragraph (a) of this section to remove the effects of geographic variation in wage levels and variation in case-mix. We would then standardize the cost data for geographic variation in wage levels using the hospital wage index. We standardized the cost data for HHA variation in case-mix using the case-mix indices and other data that indicate HHA case-mix.

Proposed paragraph (e) of this section described how we calculated the unadjusted national average prospective payment amount for the 60-day episode. Specifically, we calculated this payment amount by—

- Computing the mean standardized national cost per visit;
- Computing the national mean utilization for each discipline; then
- Multiplying the mean standardized national cost per visit by the national mean utilization summed in the aggregate for each discipline.

Proposed § 484.220 described how we calculated the national adjusted prospective 60-day episode payment rate for case-mix and area wage levels. This section specified that we adjusted the national prospective 60-day episode payment rate to account for HHA case-mix using a case-mix index to explain the relative resource utilization of different patients. We also adjusted the national prospective 60-day episode payment rate to account for geographic differences in wage levels using an appropriate wage index.

In proposed § 484.225, we explained our methods for annually updating the national adjusted prospective payment rates for inflation. We proposed to handle it in the following manner:

- We update the unadjusted national 60-day episode payment rate on a fiscal year basis.
- For FY 2001, the unadjusted national 60-day episode payment rate is adjusted using the latest available market basket factors.
- For fiscal year 2002 or 2003, the unadjusted national 60-day episode payment rate is equal to the rate for the previous period or fiscal year increased

by a factor equal to the HHA market basket minus 1.1 percentage point.

• For any subsequent fiscal years, the unadjusted national rate is equal to the rate for the previous fiscal year increased by the applicable HHA market basket index amount.

In proposed § 484.230, we explained the methodology we use for the calculation of the low-utilization payment adjustment. In this section, we specified that in calculating the low-utilization payment adjustment, an episode with four or fewer visits is paid the national average standardized per-visit amount by discipline for each visit type. We also specified that the national average standardized per-visit amount is determined by using cost data set forth in § 484.210(a) and adjusting by the appropriate wage index.

Proposed § 484.235 illustrated the methodology we used to calculate the partial episode payment adjustment. The intervening event of either a beneficiary elected transfer or discharge and return to the same HHA during the 60-day episode warrants a new 60-day episode payment and a new physician certification of a new plan of care. The original 60-day episode payment is adjusted with a partial episode payment that reflects the length of time the beneficiary remained under the care of the original HHA. The partial episode payment is calculated using the actual days served by the original HHA as a proportion of 60 multiplied by the initial 60-day episode payment.

Proposed 484.237 illustrated the methodology we used to calculate the significant change in condition payment adjustment. The intervening event, here, a beneficiary experiencing a significant change in condition during a 60-day episode that was not envisioned in the original plan of care, initiates the significant change in condition payment adjustment. The significant change in condition is calculated in two parts. The first part of the SCIC adjustment reflects the adjustment to the level of payment prior to the significant change in the patient's condition during the 60-day episode. The second part of the SCIC adjustment reflects the adjustment to the level of payment after the significant change in the patient's condition occurs during the 60-day episode. The first part of the SCIC adjustment is determined by taking the span of days prior to the patient's significant change in condition as a proportion of 60 multiplied by the original episode amount. The original episode payment level is proportionally adjusted using the span of time the patient was under the care of the HHA prior to the significant change in condition that warranted an OASIS assessment, physician change orders indicating the need for a significant change in the course of the treatment plan, and the new case-mix assignment for payment at the end of the 60-day episode. The second part of the SCIC adjustment is a proportional payment adjustment reflecting the time the patient will be under the care of the HHA after the significant change in condition and continuing until the end of the 60-day episode. The second part of the SCIC adjustment is determined by taking the span of days (first billable visit date through the last billable visit date) after the patient experiences the significant change in condition through the balance of the 60-day episode as a proportion of 60 multiplied by the new episode payment level resulting from the significant change. The initial percentage payment provided at the start of the 60-day episode will be adjusted at the end of the episode to reflect the first and second part of the SCIC adjustment.

Proposed § 484.240 described the methodology we used to calculate the outlier payment. The methodology for the calculation of the outlier payment would involve the following:

• We make an outlier payment for an episode whose estimated cost exceeds a threshold amount for each case-mix group.

• The outlier threshold for each case-mix group is the episode payment amount for that group plus a fixed dollar loss amount that is the same for all case-mix groups.

• The outlier payment is a proportion of the amount of estimated cost beyond the threshold.

• We estimate the cost for each episode by applying the standard per-visit amount to the number of visits by discipline reported on claims.

• The fixed dollar loss amount and the loss-sharing proportion are chosen so that the estimated total outlier payment is no more than 5 percent of total episode payment.

Proposed § 484.250 related to data that must be submitted for the development of a reliable case-mix. Specifically, we would require an HHA to submit the OASIS data described at the current § 484.55(b)(1) and (d)(1) (that we proposed to revise in the proposed rule) to administer the payment rate methodologies described in § 484.215 (methodology used for the calculation of the national 60-day episode payment), § 484.230 (methodology used for the calculation of the LUPA) and 484.237 (methodology used for the calculation of the SCIC adjustment).

Proposed § 484.260 discussed the limitation for review with regard to our new payment system. In this section, we specified that judicial or administrative review under sections 1869 or 1878 of the Act, or otherwise, is prohibited with regard to the establishment of a payment unit including the national 60-day episode payment rate and the LUPA. This prohibition includes the establishment of the transition period, definition and application of the unit of payments, the computation of initial standard prospective payment amounts, the establishment of the adjustment for outliers, and the establishment of case-mix and area wage adjustment factors.

III. Analysis and Responses to Public Comments

We received approximately 381 timely comments on the HHA prospective payment system proposed rule HCFA–1059–P published on October 28, 1999 (64 FR 58134). Comments were submitted by HHAs and other health care providers, national industry associations, suppliers and practitioners (both individually and through their respective trade associations), State associations, health care consulting firms, and private citizens. The comments centered on various aspects of the proposed policies governing our approach to the home health prospective payment system. We have considered all comments received during the 60-day public comment period in this final rule and have set forth our responses to the comments and corresponding policy modifications in the following section.

As noted in the proposed rule, because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are unable to respond to them individually. In particular, a number of commenters on the proposed rule raised extremely technical and detailed questions, many of which were not directly related to the proposed rule, regarding OASIS, the cost report, RHHI systems and the billing process. These questions are of the 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 policy concerns raised by the commenters that are related to the proposed rule. Summaries of the major issues and our responses to those comments are set forth below.

A. 60-Day Episode Payment Definition (§ 484.205)

Comment: We received several comments on our proposed definition of

a 60-day episode as the unit of payment under HHA PPS. The majority of commenters supported the 60-day episode approach. A few commenters suggested a shorter time period for the unit of payment.

Response: We believe the 60-day episode definition is the most appropriate approach to define the unit of payment under HHA PPS. Public support for the 60-day episode as the unit of payment under PPS centered on the general consensus that HHAs and physicians predict home care needs over a 60-day period due to current plan of care requirements and OASIS assessments that basically follow a 60-day period. As discussed in detail in the proposed rule, research indicated that the 60-day episode captures the majority of stays experienced in the Phase II per-episode HHA PPS demonstration.

We will continue to monitor the appropriateness of the 60-day unit of payment and may consider modifying our approach to the episode definition in subsequent years of PPS, if warranted.

Comment: A few commenters raised concerns with the change to a 60-day episode from the current plan of care certification and OASIS assessments requirements that follow a bimonthly period, that is, at least every 62 days. Some of the concerns centered on confusion and the possible burden associated with the change to a 60-day episode.

Response: The statute requires us to establish an appropriate unit of payment. We believe the 60-day episode is the most suitable time frame upon which to base payment and to manage home care needs of patients. To effectively implement a payment system that is built on a foundation of (1) OASIS assessments for case-mix adjustment and (2) plan of care certifications to ensure the appropriate plan of treatment, all schedules for assessment, certification and payment term should be on a parallel track. The current schedules for OASIS assessment and plan of care certification basically mirror a 60-day episode. Thus, for purposes of payment, assessment, and care planning, we do not believe it is an undue burden to adjust to a 60-day episode from a bimonthly period.

Comment: A few commenters recommended that we re-examine the language we proposed to govern the 60-day episode. The commenters referred specifically to the following statement in the proposed rule: ''An HHA that accepts a Medicare eligible beneficiary for home health care for the 60-day episode period and submits a bill for payment may not refuse to treat an eligible beneficiary who has been discharged from the HHA during the 60-day episode, but later requires Medicare covered home health services during the same 60-day episode period and elects to return to the same HHA * * *'' (64 FR 58201) Commenters suggested that HHAs should be allowed to refuse to readmit a Medicare eligible beneficiary in accordance with HHA policies when the safety of HHA staff or the patient are threatened; when the HHA does not have the staff necessary to meet the patient's needs; or when the patient or caregiver refuses to cooperate or comply with the plan of care.

Response: We proposed this policy to indicate that we would not accept a refusal to treat the beneficiary when only the HHA's economic interests were the cause of the refusal. It was not our intent to restrict the legitimate rights of an HHA that has a well-documented individualized situation that results in a determination to refuse further care of a patient. This would include threats to the safety of HHA staff or patients or failure of patients to cooperate in the care plan. As long as agencies treat all similarly situated patients equally, document the individualized situation, and comply with all Federal and State laws, they have the right to refuse to treat patients in certain well-documented situations.

B. Definition of Non-Routine Medical Supplies Included in the Episode Definition

Comment: We received several comments regarding certain non-routine medical supply costs that were not included in the computation of the 60-day national episode rate. Specifically, the commenters suggested that we include non-routine medical supplies both paid on the cost report and non-routine medical supply amounts that could have been unbundled to part B prior to PPS in the 60-day episode rate. Commenters also provided several suggestions for a revised approach to the payment for non-routine medical supplies under HHA PPS. Recommendations included the following:

- Providing for a separate payment for non-routine medical supplies used by a patient designated as a new designated home health supply payment amount separate from the prospective payment rate.
- Allowing all non-routine medical supplies to be billed under Part B.
- Carving out or adjusting the medical supply amount due to the variation in intermediary coverage guidelines.
- Adjusting the medical supply amounts to reflect the costs associated with wound patients, chux and diaper supply patients.
- Paying medical supplies as used because of the wide variation in use due to patients who sustain out-of-pocket payments.
- Carving out wound care and diabetes related medical supplies and re-examining the overall calculation of the non-routine supply costs, both bundled and non-routine supply costs that could have been unbundled, because commenters viewed the amounts inadequate to care for patients requiring supplies which then might lead to access issues.

Commenters further noted problems with the 199 HCPCs codes we used to calculate the non-routine medical supply amounts that could have been unbundled to Part B before implementation of PPS. We adjusted the proposed rate to account for the non-routine medical supply behavior prior to PPS. Several commenters suggested that the inclusion of glucose test strips codes were inappropriate codes included in the original 199 code list for non-routine medical supply costs. Other commenters believed we inadvertently omitted certain codes in the original list of 199 codes. Furthermore, several commenters centered on consolidated billing requirements for non-routine medical supplies. We note that all consolidated billing comments and responses are included under the consolidated billing portion of this section of the regulation.

Response: The goal of reviewing and calculating the non-routine medical supply costs that could have been unbundled to Part B was to ensure adequate payment for non-routine medical supplies used by a patient under a home health plan of care in the prospective payment rate. As stated in the proposed rule, we developed a list of 199 codes that could have possibly been unbundled to Part B before implementation of PPS, linked those Part B supply claims that included any of the 199 codes to home health claims for beneficiaries under a home health plan of care during calendar year 1997. We have replicated the exact claims analysis on corresponding calendar year 1998 claims data to develop an updated supply amount for this final regulation. This calculation was performed on an adjusted list of codes based upon review of comments and is described below.

As stated in the proposed rule, section 1895(b)(1) of the Act, which governs the development of the unit of payment under HHA PPS, requires all services covered and paid on a reasonable cost

basis as of the date of enactment of the BBA, including medical supplies, to be paid on the basis of a prospective payment amount under HHA PPS. The statutory language specifically refers to the inclusion of medical supplies in the prospective payment rate. We believe the statute requires the inclusion of costs of non-routine medical supplies in the episode rate. However, as stated in the proposed rule, since DME covered as a home health service as part of the Medicare home health benefit is not currently paid on a reasonable cost basis, DME will continue to be paid under the DME fee schedule as a separate payment amount from the prospective payment rates under HHA PPS.

As mentioned above, commenters also supplied us with an additional 79 codes that they believed should be included on our list of non-routine medical supplies that could have been unbundled to Part B. We re-examined our approach to the original 199 codes used to calculate the amounts that could have been unbundled non-routine medical supplies. We found that several of the recommended codes had been discontinued. Further, upon re-examination of our original list, we found that several of the original codes were inappropriately included, for example, glucose test strips. These codes have subsequently been deleted. Our analysis results in a final list of 178 codes as listed below. We have provided the following analysis in order to clarify our revised approach.

59 codes proposed in comments were discontinued codes as of 12/31/96.

A4190 ..... Transparent film each
A4200 ..... Gauze pad medicated/non-med
A4202 ..... Elastic gauze roll
A4203 ..... Non-elastic gauze roll
A4204 ..... Absorptive drsg
A4205 ..... Nonabsorptive drsg
K0197 ..... Alginate drsg > 16 <=48 sq in
K0198 ..... Alginate drsg > 48 sq in
K0199 ..... Alginate drsg wound filler
K0203 ..... Composite drsg <= 16 sq in
K0204 ..... Composite drsg > 16 <=48 sq in
K0205 ..... Composite drsg > 48 sq in
K0206 ..... Contact layer <= 16 sq in
K0207 ..... Contact layer > 16 <= 48 sq in
K0208 ..... Contact layer > 48 sq in
K0209 ..... Foam drg <= 16 sq in w/o bdr
K0210 ..... Foam drg > 16 <=48 sq in w/o b
K0211 ..... Foam drg > 48 sq in w/o brdr
K0212 ..... Foam drg <= 16 sq in w/bdr
K0213 ..... Foam drg > 16 <=48 sq in w/ bdr
K0214 ..... Foam drg > 48 sq in w/bdr
K0215 ..... Foam dressing wound filler
K0219 ..... Gauze <= 16 sq in w/bdr
K0220 ..... Gauze > 16 <=48 sq in w/bdr
K0221 ..... Gauze > 48 sq in w/bdr
K0222 ..... Gauze <= 16 in no w/sal w/o b
K0223 ..... Gauze > 16 <=48 no w/sal w/o b
K0224 ..... Gauze > 48 in no w/sal w/o b
K0228 ..... Gauze <= 16 sq in water/sal
K0229 ..... Gauze > 16 <=48 sq in watr/sal
K0230 ..... Gauze > 48 sq in water/salne
K0234 ..... Hydrocolloid drg <= 16 w/o bdr
K0235 ..... Hydrocolloid drg > 16 <=48 w/ o b
K0236 ..... Hydrocolloid drg > 48 in w/o b
K0237 ..... Hydrocolloid drg <= 16 in w/ bdr
K0238 ..... Hydrocolloid drg > 16 <=48 w/ bdr
K0239 ..... Hydrocolloid drg > 48 in w/bdr
K0240 ..... Hydrocolloid drg filler paste
K0241 ..... Hydrocolloid drg filler dry
K0242 ..... Hydrogel drg <= 16 in w/o bdr
K0243 ..... Hydrogel drg > 16 <=48 w/o bdr
K0244 ..... Hydrogel drg > 48 in w/o bdr
K0245 ..... Hydrogel drg <= 16 in w/bdr
K0246 ..... Hydrogel drg > 16 <=48 in w/b
K0247 ..... Hydrogel drg > 48 sq in w/b
K0248 ..... Hydrogel drsg gel filler
K0249 ..... Hydrogel drsg dry filler
K0251 ..... Absorpt drg <= 16 sq in w/o b
K0252 ..... Absorpt drg > 16 <=48 w/o bdr
K0253 ..... Absorpt drg > 48 sq in w/o b
K0254 ..... Absorpt drg <= 16 sq in w/bdr
K0255 ..... Absorpt drg > 16 <=48 in w/ bdr
K0256 ..... Absorpt drg > 48 sq in w/bdr
K0257 ..... Transparent film <= 16 sq in
K0258 ..... Transparent film > 16 <=48 in
K0259 ..... Transplant filmpercent 48 sq in
K0261 ..... Wound filler gel/paste/oz
K0262 ..... Wound filler dry form/gram
K0266 ..... Impreg gauze no h20/sal/yard

Seven codes included in original list should be removed because they are considered routine medical supplies and as such would not be separately billable by an HHA.

A4214 ..... 30 CC sterile water/saline
K0216 ..... Non-sterile gauze <= 16 sq in
K0217 ..... Non-sterile gauze > 16 <= 48 sq
K0218 ..... Non-sterile gauze > 48 sq in
K0263 ..... Non-sterile elastic gauze/yd
K0264 ..... Non-sterile no elastic gauze
K0265 ..... Tape per 18 sq inches

Four codes are not valid for Medicare.

A4206 ..... 1 CC sterile syringe & needle
A4207 ..... 2 CC sterile syringe & needle
A4208 ..... 3 CC sterile syringe & needle
A4209 ..... 5+ CC sterile syringe & needle

Three codes are for items that are not covered under Medicare.

A4210. ..... Nonneedle injection device
K0250 ..... Skin seal protect moisturizer
K0260 ..... Wound cleanser any type/size

One code is a DME Fee Schedule code and should not be included in accordance with the statute.

A4221 ..... Maint drug infus cath per wk

One code is not separately paid by Part B.

A4211 ..... Supp for self-adm injections

Three codes mentioned by commenters had already been included in our original list of 199 codes.

A4212 ..... Non coring needle or stylet
A4213 ..... 20+ CC syringe only
A4215 ..... Sterile needle

After further re-examination based upon the comments, we added the following code to the list:

A4554 ..... Disposable underpads

Upon further review of the original 199 codes used in the proposed rule, the following codes were deemed inappropriate to be included in the definition of non-routine medical supplies and were deleted from the list used in this final rule:

A4206 ..... 1 CC sterile syringe & needle
A4207 ..... 2 CC sterile syringe & needle
A4208 ..... 3 CC sterile syringe & needle
A4209 ..... 5+ CC sterile syringe & needle
A4210 ..... Nonneedle injection device
A4211 ..... Supp for self-adm injections
A4214 ..... 30 CC sterile water/saline
A4253 ..... Blood glucose/reagent strips
A4255 ..... Glucose monitor platforms
A4256 ..... Calibrator solution/chips
A4258 ..... Lancet device each
A4259 ..... Lancets per box
A4454 ..... Tape all types all sizes
A6216 ..... Non-sterile gauze <= 16 sq in
A6217 ..... Non-sterile gauze > 16 <= 48 sq
A6218 ..... Non-sterile gauze > 48 sq in
A6263 ..... Non-sterile elastic gauze/yd
A6264 ..... Non-sterile no elastic gauze
A6265 ..... Tape per 18 sq inches
K0137 ..... Skin barrier liquid per oz
K0138 ..... Skin barrier paste per oz
K0139 ..... Skin barrier powder per oz

The following is the *final* list of *178* codes for non- Routine Medical Supplies that have a duplicate Part B code that could have been unbundled and billed under Part B before implementation of PPS. The following codes were used to calculate additional non-routine medical supply costs to the national rate. The revised rate calculation is found in section IV.C. of this preamble.

A4212 ..... Non coring needle or stylet
A4213 ..... 20+ CC syringe only
A4215 ..... Sterile needle
A4310 ..... Insert tray w/o bag/cath
A4311 ..... Catheter w/o bag 2-way latex
A4312 ..... Cath w/o bag 2-way silicone
A4313 ..... Catheter w/bag 3-way
A4314 ..... Cath w/drainage 2-way latex
A4315 ..... Cath w/drainage 2-way silcne
A4316 ..... Cath w/drainage 3-way
A4320 ..... Irrigation tray
A4321 ..... Cath therapeutic irrig agent
A4322 ..... Irrigation syringe
A4323 ..... Saline irrigation solution
A4326 ..... Male external catheter
A4327 ..... Fem urinary collect dev cup
A4328 ..... Fem urinary collect pouch
A4329 ..... External catheter start set
A4330 ..... Stool collection pouch
A4335 ..... Incontinence supply
A4338 ..... Indwelling catheter latex
A4340 ..... Indwelling catheter special
A4344 ..... Cath indw foley 2 way silicn
A4346 ..... Cath indw foley 3 way

A4347 ..... Male external catheter
A4351 ..... Straight tip urine catheter
A4352 ..... Coude tip urinary catheter
A4353 ..... Intermittent urinary cath
A4354 ..... Cath insertion tray w/bag
A4355 ..... Bladder irrigation tubing
A4356 ..... Ext ureth clmp or compr dvc
A4357 ..... Bedside drainage bag
A4358 ..... Urinary leg bag
A4359 ..... Urinary suspensory w/o leg bag
A4361 ..... Ostomy face plate
A4362 ..... Solid skin barrier
A4363 ..... Liquid skin barrier
A4364 ..... Ostomy/cath adhesive
A4365 ..... Ostomy adhesive remover wipe
A4367 ..... Ostomy belt
A4368 ..... Ostomy filter
A4397 ..... Irrigation supply sleeve
A4398 ..... Ostomy irrigation bag
A4399 ..... Ostomy irrig cone/cath w brs
A4400 ..... Ostomy irrigation set
A4402 ..... Lubricant per ounce
A4404 ..... Ostomy ring each
A4421 ..... Ostomy supply misc
A4454 ..... Tape all types all sizes
A4455 ..... Adhesive remover per ounce
A4460 ..... Elastic compression bandage
A4462 ..... Abdmnl drssng holder/binder
A4481 ..... Tracheostoma filter
A4622 ..... Tracheostomy or larngectomy
A4623 ..... Tracheostomy inner cannula
A4625 ..... Trach care kit for new trach
A4626 ..... Tracheostomy cleaning brush
A4649 ..... Surgical supplies
A5051 ..... Pouch clsd w barr attached
A5052 ..... Clsd ostomy pouch w/o barr
A5053 ..... Clsd ostomy pouch faceplate
A5054 ..... Clsd ostomy pouch w/flange
A5055 ..... Stoma cap
A5061 ..... Pouch drainable w barrier at
A5062 ..... Drnble ostomy pouch w/o barr
A5063 ..... Drain ostomy pouch w/flange
A5071 ..... Urinary pouch w/barrier
A5072 ..... Urinary pouch w/o barrier
A5073 ..... Urinary pouch on barr w/flng
A5081 ..... Continent stoma plug
A5082 ..... Continent stoma catheter
A5093 ..... Ostomy accessory convex inse
A5102 ..... Bedside drain btl w/wo tube
A5105 ..... Urinary suspensory
A5112 ..... Urinary leg bag
A5113 ..... Latex leg strap
A5114 ..... Foam/fabric leg strap
A5119 ..... Skin barrier wipes box pr 50
A5121 ..... Solid skin barrier 6x6
A5122 ..... Solid skin barrier 8x8
A5123 ..... Skin barrier with flange
A5126 ..... Disk/foam pad +or− adhesive
A5131 ..... Appliance cleaner
A5149 ..... Incontinence/ostomy supply
A6020 ..... Collagen wound dressing
A6154 ..... Wound pouch each
A6196 ..... Alginate dressing <= 16 sq in
A6197 ..... Alginate drsg > 16 <= 48 sq in
A6198 ..... Alginate dressing > 48 sq in
A6199 ..... Alginate drsg wound filler
A6200 ..... Compos drsg <= 16 no bdr
A6201 ..... Compos drsg > 16 <=48 no bdr
A6202 ..... Compos drsg > 48 no bdr
A6203 ..... Composite drsg <= 16 sq in
A6204 ..... Composite drsg > 16 <=48 sq in
A6205 ..... Composite drsg > 48 sq in
A6206 ..... Contact layer <= 16 sq in
A6207 ..... Contact layer > 16 <= 48 sq in
A6208 ..... Contact layer > 48 sq in
A6209 ..... Foam drsg <= 16 sq in w/o bdr
A6210 ..... Foam drg > 16 <=48 sq in w/o b
A6211 ..... Foam drg > 48 sq in w/o brdr
A6212 ..... Foam drg <= 16 sq in w/bdr
A6213 ..... Foam drg > 16 <=48 sq in w/ bdr
A6214 ..... Foam drg > 48 sq in w/bdr
A6215 ..... Foam dressing wound filler
A6219 ..... Gauze <= 16 sq in w/bdr
A6220 ..... Gauze > 16 <=48 sq in w/bdr
A6221 ..... Gauze > 48 sq in w/bdr
A6222 ..... Gauze <= 16 in no w/sal w/o b
A6223 ..... Gauze > 16 <= 48 no w/sal w/o b
A6224 ..... Gauze > 48 in no w/sal w/o b
A6228 ..... Gauze <= 16 sq in water/sal
A6229 ..... Gauze > 16 <=48 sq in watr/sal
A6230 ..... Gauze > 48 sq in water/salne
A6234 ..... Hydrocolld drg <= 16 w/o bdr
A6235 ..... Hydrocolld drg > 16 <= 48 w/o b
A6236 ..... Hydrocolld drg > 48 in w/o b
A6237 ..... Hydrocolld drg <= 16 in w/bdr
A6238 ..... Hydrocolld drg > 16 <=48 w/ bdr
A6239 ..... Hydrocolld drg > 48 in w/bdr
A6240 ..... Hydrocolld drg filler paste
A6241 ..... Hydrocolloid drg filler dry
A6242 ..... Hydrogel drg <= 16 in w/o bdr
A6243 ..... Hydrogel drg > 16 <=48 w/o bdr
A6244 ..... Hydrogel drg > 48 in w/o bdr
A6245 ..... Hydrogel drg <= 16 in w/bdr
A6246 ..... Hydrogel drg > 16 <=48 in w/b
A6247 ..... Hydrogel drg > 48 sq in w/b
A6251 ..... Absorpt drg <= 16 sq in w/o b
A6252 ..... Absorpt drg > 16 <=48 w/o bdr
A6253 ..... Absorpt drg > 48 sq in w/o b
A6254 ..... Absorpt drg <= 16 sq in w/bdr
A6255 ..... Absorpt drg > 16 <=48 in w/ bdr
A6256 ..... Absorpt drg > 48 sq in w/bdr
A6257 ..... Transparent film <= 16 sq in
A6258 ..... Transparent film > 16 <=48 in
A6259 ..... Transparent film > 48 sq in
A6261 ..... Wound filler gel/paste/oz
A6262 ..... Wound filler dry form/gram
A6266 ..... Impreg gauze no h20/sal/yard
A6402 ..... Sterile gauze <= 16 sq in
A6403 ..... Sterile gauze > 16 <= 48 sq in
A6404 ..... Sterile gauze > 48 sq in
A6405 ..... Sterile elastic gauze/yd
A6406 ..... Sterile non-elastic gauze/yd
K0137 ..... Skin barrier liquid per oz
K0138 ..... Skin barrier paste per oz
K0139 ..... Skin barrier powder per oz
K0277 ..... Skin barrier solid 4x4 equiv
K0278 ..... Skin barrier with flange
K0279 ..... Skin barrier extended wear
K0280 ..... Extension drainage tubing
K0281 ..... Lubricant catheter insertion
K0407 ..... Urinary cath skin attachment
K0408 ..... Urinary cath leg strap
K0409 ..... Sterile H2O irrigation solut
K0410 ..... Male ext cath w/adh coating
K0411 ..... Male ext cath w/adh strip
K0419 ..... Drainable plstic pch w fcplt
K0420 ..... Drainable rubber pch w fcplt
K0421 ..... drainable plstic pch w/o fp
K0422 ..... Drainable rubber pch w/o fp
K0423 ..... Urinary plstic pouch w fcplt
K0424 ..... Urinary rubber pouch w fcplt
K0425 ..... Urinary plstic pouch w/o fp
K0426 ..... Urinary hvy plstc pch w/o fp
K0427 ..... Urinary rubber pouch w/o fp
K0428 ..... Ostomy faceplt/silicone ring
K0429 ..... Skin barrier solid ext wear
K0430 ..... Skin barrier w flang ex wear
K0431 ..... Closed pouch w st wear bar
K0432 ..... Drainable pch w ex wear bar
K0433 ..... Drainable pch w st wear bar
K0434 ..... Drainable pch ex wear convex
K0435 ..... Urinary pouch w ex wear bar
K0436 ..... Urinary pouch w st wear bar
K0437 ..... Urine pch w ex wear bar conv
K0438 ..... Ostomy pouch liq deodorant
K0439 ..... Ostomy pouch solid deodorant

We believe our revised approach to the calculation that incorporates both non-routine medical supplies provided under a plan of care and those non-routine medical supplies that could have been unbundled to Part B prior to the consolidated billing requirements results in an equitable payment methodology. As stated above, we have re-examined the list of non-routine medical supplies that could have been unbundled to Part B, recalculated the costs, and have adjusted the rates accordingly. We have also included any additional medical supply costs included in the audited cost report data from the sample that became available after the publication of the proposed rule.

We have thoroughly re-examined the issue of all non-routine medical supplies included in the rate. The statute does not provide for an exception for the removal of any or all supplies for certain type of patients from the PPS rate. We have used the best data available to calculate the non-routine medical supply component of the rates. We will continue to monitor the issue of non-routine medical supply costs with implementation of PPS.

Comment: Several commenters recommended that we re-examine the amount we added to adjust the LUPA per-visit amounts to account for non-routine medical supply costs. Many commenters suggested that the amount was inadequate, especially for wound care patients.

Response: As stated above, we have re-examined the issue of the appropriate level of non-routine medical supply costs in terms of wound care supplies and all non-routine medical supplies as they relate to all rates in the proposed rule, including the LUPA amounts. Based on comments, we have decided to increase the LUPA amount by paying the updated, prospective per-visit amount by discipline. We believe this per-visit amount accurately reflects an appropriate per-visit payment level, including medical supplies and other services furnished during LUPA visits. This provision is set forth in regulations at § 484.230. The revised LUPA approach is discussed in section IV.D. of this rule.

Comment: Commenters requested clarification of the application of 20 percent co-payment of non-routine medical supplies not related to the plan of care.

Response: Medical supplies are specifically listed in section 1861(m) of the Act as a covered home health service. All covered home health services are ordered by a physician for a patient under a plan of care. The 20 percent copayment does not apply to non-routine medical supplies covered as a home health service. There is currently no imposition of copayment on home health services except for DME. There is a 20 percent copayment on DME covered as a home health service. However, as stated above in section I.B. of this rule, BBRA of 1999 removed DME covered as a home health service from the consolidated billing requirements.

We note that Part B does not provide coverage of and payment for items termed ''non-routine medical supplies.'' DME may have a DME supply component, but that supply cost is related to the DME and included in the DME fee schedule payment. Further, the statute governing consolidated billing specifically refers to a patient under a plan of care. Providers cannot circumvent the consolidated billing requirements by attempting to exclude certain non-routine medical supplies from the plan of care by distinguishing between non-routine medical supplies related and unrelated to the plan of care. The comment may reflect concern with Part B services such as parenteral or enteral nutrition that are neither currently covered as home health services nor defined as a non-routine medical supply. Parenteral or enteral nutrition would therefore not be subject to the requirements governing home health consolidated billing because those Part B services are not home health services as defined in section 1861(m)of the Act. The applicable copayment or deductible requirements governing Medicare Part B outside of the Medicare home health benefit defined in section 1861(m) of the Act are not changed by this rule.

Comment: A few commenters stated that if a beneficiary has a continuing medical need for medical supplies due to a chronic illness unrelated to the condition the HHA is treating, the patient should be excluded from the PPS rate and consolidated billing.

Response: As we indicated in the proposed rule and the response to the previous comment, the law is very specific regarding the inclusion of medical supplies in the prospective rates. The law requires all services covered and paid on a reasonable cost basis as of the date of enactment of the BBA, including medical supplies, to be paid on the basis of a prospective payment amount under HHA PPS. The consolidated billing requirements at section 1842(b)(6)(F) of the Act, as amended by section 305 of BBRA, specifically require ''in the case of home health services (including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who (at the time the item or service is furnished) is under a plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or when any other contracting or consulting arrangement, or otherwise).''

The statutory language governing consolidated billing clearly states that the patient is under the plan of care. If the patient requires medical supplies that are currently covered and paid for under the Medicare home health benefit during a certified episode under HHA PPS, the billing for those medical supplies falls under the auspices of the HHA due to the consolidated billing requirements. As stated in previous comments, there is no statutory latitude for an exception or carve-out of medical supplies from the PPS rate for patients under a plan of care under HHA PPS. We have included the costs of all such supplies in the rates.

Comment: A few commenters suggested that we establish clear guidelines so that providers of medical supplies receive adequate notice when items they may be furnishing to a beneficiary become subject to HHA PPS.

Response: The law refers to a patient under a home health plan of care. All routine and non-routine medical supplies that are currently covered as a Medicare home health service are subject to the home health PPS requirements. We believe the proposed rule and this final rule as well as current Medicare policies governing coverage of medical supplies under the home health benefit provide the notice of the requirements governing the HHA PPS. We will be directing our carrier to inform suppliers of this change and will be developing efforts to prevent erroneous billings. Further clarification of routine and non-routine medical supplies can be found in section 204.1 of the Medicare home health agency manual.

Comment: A few commenters suggested that we review the non-routine medical supply coverage policies of the various RHHIs and establish a consistent national coverage policy. Adjustments to the medical supply component of the rate should be made based on the analysis of the coverage variations in the original data used to establish the PPS rates.

Response: We have re-examined our approach to the national coverage policy governing non-routine medical supplies under the Medicare home health benefit. We do not have any indication of the existence of significant inconsistencies in coverage policies across RHHIs. As stated in previous comments, we will continue to monitor the coverage and utilization of non-routine medical supplies in subsequent years of PPS implementation.

Comment: Commenters suggested that medical supplies should be paid as used due to the wide variation in supply usage across patients and because some patients have historically paid out-of-pocket for supplies although HHAs were required to furnish them.

Response: As indicated above, the law specifically includes costs of medical supplies in determining the PPS rates. We are concerned that commenters even suggested that HHAs have historically permitted or even encouraged eligible Medicare beneficiaries to pay out-of-pocket for Medicare services that patients were not required to pay. We emphasize that agencies are obligated to furnish and Medicare will pay for needed medical supplies covered under the home health benefit.

C. Possible Inclusion of Medicare Part B Therapy Services in the Episode

Comment: We received a few comments regarding certain Part B therapy costs that were not included in the computation of the PPS rates. Several commenters suggested that we collect Medicare Part B Claims information for all therapy services provided to patients while receiving home health services under the home health benefit and adjust the episode definition, payment rate, and budget neutrality factor accordingly. Commenters believed that HHAs prior to PPS, as with non-routine medical supplies, had the option to unbundle therapy services outside of the home health benefit to Part B therapy providers. Because such services cannot be unbundled under PPS, commenters suggested that, based on our analysis of Part B therapy claims during a home health stay, an adjustment to the non-standardized amount should be made to account for this additional cost for therapy services.

Response: Before implementation of PPS, HHAs were not clearly prohibited from unbundling therapies to Part B. Consistent with our approach to non-routine medical supplies that could have been unbundled to Part B prior to PPS, we again analyzed Part B therapy claims data. Section IV.B.3. of this rule describes our claims analysis of the Part B therapy claims. Based on the analysis, we have adjusted the rates accordingly with the methodology described in section V. of this rule.

D. Continuous Episode Recertification

Comment: Several commenters support continuous episode certifications because the policy permits access to home health services for eligible beneficiaries. A few commenters requested clarification of continuous episode recertification with regard to long term utilizers of Medicare home health services. In addition, commenters requested further clarification of the definition of terms associated with continuous episode recertification. Some commenters requested specific clarification of the dates governing continuous episode recertification.

Response: We proposed continuous recertifications and payment, as appropriate, for beneficiaries who continue to be eligible for home health services. The payment system set forth in this final rule will permit continuous episode recertification for Medicare eligible beneficiaries. We believe this policy negates the need for a day or time (length of stay) outlier because beneficiaries will continue to be recertified for continuous episodes as long as they remain eligible for the Medicare home health benefit. In order to address the needs of longer stay patients, we are not limiting the number of 60-day episode recertifications permitted in a given fiscal year assuming a patient remains eligible for the Medicare home health benefit.

In response to comments, our explanation of the dates governing continuous episode recertification and clarification of terms associated with subsequent episode recertifications is given below. The first day of a subsequent second episode is day 61. The first day of all subsequent episodes, whether it is the second or third, etc. continuous episode, will be termed the ''subsequent episode date.'' The first day of a subsequent episode is not necessarily the first billable visit date. Unlike the initial episode, the first day of a subsequent episode may not occur on the first billable service date. Therefore, one must distinguish between the definition of the subsequent continuing episode date and the initial episode. Further technical examples of continuous care will be found in billing instructions that will be issued after publication of this rule.

E. Transition/Blend

Comment: Several commenters and most national industry associations supported full transition to a national rate. Conversely, only one industry association supported a four-year blend of agency-specific and national PPS rates. A few commenters suggested the continuation of IPS for the first certification or assessment period or next discharge date or a blend with IPS related data. A few commenters provided other creative alternative blend approaches that fell out of the scope of the statutory authority for the transition blend.

Response: Section 1895(b)(1) of the Act provides the option for a four-year transition to HHA PPS by blending agency-specific and national rates. We proposed full transition to the 60-day national episode rate. We believed blending cost based IPS with an episode rate was not a viable, effective option. After thorough re-examination of the comments and subsequent analysis, we continue to believe that full transition to national PPS rates without any blend of current IPS on October 1, 2000 is the most appropriate alternative. A blended rate system would be overly complex, distort the positive incentives in PPS, and reallocate limited resources from more efficient HHAs to less cost-conscious providers. A national PPS system has significant advantages over IPS. It recognizes case-mix and provides additional payments for higher cost outliers.

Comment: Several commenters objected to all HHAs being paid under home health PPS effective October 1, 2000. Many commented that this was unprecedented and recommended that the implementation date should be transitioned based on cost reporting year.

Response: The law governing the effective date for home health PPS implementation is very specific. In fact, section 5101(c)(1)(A) of OCESSA amended section 1895(a) of the Act to change the effective date for PPS from a transition by cost reporting periods to an immediate start-up date for all HHAs, effective October 1, 2000. The law, as amended, does not provide implementation by cost reporting period.

F. Split Percentage Payment

Comment: Current regulations require a physician signed plan of care before a HHA can bill Medicare for payment. Several commenters suggested the need to receive the initial percentage payment based on verbal orders. Many commenters were concerned about cash flow. Further, commenters believed that if we adopt a policy that permits initial payment based on verbal orders the need for a notice of admission would be eliminated.

Response: A number of commenters expressed concerns about cash flow to providers under the proposed system. Many reasons centered on the percentage of total payment provided upfront, as opposed to the end of the episode and the potential delays in receiving payments as a result of claims processing times, documentation requirements, and medical review. We appreciate these issues and are very interested in ensuring HHAs have adequate cash flow to maintain quality services to beneficiaries. As a result, we have taken a number of steps in this final rule that include increasing the amount of the initial percentage payment for initial episodes and a number of adjustments detailed below to significantly shorten the amount of time between the submission of the request for anticipated payment (defined below) and the receipt of payment. We believe these changes will significantly lessen the time for the receipt of payment as opposed to the approach set forth in the proposed rule. We are revising our approach to the split percentage payment as originally set forth in our proposed rule. We view the initial percentage payment as a ''request for anticipated payment'' rather than a Medicare ''claim'' for purposes of the Act. However, a request for anticipated payment is a ''claim'' for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the civil monetary penalties law (as defined in 42 U.S.C. 1320a–7a(i)(2)), the Civil False Claims Act (as defined in 31 U.S.C. 3729(c)), and the Criminal False Claims Act (18 U.S.C. 287)). We also note that where we use the term ''claim'' in this final regulation, it refers to a ''Medicare claim.'' The first percentage payment will not require a physician signed plan of care before submission. The request for anticipated payment reflecting the initial percentage payment for the episode may be submitted based on verbal orders. All physician verbal orders must: (1) Be put in writing; (2) reflect the agreement between the home health agency and the physician with the appropriate detail regarding the patient's condition and the services to be rendered; (3) be compatible with the regulations governing the plan of care at

§ 409.43, § 424.22, and § 484.18; and (4) be signed by a physician prior to submission of the claim. In order to request anticipated payment for the initial percentage payment based on physician verbal orders, a copy of the plan of care with all physician verbal orders placed in writing and dated with the date of receipt by the registered nurse or qualified therapist (as defined in § 484.4) responsible for furnishing or supervising the ordered service must be completed. A copy of the plan of care, which includes the verbal orders, must also be transmitted to the physician for his or her records. We believe this documentation need is consistent with current practice. Alternatively, the request for anticipated payment may be submitted if the HHA has a signed referral prescribing the physician's detailed orders for the services to be rendered and the patient's condition. Signed orders must, however, be obtained as soon as possible and before the submission of the claim for services is submitted for the final percentage payment for each episode. The final percentage payment including all of the utilization data for the episode is the Medicare claim. The claim for the residual final percentage payment requires a signed plan of care prior to billing for payment. Since the request for anticipated payment may be submitted based on verbal orders that are copied into the plan of care with the plan of care being immediately submitted to the physician and is not considered a Medicare claim, the request for anticipated payment will be canceled and recovered unless the claim for the episode is submitted within the greater of 60 days from the end of the episode or 60 days from the issuance of the anticipated payment. The request of anticipated payment for the initial percentage payment is a request for payment of anticipated services. The claim for final payment of the residual percentage payment constitutes the claim for services furnished. We believe this revised approach to split percentage payment will alleviate cash flow concerns raised in the public comments. We revised current § 409.43(c) governing physician signature of the plan of care. Specifically, paragraph (c)(1) of this section specifies, ''If the physician signed plan of care is not available, the request for anticipated payment of the initial percentage payment must be based on—

• A physician's verbal order that—

++ Is recorded in the plan of care;

++ Includes a description of the patient's condition and the services to be provided by the home health agency;

++ Includes an attestation (relating to the physician's orders and the date received) signed and dated by the registered nurse or qualified therapist (as defined in 42 CFR 484.4) responsible for furnishing or supervising the ordered service in the plan of care; and

++ Is copied into the plan of care and the plan of care is immediately submitted to the physician; or

• A referral prescribing detailed orders for the services to be rendered that is signed and dated by a physician.''

In paragraph (c)(2) of this section, we specify that ''HCFA has the authority to reduce or disapprove requests for anticipated payments in situations when protecting Medicare program integrity warrants this action. Since the request for anticipated payment is based on verbal orders as specified in paragraphs (c)(1)(i) and/or a prescribing referral as specified in (c)(1)(ii) of this section and is not a Medicare claim for purposes of the Act (although it is a ''claim'' for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a–7a(i)(2), and the Civil False Claims Act (as defined in 31 U.S.C. 3729(c), and the Criminal False Claims Act (18 U.S.C. 287), the request for anticipated payment will be canceled and recovered unless the claim is submitted within the greater of 60 days from the end of the episode or 60 days from the issuance of the request for anticipated payment.''

Paragraph (c)(3) of this section specifies that ''The plan of care must be signed and dated—

• By a physician as described who meets the certification and recertification requirements of § 424.22 of this chapter and;

• Before the claim for each episode for services is submitted for the final percentage payment.''

Paragraph (c)(4) of this section specifies that ''Any changes in the plan must be signed and dated by a physician.''

We agree with the commenter and believe that our revised approach eliminates the need for an additional notice of admission as originally proposed. We believe that the requests for anticipated payment of the initial percentage payment based on physician verbal orders responds directly to commenters concerns with current requirements governing physician signatures prior to claim submission. Commenters were concerned that the current signature requirements could disrupt necessary cash flow under PPS. We believe the request for anticipated payment for the initial percentage payment alleviates the cash flow concerns. Further, the request for anticipated payment of the initial percentage payment will provide appropriate cash flow to all providers because the requests are not subject to the current payment floor processing restrictions. The revised request for anticipated payment approach to the split percentage payment ensures adequate cash flow to providers who rely on Medicare resources to ensure continued quality care. Both the request for anticipated payment and the claim will be subject to medical review determinations. Subsequent payment withholdings may occur, as applicable. If a provider is targeted for medical review due to a history of excessive claim denials, it may not be able to submit requests for anticipated payment.

Comment: In the proposed rule, we proposed a 50/50 split percentage payment approach to the 60-day episode payment. The majority of commenters recommended a higher initial percentage payment in order to recognize the front loading of administrative costs associated with patient admissions. Many commenters requested increasing the initial percentage payment on at least the first episode due to the up-front costs associated with new patients.

Response: Based on comments that we have received, we believe the public has raised serious issues regarding cash flow under PPS. Therefore, we have re-evaluated our original split percentage proposal and have decided to revise our proposed approach to incorporate a 60/40 split for all initial episodes in order to recognize the up-front costs associated with new admissions. This new split percentage payment approach for all initial episodes is set forth in regulations at § 484.205(b)(1). All subsequent episodes will be paid at the 50/50 percentage payment split. The split percentage payment approach for subsequent episodes is set forth in regulations at § 484.205(b)(2). We believe our revised approach to the split percentage payment will provide appropriate financial relief to HHAs, adequate cash flow, and preserve the integrity of the Medicare trust funds. We believe our revised approach to the split percentage payment to include both the higher up-front percentage for first episodes and the submission of the request for anticipated payment of the initial percentage payment based on verbal orders, alleviates the cash flow issue for non-PIP providers as well as ongoing cash flow issues for PIP

providers. PIP providers will receive their last September PIP payments during October. That continuing payment flow during the transition combined with the ability to submit all requests for anticipated payment of the initial percentage payment based on verbal orders at the onset of PPS will ensure adequate cash flow to PIP providers. The ability to submit all requests for anticipated payment of the initial percentage payment based on physician verbal orders responds directly to commenters concerns with current requirements governing physician signatures prior to submission of the claim. Commenters were concerned that the current signature requirements could disrupt necessary cash flow under PPS. We believe the request for anticipated payment for the initial percentage payment alleviates the cash flow concerns. Further, the request for anticipated payment of the initial percentage payment will provide appropriate cash flow to all providers because the requests are not subject to the current payment floor processing restrictions. We plan to continue to study the up-front rate of utilization under PPS.

G. Statutory Elimination of Periodic Interim Payments (PIP)

Comment: The majority of commenters recommended the reinstatement of PIP or a PIP-like accelerated payment under PPS to ensure adequate cash flow to PIP providers as well as all providers. One commenter specifically suggested accelerated payments for high volume HHAs.

Response: Section 4603(b) of the BBA amended section 1815(e)(2) of the Act to eliminate periodic interim payments. PIP payments are a method to periodically pay in advance before receiving a claim. Accordingly, we proposed to revise § 413.64(h)(1) to eliminate PIP for HHAs for services furnished on or after October 1, 2000. In this final rule, we are also removing paragraph (h)(2)(iv) of this section to comply with the BBA requirement that eliminates PIP for home health services upon implementation of PPS.

Based on comments received, we believe the public has raised critical issues regarding the need to provide adequate cash flow to all providers and specifically to PIP providers during the transition to PPS. However, traditional PIP is related to cost-based payment reconciliations and cannot be readily adopted to PPS rates.

As stated previously, we believe our revised approach to the split percentage billing to include both the higher up-front percentage for first episodes and the submission of the request for anticipated payment of the initial percentage payment based on verbal orders, that are copied into the plan of care with the plan of care being immediately submitted to the physician, eliminates the cash flow issue for non-PIP providers as well as ongoing cash flow issues for PIP providers. With regard to transition payments to PIP providers, they will be receiving their last September PIP payments during October. That continuing payment flow during transition combined with the ability to submit all requests for anticipated payment of the initial split percentage payment at the onset of PPS as of October 1, 2000, will also ensure adequate cash flow to PIP providers. We believe our revised methodology will reduce payment flow issues and meet the needs of all providers equitably.

In addition, accelerated payments, as historically available, may be available to HHAs that are disadvantaged by delayed payments due to unanticipated HCFA claims processing system failures or delays to ensure adequate cash flow. In regulations at § 413.64(g) for cost-reimbursed providers, and in §§ 412.116(f) and 413.350(d) for hospitals and skilled nursing facilities, respectively, that receive payment under a prospective payment system, we have provided for the availability of accelerated payments for non-PIP providers in certain situations. We do not believe that HHAs should be penalized for unanticipated claims processing system delays and are extending the availability of accelerated payments to all HHAs under PPS. Therefore, we are adding a new § 484.245 to provide HHAs the ability to request accelerated payments under home health PPS if the HHA is experiencing financial difficulties due to delays by the intermediary in making payment to the HHA.

H. Low Utilization Payment Adjustment (LUPA) (§ 484.230)

Comment: Commenters on the LUPA centered on such issues as the total elimination of the LUPA, retaining the four or fewer visit threshold at a minimum, the lack of recognition of additional costs associated with the first visit in the episode due to patient admission responsibilities, negative impact on rural and small providers, and the inadequate payment amount proposed for each standardized per-visit amount per-discipline. Many commenters suggested we increase the proposed LUPA amounts to reflect the current per-visit limits by discipline or cost per visit by discipline or by a percentage increase approach. A few commenters suggested the elimination of LUPA for the first episodes, but supported application of the LUPA for subsequent episodes.

Response: We proposed a low utilization payment adjustment in order to moderate provision of minimal or negligible care, that is, to discourage HHAs from providing a minimal number of visits in an episode. We proposed episodes with four or fewer visits be paid the wage adjusted national standardized per-visit amount by discipline for each of the four or fewer visits rendered during the 60-day episode. We solicited comments on the most appropriate threshold and specifically solicited comments on the use of the higher threshold of six or fewer visits. We will retain the original four or fewer visit threshold as no commenters supported moving the threshold to six or fewer visits. In this final rule, we respond to the recommendation to increase the proposed LUPA amount by now calculating the LUPA based on a higher national average per-visit amount by discipline updated by the market basket to FY 2001. This will provide a higher level of payment and fully compensate HHAs for such visits. We are revising our regulations at § 484.230 to reflect the higher per-visit amounts that will be used to calculate the LUPA payments. We are not adopting the comment to increase the payment only for the first visit to account for the front-loading of costs in an episode because we believe the approach set forth in this rule will adequately account for the costs for low utilization episodes. We will continue to monitor the impact of the four or fewer visit threshold and the revised LUPA per-visit amounts on all types of providers under PPS. The revised LUPA methodology and rate tables are found in section IV. of this rule.

Comment: Commenters suggested that we apply LUPA only to acute patients and not to chronic patients who require B–12 injections or catheter changes.

Response: The LUPA payment approach does not distinguish between an acute or chronic home care patient. The goal of the LUPA is to appropriately pay for low utilization episodes. As stated above we have revised § 484.230 to reflect the higher per-visit amounts that will be used to calculate the LUPA payments. We believe the revised approach to calculating the LUPA per-visit amounts by discipline will more adequately reflect average costs associated with low volume episodes.

Comment: A few commenters suggested the removal of wage index adjustment in the LUPA payment

approach. Commenters also suggested that we case-mix adjust the LUPA.

Response: The LUPAs are not case-mix adjusted because they are calculated using national claims data for episodes with four or fewer visits. The claims data is only wage adjusted, not case-mix adjusted. We believe it is important to adjust the labor component of the LUPA based on the most recent pre-floor and pre-reclassified hospital wage index as historically reflected in the labor portion of home health services.

Comment: One commenter requested clarification of whether telephone contact or a telemedicine visit will count as a visit for purposes of the LUPA policy.

Response: The current definition of a Medicare home health visit has not changed with the implementation of home health PPS. The definition of a visit is set forth in § 409.48(c) of the regulations specifies that ''A visit is an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA for the purpose of providing a covered service.'' A telephone contact or telemedicine visit does not meet the definition of a visit and therefore would not count toward a LUPA visit.

Comment: A few commenters requested clarification of the type of practitioner that would provide a LUPA visit.

Response: The current personnel qualifications and coverage guidelines governing the provision of covered home health services are not changed by home health PPS. All visits provided under HHA PPS regardless of the provision under an episode rate or LUPA rate must meet current Medicare coverage guidelines.

Comment: A few commenters requested a specific HHRG level for LUPA cases.

Response: We do not believe the case-mix weight methodology as proposed would accommodate an HHRG specific weight for the LUPA. The LUPA is a wage adjusted per-visit payment. Constructing a LUPA specific HHRG would confuse the concept of case-mix adjustment and per-visit payment for LUPAs. However, we will continue to consider this proposal as we further refine PPS in the future.

I. Partial Episode Payment Adjustments (PEP Adjustment)

Comment: Several commenters did not support the use of billable visit dates to calculate the PEP adjustment due to possible gaps in days that may not be recognized in the payment. Many commenters recommended the use of the first billable visit date through the day before the intervening event or discharge date as the span of time used to calculate the proportional payment. Many commenters did not believe the PEP reflected the increased costs associated with admission during the start of the episode. Commenters proposed eliminating the proportional payment aspect of the provision thus yielding a full episode payment for the initial HHA and a full episode payment for the HHA receiving the patient due to the intervening event. Several commenters provided alternative payment approaches to the PEP policy as set forth in the proposed rule.

Response: In the October 28, 1999 proposed rule, we proposed a PEP Adjustment to address the key intervening events of the beneficiary elected transfer to another HHA and the discharge of a beneficiary who returns to the same HHA during the 60-day episode. We proposed to restart the 60-day episode clock due to the two intervening events and end the original episode payment with a proportional payment adjustment. The proportional payment adjustment would be calculated by using the span of billable visit dates prior to the intervening event. We are not adopting the commenters' suggestions to use the day before the intervening event or discharge date to calculate the proportional payment. We are retaining the use of billable service dates to determine the appropriate payments because of the HHAs involvement in decisions influencing the intervening events for a beneficiary elected transfer or the beneficiary is discharged and returns to the same HHA during the same 60-day episode period. Proportional payments based on billable visit dates will continue to be the payment methodology for the initial HHA as a result of the intervening event. We believe the new 60/40 percentage payment split for first episode payments as specified in regulations at § 484.205(b)(1) will alleviate concerns with costs associated with new patients.

Comment: A few commenters requested clarification of the calculation of the therapy hour threshold in the case of the transfer PEP Adjustment.

Response: The therapy threshold will apply separately to the proportional portion of the first episode and the new episode that results from the intervening event. The initial HHA will have the period of time of the first billable service date through the last billable visit date in the original plan of care prior to the intervening event to reach the therapy threshold. The new episode resulting from the intervening event will not incorporate therapy usage from the prior period but will determine the therapy needs for the patient resulting from the new certified plan of care. Each part of the episode, the PEP adjusted portion and the new 60-day episode resulting from the intervening event is subject to separate therapy thresholds. The therapy threshold is not combined or prorated across episodes. Each episode whether full or proportionally adjusted is subject to its own unique therapy threshold for purposes of case-mix adjusting the payment for that individual patient's resource needs. This PEP approach to the therapy threshold applies to both intervening events of the beneficiary elected transfer and the discharge and return to the same HHA during the same 60-day episode period.

Comment: Several commenters suggested the elimination or modification of the proposed policy that prevents the PEP adjustment when a beneficiary elects to transfer to an HHA that is under common ownership with the initial HHA. We proposed that transfers among HHAs under common ownership would be paid as an under arrangement situation. Commenters believed that the proposed common ownership policy should not apply when the transfer was made because the patient moved out of the first HHA's geographic service area defined by the agency's license. Further, commenters were concerned that if the proposed language regarding common ownership was not changed to conform to the rules currently governing related parties, it would be viewed as an attempt by HCFA to pierce the corporate veil and offset the liabilities of one corporation against payments due to another.

Response: In response to these concerns, we are providing further clarification of our definition of common ownership for purposes of the PEP adjustment for beneficiary elected transfers. If an HHA has a significant ownership interest as defined in § 424.22 (Requirement for home health services), then the PEP adjustment would not apply. Those situations would be considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the ownership interest until the end of the episode. The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moved out of their MSA or non-MSA during the 60-day episode before the transfer to the receiving HHA. The transferring HHA not only serves as the billing agent, but must also exercise professional responsibility over the

arranged-for services in order for the services provided under arrangements to be paid.

Comment: A few commenters requested that we clarify how we apply our PEP policy when a home health patient elects hospice before the end of the episode. The comments focused on a hospice that is under common ownership with the HHA.

Response: If a patient elects hospice before the end of the episode and the patient did not experience an intervening event of discharge and return to the same HHA, or transfer to another HHA during an open 60-day episode prior to the hospice election, the HHA receives a full episode payment for that patient. Upon hospice election, the beneficiary is no longer eligible for the home health benefit. The common ownership restriction for the PEP adjustment applies only to the relationship between two HHAs providing covered home health services to a home health eligible beneficiary.

Comment: A few commenters requested clarification of whether a PEP adjustment will apply to the initial HHA when a physician or patient-initiated termination of home health services occurs and the treatment goals have not been reached. In addition, commenters further requested clarification of the beneficiary elected transfer PEP policy when the beneficiary transfers because the HHA provided minimal or negligible services.

Response: To account for the situation when a patient initiates the termination of services for any reason and requests a transfer to another HHA, we developed the PEP adjustment to assure that the patient's freedom of choice was honored and that the Medicare Trust funds were protected by a policy that ensures adequate payment levels that reflect the time each HHA served the patient under a transfer situation. Unless the beneficiary refused further care or was a safety risk to the HHA staff, we do not envision a situation in which a physician would terminate care prior to the completion of treatment goals. However, we would focus survey or medical review resources to investigate complaints of minimal or negligible service delivery as a motivating factor for a beneficiary's election to transfer from the original HHA.

Comment: A few commenters suggested that we allow the physician to reinstate the initial plan of care rather than requiring a new plan of care in the situation of discharge and return to the same HHA during the same 60-day episode.

Response: We are not adopting this comment. We believe that a new certified plan of care is a critical feature of any episode payment, regardless of whether prior treatment goals were met and the patient was formally discharged. We do not believe that it is unduly burdensome because the HHA will be receiving access to an entire 60-day episode payment. Further, a patient that returns to the HHA for admission after discharge would require a new OASIS assessment and new plan of care under current practice guidelines.

Comment: Some commenters asked if the PEP adjustment is applied when a patient dies.

Response: A full episode payment will be paid in the event of a patient's death during a 60-day episode. No PEP adjustment will be calculated due to a patient's death during an episode.

Comment: A few commenters argued that the PEP adjustment policy approach does not adequately address ''snow birds'', persons who seasonally migrate from one place to another.

Response: We believe the PEP adjustment will adequately address this situation. As stated previously, if for any reason, a beneficiary elects to transfer to another HHA, the original HHA's episode payment would be proportionately adjusted with a PEP adjustment to reflect the time the HHA served the patient prior to the intervening event of the transfer. This would include the ''snow bird'' situation. We do not believe there is a need for an exception from the transfer policy regarding ''snow birds''. Our PEP adjustment policy governing transfers provides for a clean slate for a 60-day episode payment, OASIS assessment, and certification for the receiving HHA. We believe this is an equitable approach to intervening events during the 60-day episode.

Comment: Commenters argued PEP adjustment governing discharge and return should not apply when there is a readmission for the same diagnosis. Commenters stated that the discharge and return to the same HHA during the 60-day episode PEP adjustment requires the goals in the original plan of care to be met prior to discharge. Commenters requested further clarification of meeting treatment goals in the original plan of care.

Response: We will not provide for payment for two full episodes at any time during a given certified 60-day episode. If an HHA discharges a patient, it is assumed that the patient has met the course of treatment set forth in conjunction with physician orders in the patient's original plan of care. If the patient returns with the same diagnosis, it may not indicate the same plan of care. Even if the HHRG level did not change upon return, the patient's initial discharge indicated completion of the original course of treatment. The original episode payment would be proportionately adjusted to reflect the time prior to discharge with a PEP adjustment.

J. Significant Change in Condition Payment Adjustment (SCIC Adjustment) (§ 484.237)

In the October 28, 1999 proposed rule, we proposed a significant change in condition adjustment to recognize the event of a significant change in patient condition that was not envisioned in the original plan of care. The SCIC adjustment is calculated as a proportional payment reflecting the time both before and after the patient experienced the significant change in condition. Billable visit dates are used to calculate the proportional payments.

Comment: Some commenters did not support the use of billable visit dates due to the potential gaps in payment days used to calculate the SCIC adjustment. Commenters suggested using the dates that the patient received comprehensive case management or all the days in the 60-day episode. Many commenters suggested the restart of the 60-day episode clock due to the patient's significant change in condition, resulting in two full episode payments or a prorated payment plus a full new episode payment. Other commenters suggested that the admission to an inpatient facility should indicate close of a previous episode for outcome data collection, similar to the PEP proportional payment approach. Other SCIC comments centered on prorating payments based on visits or increasing the SCIC proportional payments by an equitable percentage increase to each proportional payment for the original diagnosis.

Response: The use of billable visit dates as the boundaries for the payment adjustment encourages appropriate service use and supports the delivery of all needed care. We further believe that the current SCIC adjustment policy provides financial relief to HHAs who would otherwise be locked into a case-mix adjusted payment based on a point in time of the patient's condition at the beginning of the episode. We will retain the current SCIC adjustment policy and are not adopting the commenters' suggestions. The SCIC adjustment ensures HHAs will have adequate resources to meet the changing patient needs of its mix of patients. The SCIC adjustment provides HHAs with the

ability to meet the changing resource needs of their patients.

Comment: Many commenters requested clarification, and others requested removal, of the policy set forth in the preamble of the proposed rule governing intervening hospital stays during a 60-day episode. In the proposed rule, we stated that if a patient experiences an intervening hospital stay during an existing 60-day episode under an open plan of care, then the patient would not have met all of the treatment goals in the plan of care. Therefore, the intervening hospital admission during an existing 60-day episode could result in a SCIC adjustment, but could not be considered a discharge and return to the same HHA PEP adjustment. Currently, HHAs are provided the option to discharge patients upon transfer to an inpatient facility.

Response: We believe that HHAs should be given the option to discharge the patient within the scope of their own operating policies; however, when an HHA discharges a patient as a result of a hospital admission during the 60-day episode that discharge will not be recognized by Medicare for payment purposes. Either an intervening hospital stay will result in an applicable SCIC adjustment or if the Resumption of Care OASIS assessment upon return to home health does not indicate a change in case-mix level, a full 60-day episode payment will be provided spanning the home health episode start of care date prior to the hospital admission, through and including the days of the hospital admission, and ending with the 59th day from the original start of care date of the episode.

Comment: Commenters requested clarification that the SCIC adjustment will only apply in cases of deterioration, that is, increased payment due to a new HHRG and not improvement resulting in a possible decrease in payment for the second part of the SCIC adjustment.

Response: We designed the SCIC adjustment to permit the HHA to adjust the assessment and the concomitant HHRG assignment when the patient's condition changes in a significant way that was unanticipated in the context of the initial assessment. The SCIC adjustment will occur in both situations of significant patient deterioration and improvement. Excessive use of the SCIC adjustment for patient deterioration will be monitored under PPS to ensure the legitimacy of claims for increased payment.

Comment: A few commenters asked if there is a limit to the number of SCIC adjustments in one 60-day episode.

Response: Although there is the clinical possibility of more than one SCIC adjustment during a given 60-day episode, we believe it will be a rare occurrence. While we will permit more than one SCIC per episode, providers who demonstrate a pattern of multiple SCIC adjustments will likely be subject to review to assure the validity of such situations.

Comment: Several commenters suggested the use of a modified OASIS assessment for purposes of SCIC Adjustments. Commenters requested that we require only those OASIS and other items necessary for case-mix for the determination of a SCIC adjustment.

Response: Totally apart from PPS, the current protocol governing OASIS assessment schedules, requires the complete OASIS assessment at points in time when the patient experiences a significant change in condition. Further, we believe it is necessary to have all OASIS items relevant for outcome measures to monitor the use of SCIC adjustments under PPS. We are not adopting this comment on the approach to SCIC adjustments. The SCIC adjustment provides an additional payment adjustment without which PPS would have locked the HHA and patient in a 60-day episode payment level according to the patient's status at the beginning of the 60-day episode. We do not believe the completion of the full OASIS assessment generates a cost that outweighs the benefit of the SCIC adjustment from a payment and quality of care perspective.

Comment: Commenters had additional questions regarding our policies governing the SCIC adjustment. Specifically, commenters asked if physician verbal orders would suffice to precipitate a SCIC adjustment or would the form 485 have to be completed.

Response: The SCIC adjustment occurs when a beneficiary experiences a significant change in condition during the 60-day episode that was not accounted for in the original plan of care. In order to receive a new case-mix assignment for purposes of the SCIC adjustment payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain necessary change orders reflecting the significant change in treatment approach in the patient's plan of care. While the physician's verbal order and the corresponding OASIS reassessment may precipitate the new case-mix level and corresponding payment grouping the HHRG for the balance of the 60-day episode, the SCIC adjusted episode, like any other episode, requires a signed plan of care prior to submission of the claim for the final percentage payment.

Comment: Commenters requested clarification of whether the LUPA will apply in situations of the SCIC adjustment.

Response: A SCIC adjusted episode payment could be further adjusted to reflect the LUPA, if applicable. However, because a LUPA payment is not case-mix adjusted, the SCIC would have no payment consequence on an episode paid at the LUPA level. This would be a limited, but not inconceivable, occurrence that would likely be targeted by medical review.

K. Case-Mix

Caregiver Variables on OASIS Not Used in Case-Mix System

Comment: In the proposed rule we stated that caregiver variables would be omitted from the case-mix model. Some commenters were concerned that failure to consider caregiver availability may result in inadequate payment. One commenter stated that returning to independence or assuming care on a long-term basis often depends on the patient's support system or lack thereof. Commenters stressed that caregiver availability is a particularly strong factor in rural areas where patients have fewer community supports to make up for the lack of caregiver assistance in the home.

Response: In the proposed rule, we discussed our basis for excluding such variables. We recognize that adjusting payment in response to the presence or absence of a caregiver may be seen as inequitable by patients and their families. To the extent the availability of caregiver services, particularly privately paid services, reflects socioeconomic status differences, reducing payment for patients who have caregiver assistance may be particularly sensitive in view of Medicare's role as an insurance program rather than a social welfare program. Furthermore, adjusting payment for caregiver factors risks introducing new and negative incentives into family and patient behavior. It is questionable whether Medicare should adopt a payment policy that could weaken informal familial supports currently benefiting patients at times when they are most vulnerable.

Notwithstanding these considerations, we examined the usefulness of caregiver factors but found them to be only minimally helpful in explaining or predicting resource use. A variable on the availability of a caregiver had no impact on average resource cost (Abt Associates, Second Interim Report, September 24, 1999), and only a modest impact after controlling for other patient characteristics (Abt Associates, First Interim Report, July 1998 [Revised December 1998]). This could result if patients who are able to remain in the

home without a caregiver are inherently less impaired and more able to provide self-care than other home care patients. (One commenter seemed to confirm this hypothesis in stating that caregiver availability can determine whether a patient can safely live at home.) A strong relationship between caregiver assistance and patient health/functional status could make it difficult analytically to identify a cost impact resulting from the caregiver's lack of availability. As a technical matter, this problem could hinder accurate incorporation of caregiver availability into the case-mix system, were it deemed appropriate.

Results from the Phase II per-episode prospective payment demonstration lend credence to the limited value of caregivers in explaining resource use under a PPS system. Evaluation of the demonstration indicated that reductions in service utilization among PPS patients were the same, regardless of whether the patient had other caregiving (Mathematica Policy Research, Inc., ''Per Episode Prospective Payment for Medicare Home Health Care Sharply Reduces Service Use,'' Draft Report, December 1998). The findings suggest that, despite intentions to rely more heavily on other caregivers as a way of reducing home care costs, PPS agencies did not target their service reductions more heavily on patients with caregivers. The reason for this outcome is unclear. (There was also little or no indication that PPS agencies tried to avoid patients without caregivers.)

Other caregiver variables examined in the case-mix study, measuring frequency of assistance and caregiver health/psychosocial status, also exhibited a relatively modest impact on resource cost. When added to the existing model they added less than one point to the model's explanatory power (R-squared) (Abt Associates, Second Interim Report, September 24, 1999). These findings weaken the assertion that failure to adjust for caregiver factors could render payments inadequate. It should also be noted that, based on preliminary data, these caregiver variables did not have particularly strong item reliability (Abt Associates, Second Interim Report, September 24, 1999, Appendix G). Low reliability means an assessment item is prone to mis-measurement. In measuring case-mix for payment purposes, we wish to avoid, to the extent possible, items with weaker reliability. (We will continue to examine the reliability data as they are finalized.)

In summary, we believe that in light of data that support our policy concerns surrounding caregiver variables, and their insignificant contribution to predicting resource use, these OASIS items are not appropriate for use in the case-mix adjuster.

Comment: Several commenters urged us to continue to study the issue of caregiver impacts, including further study of language used in the caregiver items for the OASIS.

Response: We will continue to examine OASIS caregiver variables and their impact as we analyze national OASIS and claims data to pursue refinements to the case-mix system. However, in the absence of policy consensus that caregiver variables are appropriate to include, it would not be cost-effective to commission further studies of alternative wording of caregiver-related assessment items.

Variables Identifying Preadmission Location in the Services Utilization Dimension

In the proposed rule we set forth a services utilization dimension within the case-mix model. We proposed including variables indicating whether certain inpatient stays occurred in the 14-day period immediately preceding the home health episode. Not only are pre-admission inpatient stays a traditional indication of need in clinical practice, but also such variables were useful correlates of resource cost in our analyses of the case-mix data (Abt Associates, First Interim Report, July 1998 [Revised December 1998], Abt Associates, Second Interim Report, September 24, 1999).

Comment: Several commenters requested clarification about the derivation of the scores and severity grouping in the services utilization dimension.

Response: Our data indicate that an acute care hospital discharge (without follow up post-acute inpatient stay) within the 14 days immediately preceding admission to home care is associated with the lowest costs during the 60-day episode. Other research has shown similar findings. For example, in the home health Phase II per-episode prospective payment demonstration research, multivariate analysis of home care utilization in the year following admission also suggested that pre-home-care hospital stays were associated with reduced home care utilization. In the case-mix data, episodes involving patients with no pre-admission inpatient stay had the second-lowest cost; episodes involving patients who had both a hospital and post-acute-care institutional stay (that is, skilled nursing facility (SNF) or rehabilitation facility) had the third-lowest cost; and episodes involving patients who had only a SNF or rehabilitation facility stay had the highest cost. The highest-cost category (SNF or rehabilitation stay alone, given a 14-day window) may actually be comprised predominantly of relatively long stays. These stays appear to be indicators for patients who, upon their return home, have high care needs during the 60 days following home health admission.

In the case-mix data, if a patient who had a hospital stay in the 14 days preceding admission is evaluated to need significant home therapy, then the resource costs increase sharply. Likewise, therapy utilization markedly increased resource cost for the episodes preceded by the other three pre-admission locations. Because the therapy utilization was to be considered simultaneously with the preadmission location in the services utilization dimension, we examined the resource cost according to eight categories. These eight categories are the four pre-admission locations (hospital stay alone, no inpatient hospital or SNF/rehab stay, a hospital-stay-plus-SNF/rehab-stay, or a SNF/rehab stay alone) with and without therapy utilization of at least eight hours.

The resulting array of average resource cost indicated that among episodes not meeting the therapy threshold, those following a hospital stay, no inpatient hospital or SNF/rehab stay, or a hospital-stay-plus-SNF/rehab-stay all had similar resource costs. We assigned increasing scores—zero to 2—for these groups, in accordance with the trend in the data overall, but ultimately grouped them into a single severity level reflecting their similar resource costs. Episodes not meeting the therapy threshold but with a SNF/rehab stay alone were effectively assigned a score of three (from the combination of scoring for the hospital stay and SNF/rehab response categories) and grouped separately into the second severity level, because their resource cost was significantly higher than patients with a score of zero to 2.

The remaining two severity groups were for episodes that met the therapy threshold. Therapy-threshold patients coming from the first three locations were grouped together into a third severity level because of the similarity in their resource costs. Scoring for these patients again reflected the overall trend by preadmission location (scores of zero, one, and two for hospital stay, no inpatient hospital or SNF/rehab stay, or a hospital-stay-plus-SNF/rehab-stay, respectively) but included an additional four points to reflect the cost impact of the therapy. High-therapy patients from the fourth pre-admission location (SNF/

rehab stay alone) had the highest costs of any group, so we placed them in the fourth and final severity category. Following the existing scoring logic, these episodes had a total score of seven based on three points for the preadmission location and four points for the therapy need.

Comment: Some commenters stated that their own experience did not confirm the relationship between pre-admission institutional stays and resource cost as indicated in our case-mix research data. Specifically, commenters indicated that patients coming from the hospital are often more acutely ill and resource-intensive than other patients, particularly patients who had no preadmission institutional care. For example, these patients typically need more frequent visits and teaching. As a result, according to these comments, the case-mix system fosters a disincentive to admit post-acute-hospital patients.

Response: The conclusion reached by the commenters is incorrect because the severity grouping (though not the scoring) is neutral with regard to pre-admission hospital stays. Patients with such stays, as well as patients without any institutional stays, and patients with hospital-plus-SNF/rehab care, are all grouped together in the same severity category. The patients who were admitted with only a SNF/rehab stay in the previous 14 days are grouped into a separate severity category. Within each of these two severity categories, the patients meeting the therapy threshold are split off into an analogous severity category reserved for therapy patients. It is the severity category that determines the case-mix weight. (In the services utilization dimension, the scoring system is simply a device to organize the assessment data on preadmission location and therapy threshold.)

Comment: Several commenters suggested that the 14-day definition for the preadmission location on OASIS actually encompasses a heterogeneous group of patients, and that comparison of patients admitted to home care within 1 or 2 days of discharge with patients admitted within 5 to 14 days of discharge would reveal a cost difference.

Response: While this distinction or others related to the time since discharge might prove useful, the OASIS assessment does not provide the level of detail necessary to recognize any difference. In analyzing the data available to us, we examined the cost separately for the subset of patients who experienced a SNF/rehab stay as well as an acute care stay (and thus were unlikely to be among the patients admitted to home care within one to two days of discharge). This subset of patients was generally about as costly as the hospital-stay-only patients. This suggests that in the absence of the SNF/rehab stay, the agency would have otherwise incurred higher resource costs by admitting the patient to home care directly from the acute-care-hospital. The timing of the home health admission is to some extent correlated with SNF use, which in turn may be correlated with case severity. Under these conditions, it may be difficult to quantify a suspected relationship between the timing of the admission and resource use. (This is similar to the comment noted earlier concerning caregiver variables; that is, a variable such as caregiver availability or SNF use may tend to offset resource cost for particularly costly patients, making it difficult to observe the relationship between these patients' severity and their presumed costliness.) We will continue to examine this issue in the future using claims and linked OASIS data.

Comment: Another comment stated that paying a higher rate for patients experiencing a pre-episode SNF or rehab stay puts rural agencies at a disadvantage, because many patients elect to return directly home from the hospital due to a shortage of post-acute institutional care facilities.

Response: As stated earlier, three pre-admission location categories are all grouped in the same severity level. The fourth category was grouped separately—patients experiencing only a SNF/rehab stay within the previous 14 days. As we noted in the proposed rule, these patients likely experienced a relatively long SNF stay, which appears to be an indicator for exceptionally high case severity. Whether such cases from rural areas systematically fail to be placed appropriately in post-acute-care institutions deserves further study. Our impact analysis suggests, however, that rural agencies will experience payment increases under PPS (see Table 11). Examination of payment-to-cost ratios in the Abt case-mix data also suggests that rural agencies will experience payments under the PPS system that exceed their historical cost levels (Second Interim Report, September 24, 1999).

Comment: One commenter stated that recent hospitalization affects the plan of care, particularly within the first 30 days. We also received a comment noting the costliness of care for ''chronic, long-term'' patients coming from the community as their pre-admission location, but with high clinical and functional severity.

Response: We emphasize that the resource cost used to develop the case-mix system was measured over the patient's first 60 days under the care of the HHA. Thus, it is entirely possible that patients with contrasting pre-admission locations could have similar total resource costs albeit with different care trajectories. For example, for relatively healthy patients who are bound for recovery from an acute illness, and who may therefore be discharged from home care fairly soon after a short, intensive period of teaching and support, the total 60-day resource cost may be comparable to the cost for certain chronically ill patients who have less-intensive but more sustained needs over the course of the 60-day episode.

Comment: A commenter urged us to revise the services utilization scoring of OASIS item M0170 because a patient coming from the community is similar in resource need to one coming from a rehabilitation hospital or SNF, but they have different scores on the services utilization category.

Response: We have not revised the scoring of M0170 because the combination of scoring for M0170, lines 1, 2, and 3, allows for differentiation between SNF or rehabilitation patients with and without hospital discharge. This distinction is important in case-mix system grouping.

Comment: Commenters also indicated concern about the accuracy of reporting on the OASIS for the preadmission location.

Response: We agree that assessing clinicians may have difficulty in some instances obtaining accurate data on the type of institution and the dates of discharge. The fact that the severity levels in the services utilization dimension are neutral with respect to most pre-admission location scenarios partially mitigates this concern. Assessing clinicians would be well-advised to confirm information with multiple sources (for example, the patient, family, referring physician, local hospital) to ensure its accuracy. The clinician may also ask to see the patient's discharge instructions. Virtually all institutional stays that require ascertainment for case-mix purposes are covered by Medicare. The National Claims History and other data bases eventually record these events, potentially affording Medicare's fiscal intermediaries opportunities for reviewing case-mix accuracy on a post-pay basis. We will instruct the fiscal intermediaries to take into consideration the challenges faced by agencies in accurately reporting the preadmission

location, and formulate review policies accordingly.

Comment: A commenter expressed concern that preadmission location variables are a matter of timing for a service rather than a measure of acuity. The commenter questioned why a SNF discharge 16 days before would differ from one 14 days before home health admission.

Response: The preadmission location item M0170 was originally included in OASIS as one of many variables useful for risk adjusting outcome measures. A recent institutional stay (discharge within two weeks) continues to be a frequent event preceding home care. The two-week definition is unambiguous, and has proven statistical impact in both a case-mix and outcomes research context. Using a longer recall period would present measurement problems and would be less helpful in explaining resource use.

Comment: A commenter stated that the OASIS item on prior location (M0170) creates an artificial distinction between patients who received care in a rehabilitation wing of an acute care hospital and patients who received care in a rehabilitation facility.

Response: OASIS instructions define a rehabilitation facility as a freestanding rehabilitation hospital or a rehabilitation distinct part unit of a general acute care hospital. Therefore, a rehabilitation wing (that is, distinct part unit) is included in the OASIS rehabilitation facility definition.

Comment: A commenter stated that the language regarding nursing facilities was inconsistent between Table 7 in the proposed rule and OASIS. A related comment suggested that we clarify the response categories in OASIS item number MO170 to distinguish between stays in skilled nursing facilities and extended care facilities.

Response: We are revising the OASIS MO170 response categories to allow separate reporting of skilled nursing facility discharges within the previous 14 days. This change will resolve the inconsistency.

Comment: A commenter requested clarification of Case 1 in the proposed rule (page 58179) and asked whether the case information or Table 7 is correct.

Response: We apologize for this error in the case description. The Service Dimension should have read ''Service Domain=4 (therapy more than 8 hours).''

Comment: A commenter stated that there should be much less emphasis on where the patient is located and more on the patient's clinical needs.

Response: We included preadmission location information in the services utilization dimension because it has traditionally been associated with variation in home care services utilization, and in our case-mix research it helped to explain variation in home care resource use. We do not believe the case-mix system places excessive emphasis on this type of predictor variable. Clinical needs are addressed in the clinical dimension.

Variables Measuring Therapy Utilization in the Services Utilization Dimension

To ensure that patients who require therapy would maintain their access to appropriate services under the HHA prospective payment system, in the proposed rule we grouped patients according to their therapy utilization status. Specifically, we defined a therapy threshold of at least eight hours of combined physical, speech, or occupational therapy over the 60-day episode, to identify high therapy cases. We proposed a threshold of eight hours of therapy based on clinical judgment about the level of therapy that reflects a clear need for rehabilitation services and that would reasonably be expected to result in meaningful treatment over the course of 60 days. Subsequently, further development and refinement of the Abt case-mix model assumed this threshold as part of the grouper logic.

The 15-minute-increment billing requirement in principle allows the RHHI payment system to verify the case-mix therapy threshold. However, there is uncertainty about the completeness and accuracy of the 15-minute reporting. This led us to propose that, pending resolution of this issue, the therapy threshold be expressed in a defined number of visits. Returning to the resource use data of the Abt study, we determined that on average a therapy visit lasted approximately 48 minutes. This implies that on average eight hours of therapy would be exhausted in 10 visits.

Comment: Several commenters urged us to change the conversion to eight visits to be consistent with current cost reporting and salary equivalency practice equating one visit to one hour. Commenters suggested that, without such a change, the proposal effectively reduces therapy payments. Some commenters argued that a conversion to eight visits (or fewer—other commenters proposed six visits and four visits) would compensate for excluding time spent on a case outside of the home from the calculation of resource cost in the Abt study. In addition, commenters pointed out that some patients will achieve eight or more hours in fewer than 10 visits, so HCFA should recognize that the therapy threshold has been met as soon as the eight hours are achieved.

Response: We see no reason to associate the cost reporting and salary equivalency practices with the independent, congressionally mandated 15-minute-increment reporting requirement. The origin of this requirement was Congress's intent that adequate data be available to both develop and refine the HHA prospective payment system. We see these data potentially as key resources for improving the case-mix system in the future. Upon linking the claims with the OASIS assessments, a data resource comparable to the Abt case-mix study data will be available for research purposes. This resource promises to improve upon the Abt data by virtue of the large sample sizes it would provide. Many suggestions from commenters for improvements that need study can be pursued once these data are assembled. We believe there are advantages to the continued gathering of 15-minute billing information. We urge home health agencies to continue their diligent collection of these data so that eventually the therapy threshold can be used as originally defined—in terms of time spent in the home, not visits.

The PPS pricer developed for the first year of PPS will determine the case-mix adjustment based on the 10-visit threshold without consideration of the 15-minute-increment billing data on the claim. Upon analysis of national claims data under PPS, we will determine whether the pricer should be changed to take into account information from the 15-minute-increment reporting. We are concerned that counting visits rather than hours to satisfy the therapy threshold in the case-mix groupings could become a source of potential abuse. Therefore, if we identify providers whose therapy visits are systematically and significantly shorter than the 48-minute standard, yet meet the 10-visit threshold, we will examine such cases and reduce the case-mix assignment if evidence documents that therapy hours were well below the 8-hour threshold.

The commenters' suggestion that we compensate for excluded time spent outside the home by adopting a lower therapy threshold does not resolve a significant issue that requires further study. The commenters' proposal can result in diminished payment accuracy, because the relative weights are based on groups defined from the 8-hour threshold. If, over time, the composition of the therapy groups shifts to lower-cost patients, the relative weights would need to be adjusted accordingly.

If we adopted a lower therapy threshold or a graduated threshold, as some commenters suggested, we believe the result would be an increase in the incentive to maximize payment by manipulating the delivery of therapy. Comments proposing that Medicare prorate the therapy factor in transfer or in cases where the therapy utilization is spread over more than one episode, present problems for this reason as well. The comment suggesting that the therapy factor be prorated when utilization is spread over more than one episode appears to reflect a misunderstanding of our intent to have the therapy threshold, as applied within the 60-day episode, target patients with significant therapy needs. The rationale for recognizing a therapy utilization factor is to ensure that agencies will be adequately compensated for delivering this high-cost service, thus preserving access for patients with therapy needs. It is the same rationale that underlies case-mix adjustment itself. Payment weights for groups containing patients whose therapy utilization is spread over multiple episodes reflect the reduced resource costs of these patients per each 60-day episode. As discussed previously, in a PEP situation (for example, a transfer), the therapy threshold is separately measured for the proportional episode and the new episode resulting from the beneficiary elected transfer. In the SCIC situation, the therapy threshold applies to the total therapy visits provided to the beneficiary during the episode both before and after the significant change in condition occurred.

Further suggestions that skilled nursing time as well as aide time be measured and treated the same as therapy hours would also seem to reinforce these undesirable incentives, as skilled nursing visits make up the single largest discipline category in home health care, and aide visits the second largest, with both far outweighing therapy visits.

Comment: Several commenters questioned the decision to use a therapy threshold in the case-mix adjustment system.

Response: We recognize that, as we indicated in the proposed rule, using a utilization variable such as the therapy measure is susceptible to manipulation. However, currently our best available data requires us to rely in part on the therapy measure. Without it, we cannot achieve the preferred level of payment accuracy, notwithstanding its potential susceptibility to manipulation. We note that the case-mix system for home health is similar to the other major Medicare case-mix systems, in that these others also use measures of treatment planned or received. We will continue to review the use of a utilization variable in this system over the long term.

Comment: We received several suggestions from commenters that amounted to changing the group assignment for certain types of patients so that the payment weights for these patients would be comparable to or even higher than the existing therapy-group weights. For example, one suggestion was to award points to the services utilization dimension when the patient is assessed at the highest level of the clinical and functional dimensions. Another suggestion was to add points to the services utilization dimension when the patient is a user of multiple therapies, perhaps by defining a fifth severity level within the services utilization dimension.

Response: We appreciate these comments as they will aid us as we further refine the case-mix model. At this time, however, it is not clear that such changes would provide a satisfactory remedy for the problems the commenters have raised. In deciding on the basic structural characteristics of the case-mix system, we had to balance clinical acceptability, complexity, and technical issues, such as the feasibility of estimating payment weights from varying group sample sizes. Thus, suggestions that imply a larger number of groups must be evaluated in terms of their potential to impact the accuracy of the payment weights, the system's clinical logic add to, not lessen, the complexity of administering the system. Any grouping changes potentially affect the entire array of payment weights because they are relative values.

Comment: One commenter stated that it will be very difficult for agencies to comply with the requirement to project the number of therapy hours at the start of care, because physicians' orders in the plan of care do not typically indicate the number of anticipated therapy hours or visits.

Response: The Home Health Certification and Plan of Care (HCFA 485) requires the physician orders to specify the amount, frequency, and duration for disciplines and treatments. We expect agencies to make the projection from these orders.

Comment: A commenter sought confirmation that the reconciliation of projected therapy use with actual therapy services furnished during the 60-day episode has the potential to either decrease or increase final payment.

Response: The commenter is correct. The final payment may increase or decrease in response to a difference between the therapy projected at the start of care and the therapy received by the patient by the end of the 60-day episode.

Comment: A commenter stated that the Phase II per-episode prospective payment demonstration research indicated barriers to occupational therapy (OT) services under PPS. The commenter recommended that we consider a more interdisciplinary approach to OASIS so occupational therapy would not be underutilized.

Response: The therapy threshold in the case-mix adjuster is based on all three therapy disciplines combined. The design of the demonstration did not include a case-mix adjuster with a therapy threshold of any sort. It does not necessarily follow that the national PPS would introduce a barrier to OT services.

Comment: A commenter recommended that therapists should assess the patient's functional status to minimize errors in measurement. In addition, the commenter believes monitoring will be needed to prevent payment incentives from distorting functional assessment measurements.

Response: We expect that agencies will measure functional status as accurately as possible, consistent with incentives for efficiency in the prospective payment system. We have no authority to mandate functional status assessment by a particular discipline. We agree that medical review activities should include review of functional assessment results.

Comment: A commenter stated that, as a result of the therapy threshold, the case-mix system will divert utilization of the home health benefit away from the frail elderly and in favor of the short-term patient.

Response: It is not our intention to change access under the home health benefit through a case-mix adjusted prospective payment system. Moreover, the payment for continuous 60-day episodes of care under PPS will be more conducive to the care of longer stay patients than the current interim payment system. We expect that evaluations of the system's impact will study the question raised by this commenter.

Comment: A commenter recommended standardizing therapy visits in hours or 15-minute increments to meet the current statutory requirements of section 4603 of the BBA that specify that home health visits are reported in 15-minute increments.

Response: We have not accepted this recommendation. We believe this would

restrict agencies' ability to manage care efficiently.

Comment: One commenter was concerned about the high relative payment weight associated with therapy-threshold case-mix groups, and because of this concern, questioned whether the Abt Associates sample was representative of agencies in the industry offering therapy programs.

Response: The Abt Associates sample used to develop the case-mix groups was selected to be representative of national service delivery patterns. The 90 participating agencies were selected from all four census regions of the country, from among different ownership categories (freestanding for-profit, freestanding voluntary/private nonprofit; hospital-based; and government), from both urban and rural areas, and from among agencies with high, medium, or low practice patterns (as measured by the number of visits per-episode in 1995). As we note elsewhere in this rule, in our subsequent analysis of OASIS data and utilization data for the nation as a whole, we have found that these agencies on average appear to resemble the nation closely. We have no reason to believe that their therapy service delivery is unusual and would result in an inaccurate relative weight for therapy-threshold cases.

Wound Care Patients

Comment: Many commenters argued that services for many wound patients would be inadequately reimbursed under the proposed case-mix system. One often cited reason was the high cost of wound supplies for some patients. Some commenters recommended that wound supplies costs should be directly reimbursed, rather than being bundled into the episode payment.

Response: We have not adopted this recommendation. We have no statutory authority to unbundle the wound supplies costs. All supplies costs are now in the base costs used in determining the payment amount. As we note in our response to comments on omission of time spent outside the home from the calculation of resource costs, the current system of relative weights assumes that the omitted costs are directly proportional to time spent in the home. We will consider methods for testing this assumption, including the impact on wound care reimbursement. Case-mix model revisions, adopted in response to comments concerning wound care patients, have resulted in increased payments for wound care patients. These are described below and in the section on changes to the case-mix model.

Comment: Several commenters noted that the clinical dimension does not address wounds from trauma.

Response: In response to this comment, we have added a variable to identify trauma and burn patients who have wounds. This variable is now included in the clinical dimension. If a patient has a primary diagnosis of trauma or burns and OASIS item M0440 indicates that there is a wound, the clinical score is increased by 21 points.

Comment: A commenter recommended that the scoring for pressure ulcers in the clinical dimension should take into account their number, size, condition, or complexity.

Response: The clinical dimension in the proposed rule took into account the stage of the most problematic observable pressure ulcer, if any. OASIS does not record the size of pressure ulcers. The assessment covers the number of pressure ulcers at each stage. The status of the most problematic observable pressure ulcer is also reported. These stage and status measures are intended to measure the condition and complexity of the pressure ulcers.

In accordance with the comments on pressure ulcers, we re-examined the impact of the pressure ulcer stage and status variables, and the number of pressure ulcers by stage, in the Abt data. We analyzed a newly available larger learning sample of 11,503 episodes. As a result of these analyses, we identified a statistically significant score to add to the clinical dimension score if the number of pressure ulcers at stage three or four is two or more. This variable is now included in addition to the original variable measuring the stage of the most problematic pressure ulcer. It adds 17 points to the clinical score. As in our earlier investigations, the status of the most problematic observable pressure ulcer did not contribute significantly to the model after the other variables were included. As we continue to study revisions to OASIS, we will consider including additional data on such factors as the size of pressure ulcers.

Comment: Several commenters indicated that wound variables should be more detailed to provide better reimbursement for wound patients who score low on the clinical dimension but nevertheless incur high costs. For example, a commenter stated that if a stasis ulcer status is early/partial granulation, no points are given, but this does not make sense if the goal is to heal the wound. Another commenter recommended that early/partially granulating stasis ulcers should be given 24 points to make the case-mix system's treatment of stasis ulcers consistent with its treatment of surgical wounds.

Response: In addition to analyses on pressure ulcers (described above), we re-examined the definition of the case-mix variables for the status of stasis ulcers and surgical wounds. We used the newly available larger learning sample of 11,503 episodes. As a result, we have identified separate score values to add to the clinical dimension for early/partial granulation. These scores are 14 and 7 for the early/partially granulating most problematic stasis ulcer and early/partially granulating most problematic surgical wound, respectively. Revised scores for the most problematic nonhealing stasis ulcer and most problematic nonhealing surgical wound are 22 and 15, respectively.

In further attempts to more accurately measure the severity of wound patients, we investigated interactions between wound severity and several comorbidities (for example, diabetes) and immobility, but statistical results generally did not support including such interactions as additional score-bearing variables. In future work refining the case-mix model, we plan to use national claims and OASIS data to continue investigating comorbidities. Agencies could assist such efforts by reporting diagnosis codes on OASIS at the complete four-digit or five-digit level, as recommended by the official coding guidelines.

Comment: One commenter reasoned that costly wound patients, especially severe pressure ulcer patients, often may receive additional points in the clinical dimension for other problems (for example, diabetes or vision problems), but there is no recognition in the case-mix system for a sum of clinical points exceeding 27. In a similar vein, another commenter recommended creating a fifth severity level in the clinical dimension to increase payments for severe wound patients.

Response: In addition to refining measures for pressure ulcers, stasis ulcers, and surgical wounds, in a further effort to improve payment accuracy for wound patients, we have revised the case-mix system by re-defining the clinical severity score intervals. The revised score intervals are as follows: minimal severity: 0–7; low severity: 8–19; moderate severity: 20–40; high severity: 41+. The relative frequencies in the Abt sample for the revised clinical severity levels are 30 percent, 36 percent, 28 percent, and 6 percent, for minimal, low, moderate, and high clinical severity, respectively. (In the proposed rule, the corresponding percentages were 30 percent, 30 percent, 23 percent, 17 percent) This change has

generally resulted in higher case-mix relative weights for the case-mix groups involving moderate and high clinical severity. It has also resulted in a wider range of weights for therapy-threshold case-mix groups and non-therapy-threshold case-mix groups. We have not added a fifth level of clinical severity. Given the array of the clinical scores in the sample, the amount of sample data available, and our objective of administrative feasibility, at this time we believe that four clinical severity levels is an appropriate structure for the case-mix model.

Comment: In commenting on the status of wound care patients under the case-mix system, several commenters specifically stated that services for daily care wound patients would be inadequately reimbursed under the proposed rule. Some commenters recommended that we add a variable to the services utilization dimension that recognizes skilled nursing hours, analogous to our use of therapy hours in the services utilization score. They suggested that this would be a way to remedy inadequate payment for daily wound care patients while recognizing the skilled wound treatments that contribute to their higher costs.

Response: The wound care patient must be deemed eligible for the Medicare Home Health Benefit which dictates that the skilled nursing care be provided on an ''intermittent'' basis, as required by sections 1814(a)(2)(C) and 1835(a)(2)(A). The ''intermittent'' skilled care provided must be either provided or needed on fewer than 7 days each week or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable). The need for skilled nursing care for a wound care patient on a continuing basis is contingent upon evidence documented in the patient's record that the wound is improving in response to the wound care provided. It is neither reasonable nor medically necessary to continue a given type of wound care if evidence of wound improvement cannot be shown.

For the following reasons, we are not accepting the recommendation that skilled nursing hours be treated comparably with therapy hours in order to address the needs of costly wound care patients. First, as described previously concerning changes to the case-mix system, we have made additions and modifications to the clinical dimension in an attempt to better capture variations in clinical severity associated with wound care patients. Second, we are concerned that adopting an additional utilization-based measure strongly compromises the intention of home health payment reform to move away from a cost-based system. Finally, we are also concerned that in some instances extended wound care episodes may reflect inattention to the statutory eligibility requirement regarding ''finite and predictable'' need, and to our policy that continuing wound care must be efficacious. We will, however, continue reviewing the OASIS wound measures and the case-mix system's ability to adequately reflect the needs of wound care patients.

Daily Insulin Injection Patients

Comment: Many commenters identified diabetic patients requiring daily insulin injection as a group similar to daily wound care patients in terms of their extraordinary costs. They maintained that such patients might experience access barriers because the case-mix system does not account for their extraordinary care needs. They further indicated that the proposed outlier payment methodology would not necessarily result in payments adequate to compensate agencies for the cost of these patients.

Response: The OASIS does not provide information allowing accurate identification of these diabetic patients. Daily insulin patients appear to be a heterogeneous group, some of whom can be taught self-injection. There are no variables on the OASIS assessment that clearly distinguish such patients from others unable or unwilling to self-inject. As the outlier payment is intended to compensate for difficulties in case-mix measures, we have determined that daily insulin injection patients are likely candidates for outlier payments. We assume that daily injection visits tend to be low-cost visits, so it is likely that outlier payments will be adequate for many daily insulin patients.

Diagnoses Included and Excluded From the Clinical Dimension

Comment: The case-mix system discussed in the proposed rule recognized three diagnostic categories in the clinical dimension. These were certain orthopedic and neurological diagnoses, and diabetes. Diagnoses in these groups are assigned a score to help determine the patient's clinical dimension total score when the diagnoses appear in the OASIS primary home care diagnosis field (M0230A). A commenter suggested that we classify all diagnoses. Other commenters stated that the three categories proposed do not include all high-acuity diagnoses.

Response: From our work with the Abt Associates sample, we concluded that a complete classification of all diagnoses would not necessarily make the case-mix system appreciably more accurate, but it would make the grouping system more complex. In developing the clinical dimension, we studied the effect of placing every patient in one of several defined groups of diagnoses (such as orthopedic, cardiovascular/pulmonary, psychiatric). We investigated how this classification contributed to explaining resource use in home care. The three groups in the proposed rule stood out as accounting for significantly higher costs on average than other groups we defined. Adding the other groups to the model did not appreciably raise the explanatory power of the case-mix adjuster. Consequently, we believe that restricting recognition in the clinical dimension to the orthopedic, neurological, and diabetes groups balances our payment policy objectives of payment accuracy and administrative feasibility. We have not added any diagnoses to these three groups published in the proposed rule. However, we have added a variable to identify certain wound patients. This variable uses selected diagnoses codes from the primary diagnosis (OASIS item M0230, line a). We added this new variable to respond to comments we received about wound patients.

We are continuing to study a variation of the case-mix system that recognizes more diagnostic groups, but it would be a more complicated system with a substantially larger number of groups. We would require any such system to explain significantly more variation in resource cost than does the current model, in order to justify the added administrative complexity.

Currently, the OASIS instructions do not require complete four-digit and five-digit coding of the primary and secondary home care diagnoses. Three-digit coding of the category code is allowed, although agencies may voluntarily report complete four and five-digit coding. In the interests of future case-mix refinement, we will consider requiring that all agencies report the complete code. Such a requirement would conform OASIS with existing coding guidelines in the Medicare program and nationally.

Comment: One commenter pointed out that we did not list all diagnoses in the three groups in the clinical dimension, and requested confirmation that this was an error.

Response: The list of code categories presented in the proposed rule was complete. We omitted certain code categories based on clinical judgment and knowledge of coding practices in the community. We believe that

including these codes would reduce the explanatory power of the model, because they are likely to consist of heterogeneous or low-cost cases. When we examined the resource cost of orthopedic diagnoses omitted from the orthopedic group, we found indications that confirmed our decision.

Comment: Several commenters indicated that they believed the list should not exclude common diagnoses.

Response: Some of the diagnoses cited by commenters are frequently encountered in home care. It was not our objective to identify common diagnoses, but to pinpoint conditions that were associated with variations in resource cost. Some common diagnoses are associated with widely varying needs for home care services, which would tend to make them poor predictors statistically.

Comment: Some commenters suggested that the case-mix system recognize certain diagnoses in addition to those listed. Several commenters mentioned cardiac, respiratory, cardiopulmonary, and ''other circulatory'' diagnoses.

Response: As noted previously, cardiac, vascular, and respiratory diagnoses were a category studied during development of the clinical dimension, but the category did not demonstrate a contribution to the model sufficient to justify its inclusion, after we accounted for existing elements such as dyspnea and wound problems. We will continue to study this group of diagnoses.

Comment: We received various comments suggesting that we should have included psychiatric, mental health, or behavioral diagnoses. A commenter stated that three points for mental health conditions is inadequate, citing the additional credentials Medicare requires for psychiatric nurses as a reason for higher costs of psychiatric patients. Another commenter noted that depression, common among many elderly patients with health problems, negatively affects response to treatment. One commenter suggested the addition of ''780 (alteration of consciousness)'', in order to ensure access for psychiatric patients.

Response: In the clinical dimension, we included MO610 on behavioral problems to capture both cognitive and behavioral factors affecting resource cost. If the assessing clinician checks one or more of the response categories, three points are added to the clinical dimension. During case-mix system development, we examined diagnoses and various OASIS assessment items relating to mental health, sensory, and cognitive status. Specific to mental health, we looked at the relationship between home health resource use and mental health diagnoses (psychoses, drug psychoses, and neurotic disorders). We found that this group of conditions did not greatly contribute to explaining variation in resource use in home care after including functional, clinical, and service factors in the case-mix model.

However, we do *not* interpret our statistical results as necessarily indicating that mental health issues are unimportant in home care. One reason our statistical findings do not support including further information specific to mental health status is that the remaining functional and service factors in the case-mix system already capture the costliness of these patients. Thus, the impact of behavioral health issues is being recognized in factors other than diagnosis-specific elements. Other possible reasons for our statistical findings may stem from the extreme impairment of many psychiatric patients, which can lead to periods of institutional care and extensive informal support in the home. Such factors may tend to reduce the measured resource cost.

In future review of the case-mix system, we will continue to study case-mix measures for mental health patients.

Comment: A few commenters suggested that we include cancer diagnoses in the list of diagnoses for clinical dimension scoring.

Response: Several cancer diagnosis code categories appear in the orthopedic and neurological lists used in the case-mix model. We found no evidence during case-mix development activities that cancer diagnoses should be a separate group in the clinical dimension. We believe that part of the reason is that care needs for certain cancer patients (for example, functional assistance, wound care, pain management) are already accounted for in the case-mix model. Therefore, we have not added any more cancer diagnoses to the final regulation.

Comment: A commenter suggested that we include terminal cancer patients as a diagnosis group. Another commenter stated that end-stage cardiac/respiratory disease cases should be included.

Response: We have not added terminal cancer patients or end-stage cardiac/respiratory cases as a special diagnostic category. There are no OASIS items directly identifying these cases. In developing the case-mix model, we considered including OASIS items assessing overall prognosis and life expectancy, which potentially have a use in identifying terminal cancer patients. However, we concluded that these items are inappropriate elements for payment policy because of their inherent subjectivity and vulnerability to gaming. Moreover, statistical analyses have suggested the life expectancy item has poor scientific reliability.

Comment: A commenter suggested that we add category code 438, ''late effects of cerebrovascular disease'', to the list of neurological diagnostic categories because it is extremely common in home care and is the correct code assignment following hospitalization for an acute cerebrovascular accident (codes 434 and 436). The commenter added that we should delete codes 434 and 436 because coding guidelines reserve them for hospital coding.

Response: We have not adopted this suggestion. Codes 434 and 436 are being used in home care, notwithstanding the coding guidelines. In the Abt case-mix data, episodes coded with 436 are about nine times as common as episodes coded with 438. Code 434 is also used, but appears only about one-third as often as 438. The definition of 438 encompasses sequelae whose lags may be of any length. For this reason, we believe that including 438 presents significant risks of inappropriate payment. We will continue to examine the applicability of code 438 in future work.

Comment: A few commenters suggested that we include joint replacement diagnoses in the orthopedic diagnosis group.

Response: Joint replacement diagnoses are V-codes, which are not used on the OASIS assessment. Therefore, we did not study or specify including such codes in the case-mix system. However, care needs of many joint replacement patients are addressed in the therapy-threshold variable of the services utilization dimension and in the functional dimension. In setting the therapy threshold, based primarily on clinical judgment, we had in mind the treatment needs of the many joint replacement patients covered by the Medicare home health benefit.

Comment: Several commenters requested clarification about the omission of certain orthopedic diagnosis codes from the orthopedic group. These comprised 715 (osteoarthrosis and allied disorders), 719 (other and unspecified disorders of joint), 726 (peripheral enthesopathies and allied syndromes), 727 (other disorders of synovium, tendon and bursa), and 729 (other disorders of soft tissues).

Response: The exclusion of these diagnoses was intentional, based on clinical judgment that they are often

reflective of low case severity, and therefore unsuitable for the purposes of the groups defined in the proposed rule. Statistical information supports this judgment. In the Abt data, the average resource cost of the omitted diagnoses was 85 percent of the average resource cost of the included diagnoses, an indication that the excluded codes' cost impact is significantly lower. We also found statistical evidence that including these code categories in the current orthopedic diagnosis group does not improve, and may slightly reduce, the predictive value of the diagnosis groups included in the clinical dimension.

Comment: A commenter recommended that we add category code 733, ''other disorders of bone and cartilage'', to the orthopedic group because this category includes pathological fractures. The commenter added that requiring greater specificity in code assignment, beyond the three-digit category code, would allow inclusion of the pathological fracture codes without inclusion of other diagnoses in category 733.

Response: We disagree. We did not add 733 because the range of severity in this category may be very wide. For example, this code category includes osteoporosis, a very common condition in the elderly population. On the other hand, 733 also contains aseptic necrosis of bones, and aseptic necrosis of the femoral head is an indication for hip joint replacement. Without more information about the specific frequency of diagnoses, we expect that the osteoporosis cases would be much more common. We believe that adding this category code to the orthopedic group increases the risks of inappropriate payment. We will continue to study the excluded diagnosis codes. We agree that greater specificity in coding could solve this problem. Agencies can assist our efforts to develop information about the usefulness of specific codes in case-mix models by reporting diagnoses at the complete four-digit and five-digit code level.

Comment: One commenter suggested that we add diagnosis code category 707 (chronic ulcers) to the orthopedic category because these patients may present high costs for such services as debridement and dressing changes.

Response: The orthopedic group is not an appropriate placement for this code. However, as noted elsewhere in this rule, we have added assessment items to the clinical dimension in an attempt to strengthen the case-mix measurement for wound patients.

Comment: A commenter stated that we should include the diagnosis severity index on OASIS in the clinical dimension scoring.

Response: We did not include this assessment item because we believe its inherent subjectivity and vulnerability to gaming make it unsuitable for use in the case-mix model. Preliminary statistical analysis suggests the scientific reliability of the index is low for orthopedic and neurological diagnoses.

Comment: One commenter stated that the categories included in the diagnosis groups were unrealistic and unrelated to the need for home care services in an elderly population.

Response: Our statistical information indicates otherwise. The statistical results are shown in Abt Associates, Second Interim Report, September 24, 1999, Appendix H. They indicate that the incremental cost associated with each of the diagnosis groups is large and highly statistically significant.

Comment: We received various general and specific comments suggesting the use of secondary or multiple diagnoses in the clinical dimension. Some commenters stated that comorbidities are important in determining patient needs, and therefore they should be recognized in the case-mix system. A commenter suggested that, to improve the accuracy of the clinical dimension score, patients with multiple diagnoses from the existing groups should be credited with additional points in their clinical dimension measurement. One commenter suggested considering the first three diagnoses in order of importance. A couple of commenters mentioned diabetes as a secondary diagnosis that may appear in conjunction with wound care as a primary diagnosis, a situation that, if accounted for in scoring, might improve payment accuracy.

Response: Although we agree that multiple diagnoses and comorbidities warrant consideration, we have not used any of these suggestions because data and time constraints do not allow adequate evaluation of their contribution and impact on resource cost. To conduct an orderly exploration of the impact on case-mix measurement, and to assign a valid score in such cases, would require more observations than the Abt data set contains. We did test the impact of diabetes on severe wound patients, but the results suggested that some of the most severe wound patients would be paid inappropriately if the clinical score was increased. Further analysis of these suggestions to fully understand the implications can be undertaken with appropriate resources. We intend to use national claims data linked to OASIS to investigate multiple diagnoses/comorbidity issues in future case-mix analyses. We believe that such an effort would be significantly aided by complete four-digit and five-digit diagnosis coding on the OASIS record.

Comment: Commenters suggested that we credit the points published in the proposed rule for the neurological, orthopedic, or diabetes groups to the patient's clinical dimension score whether the diagnosis is primary or secondary.

Response: We believe such suggestions should be tested empirically to derive an appropriate score as there is more than one way to implement this suggestion. These are subjects for study when larger data resources become available.

Comment: Two commenters stated that the adjuster's use of a limited number of diagnosis groups will lead to more coding of the specified diagnoses as the primary diagnosis, distorting national data that would be used to make refinements of the system.

Response: We believe such practices would be counterproductive. Payment-motivated coding can eventually lower the predictive ability of a case-mix measure, and result in less differentiation among case-mix groups. We will continue to examine the accuracy of the case-mix model and the reliability of the data used for determining payments. If necessary, we would adjust the case-mix weights in response to those studies. As stated in the proposed rule, we intend to revise the case-mix weights over time to adjust for changes in patient population, actual changes in home health care practice patterns, and changes in the coding or classification of patients that do not reflect real changes in case-mix.

Comment: A commenter expressed concern that the quality of the diagnosis codes reported for home care are of such poor quality that they would be of no value in the development of the prospective payment system.

Response: We recognize the commenter's position, but we believe diagnoses are still useful in developing a case-mix model. The three diagnosis code categories in the model are the strongest contributors of all the diagnosis groups we defined in conducting our analyses on the Abt sample. We will continue to study the usefulness of diagnoses, and believe that agencies can assist our efforts by reporting diagnoses at the complete four-digit and five-digit code level.

Comment: One commenter urged us to clearly define ''primary home care diagnosis'' to prevent inappropriate upcoding.

Response: The OASIS implementation manual suggests strategies for the assessor to use in identifying the diagnoses for the diagnosis reporting items (M0230 and M0240). There is no specific guidance on differentiating the primary from secondary diagnoses. However, a definition for the primary diagnosis on the physician certification and plan of care (HCFA form 485) is discussed in the Medicare Home Health Agency Manual. We believe agencies are very familiar with the instructions in the Manual. The diagnosis guidance in the Manual is consistent with the language used in the OASIS instructions. (One difference, however, is that the Manual allows V-codes and the OASIS does not.) Nonetheless, we agree that it might be desirable to expand the instructions on the OASIS in the future. We will consider this in modifications to the OASIS form.

Comment: One commenter stated that the OASIS diagnosis reporting requirement that allows only three-digit ICD–9–CM category codes to be reported has a severe adverse impact on clinical severity data and, thus, adversely impacts the design of the home health classification system. The commenter noted that this practice violates official coding guidelines.

Response: We agree that a lack of specificity in code assignment somewhat diminishes accurate case-mix development and ascertainment. To help rectify the situation, we urge agencies to voluntarily code to the complete four-digit or five-digit code level.

Comment: A commenter expressed concern that the OASIS reporting requirements do not allow V-codes, in contrast to official coding guidelines approved by HCFA which accept V-codes as potentially the most appropriate codes in some circumstances in the home health setting. The commenter cited the distinction between acute fracture codes in the hospital setting and aftercare codes in the home health setting. According to the commenter, this conflict with the official coding guidelines threatens the consistency and uniformity of national health care data, resulting in data that are of poor quality and little value.

Response: The OASIS instructions state that instead of V-codes the agency should list the relevant diagnosis. This requirement was installed to serve the needs of OASIS as it was originally designed—as a quality assurance tool. We have adopted OASIS as a valuable quality assurance tool. Therefore, any changes in coding policy on OASIS would have to balance the quality assurance objectives with the consistency and uniformity objectives articulated by the commenter. At this time we do not believe that adopting V-codes is consistent with the needs of either OASIS or the case-mix system. Regarding case-mix, one of our objectives is to classify patients with minimal reliance on treatments planned or received. Given that objective, there is little clear benefit from adopting the applicable V-codes intended to indicate aftercare services.

Comment: A commenter stated that certain category codes in the three diagnosis groups to be identified from the OASIS primary diagnosis field (M0230) should never be reported as primary diagnoses, according to ICD–9–CM coding rules and official coding guidelines. These diagnoses must be used with a higher-coded diagnosis that indicates the etiology. The affected ICD–9–CM category codes are 711, 712, 713, 720, 730, 731, 320, 321, 323, 330, 331, 334, 336, 337, 357, and 358.

Response: In accordance with this comment, we have listed the affected codes (not code categories) in Table 8 as either primary or secondary diagnoses at the applicable four- or five-digit level. We will recognize these diagnosis codes in the case-mix adjuster only if the following conditions are met: (1) Manifestation codes (that is, codes that can never be used as the primary diagnosis) must appear as the first secondary diagnosis (line b, under ''other diagnoses'' in OASIS M0240) and must appear with all digits required by ICD–9–CM coding rules. (2) Remaining codes from the affected categories must appear as the primary diagnosis (line a, under OASIS M0230) and must appear with all digits required by ICD–9–CM coding rules. The requirement to report manifestation codes as the first secondary diagnosis is consistent with our intention to recognize the primary diagnosis for case-mix purposes. In this circumstance, the primary diagnosis is indicated by the combination of the manifestation code preceded by the underlying disease code in the primary field.

Structure of the Case-Mix System

Comment: Several commenters suggested adding a fifth level of severity to the clinical dimension, in view of the large score range in the fourth and highest severity level. In contrast, other commenters suggested that 80 groups was too large a number; they recommended greatly reducing the number of groups. A related question was why some groups with a small incidence of episodes warranted establishment of an HHRG.

Response: At this time, we have not changed the basic structure resulting in 80 groups. Adding a fifth clinical severity level would increase the number of groups to 100. Reducing the number of groups may obfuscate the clinical logic we used to help shape the system. Also, we feel it is prudent at this early stage of the model's application to avoid imposing additional structural streamlining before larger data sets become available allowing exploration of refinements to the model.

Comment: A commenter stated that the case-mix system should have as many episodes at the high end of the scale as the low end.

Response: We disagree. It is more important for the structure of the groups to differentiate episodes with similar severity and costliness. Severity and costliness are not evenly distributed in the population of episodes. The most resource intensive episodes are infrequently encountered.

Comment: A commenter criticized the use of a scoring range from 27 to 160 for the highest level of severity in the clinical dimension, saying it is too broad.

Response: In response to several comments on the adequacy of payment for severe wound cases, we have revised the severity score intervals along with making additions to elements in the clinical dimension. We discuss changes to the case-mix system in section IV.G.1.

Comment: It was suggested that the case-mix assignment be made at the end of the episode, because of difficulties agencies may have in obtaining accurate information about patient status early in the episode.

Response: OASIS data collected as part of the comprehensive assessment must be collected within 5 days of the start of care. After collection, agencies have 7 days to ''lock'' the assessment. Therefore, agencies have a maximum of 12 days to establish the case-mix assignment. We think this time period is adequate to resolve uncertainties about the health and functional status items on the OASIS. Further, the therapy threshold used in the case-mix system is projected at the start of care, and is updated by the end of the episode to determine the final case-mix adjusted payment.

Omission of Time Spent Outside the Home From the Calculation of Resource Costs

Comment: We received comments faulting the case-mix adjuster for limiting the measurement of resource costs to time spent in the home. Commenters argued that time spent

outside of the home, travel time, and resource costs of equipment and supplies should be included. One commenter maintained that failure to account for medical supplies leads to two inconsistent reimbursement methodologies, one for services and the other for supplies. In the case of wound patients using very expensive dressings and supplies, commenters argued the resource cost is seriously underestimated.

Response: We acknowledge the underlying concern from the commenter but we are limited in our ability to address this comment in the near term. Variation in costs other than visit time is a subject for careful empirical study that will take time. Were we to adopt imprecise estimates in a hasty attempt to rectify perceived errors in the payment weights, we would risk introducing other errors and potential inequities into the payment system. The model as developed to date assumes that the omitted resource costs are directly proportional to time spent in the home. In future years, we plan to consider methods for testing this assumption. Studies to directly account for costs beyond time spent in the home pose significant challenges in terms of their feasibility, cost, and reliability. The Abt study did not attempt to measure non-home resource costs because it was believed the complexity of the necessary measurement procedures would jeopardize agency recruitment and data accuracy.

Use of OASIS Data To Validate the Case-Mix System

Comment: Several commenters advised us against using early OASIS data to validate the case-mix grouping system. They believe that the data are flawed because agency personnel are still learning how to conduct assessments. A couple of commenters sought confirmation that we validated the system, and requested information about how we validated the system.

Response: It is not possible to use the OASIS data for complete system validation, because validation requires information about resource cost as well as patient characteristics. OASIS data provide only patient characteristics. However, as discussed in the proposed rule, we did validate the case-mix grouping system using a split sample methodology with the Abt case-mix data (see Abt Associates, Second Interim Report, September 24, 1999).

Our primary purpose for using the OASIS data was for payment allocation during the first year of PPS. Specifically, we hoped the OASIS data could be used to estimate the distribution of case-mix in the population, which is information needed to accurately establish the standardized payment amount. As described elsewhere in this regulation, we used OASIS data to achieve this purpose.

Comment: A few commenters recommended allowing therapy assistant services and rehabilitation nurse services to count towards the therapy threshold.

Response: We do not believe that any changes to the current coverage rules governing the coverage of physical therapy, occupational therapy, and speech-language pathology services under the Medicare home health benefit is warranted at this time. If we believe coverage revisions are necessary for future refinements to the HHA PPS, we may consider revisiting the coverage guidelines at that later time. Under the case mix methodology, patients with intense therapeutic needs are classified in higher payment groups. A physical therapist, occupational therapist or speech-language pathologist would have to diagnose the therapeutic needs of the patient. If significant assistant substitution occurs under PPS, we may focus medical review efforts or reprice the case-mix groups. Rehabilitation nurses have never met the personnel qualifications or coverage criteria for physical therapy, occupational therapy or speech-language pathology services under the Medicare home health benefit.

Other Comments

Comment: A commenter stated that we should add more variables to the case-mix system to increase the R-squared.

Response: In an effort to better capture resource cost for severe wound patients, we have added several more variables as explained in the discussion of changes to the case-mix system in section IV.G. The R-squared has increased. Future refinement activities may result in more additions and better ways to use existing variables.

Comment: A few commenters asserted that an R-squared (proportion of variation explained) of .32 for the case-mix system is too low, and one asked whether the system was validated.

Response: We used a split sample methodology to validate the case-mix system. The R-squared for the validation sample changed little. The R-squared for the initial case-mix system is comparable to that for other case-mix systems in their early stages. We should expect future research, using better data (such as improved diagnosis coding) and more observations, to result in higher predictive power.

Comment: Some commenters recommended that we add to the case-mix model OASIS items measuring such nonclinical factors as safety hazards and other environmental variables, and socioeconomic status variables.

Response: OASIS includes these variables to use as risk factors in analyses of the outcomes of home health care. But as we discussed in the proposed rule, we do not believe they are appropriate factors in determining payment.

Comment: Some commenters disagreed with our decision to exclude items dealing with signs and symptoms such as fluid retention and diet, on the grounds that these are important clinical changes with a direct relationship to care quality and outcomes.

Response: As we noted in the proposed rule, we are concerned about the vulnerability to manipulation for payment maximization of some possibly transient clinical items. Our statistical analysis also suggests weakness in their scientific reliability. Moreover, inclusion of these items would require a change to the OASIS data collection procedure, causing additional burden on home health agencies. Lastly, after all other elements are included in the model, they do not make any independent contribution to explaining variation in resource use.

Comment: A commenter stated that patients with low or moderate scores who need to be observed and assessed, and taught how to manage their medication and diagnosis, would not receive adequate reimbursement. A couple of other commenters suggested adding variables concerning multiple medications.

Response: During the early phases of model development, there were indications that a variable measuring multiple medications would be useful, but as it was not an OASIS variable we sought to substitute similar OASIS items. We found substitutes in the two OASIS variables measuring the patient's ability to manage oral and injectable medications. Statistical results suggest only one of these variables (injectable medications management) contributes independently to explaining resource variation after accounting for the other variables in the case-mix model. However, we believe using this variable makes the case-mix system vulnerable to manipulation, and have decided against including it at this time. As we refine the case-mix system, we will continue to look for ways to capture nursing functions mentioned in the comment.

Comment: Two commenters responded critically to the absence of

respiratory treatments from the clinical dimension.

Response: This variable was excluded from the model because it was statistically insignificant and inversely related to resource cost.

Comment: Several commenters stated that the system should specifically allocate points for limitations affecting medication management, meal preparation, feeding, and the ability to structure time.

Response: Measures of medication administration, meal preparation, and feeding dependence were tested but did not contribute significantly to explaining home health resource use. We note the case-mix system recognizes patients with memory deficit, impaired decision-making and behavior problems.

Comment: Stating that patients with multiple treatments at home (intravenous infusion, parenteral/enteral therapies, OASIS M0250) are often observed in home care, a commenter asked why these patients are not assigned the sum of scores for each treatment.

Response: At this time the case-mix model does not assign the sum of two scores when patients are receiving multiple treatments. In terms of care quality, we are concerned about the potential incentive to make patients' care more complex if scores for this OASIS item are additive. Currently, patients who receive both intravenous infusion and enteral nutrition, the most plausible combination, would receive 24 points for enteral nutrition, the highest score possible among the three treatments and the second-highest single score in the clinical dimension. Given our understanding of the needs these patients may present, this score seems appropriate pending further review of data for multiple-treatment patients. The Abt sample did not contain any patients receiving more than one of these treatments. As these treatments do not appear to produce additive work, we believe it is prudent to wait until more-reliable scores for multiple-treatment patients can be developed during refinement activities using larger data sets.

Comment: Commenters also criticized us for omitting types of specific OASIS items or response categories that indicate lower severity than items/categories currently in the case-mix model. For example, one commenter stated, the presence of ''any pain'' would affect the plan of care. The pain response categories that are allocated points are ''daily but not constantly'' and ''all of the time'.

Response: We understand the commenter's recommendation for more specificity in the case-mix system. We note that generally, the case-mix model captures levels of severity that were reliably associated with variations in resource use. Constructing variables for the model involved both statistically based decisions as well as judgments about how many grades of distinction are desirable from clinical, policy, and structural points of view. For example, in response to comments about wound care patients, we have elaborated certain wound variables to capture finer distinctions in wound status, while retaining statistical reliability for the clinical dimension. We have traded off some structural parsimony for slightly increased accuracy. As larger data sets become available to refine the case-mix system, we may have an opportunity to incorporate still more detailed variable levels, but we will continue to evaluate them in light of their clinical, policy, and structural implications.

Comment: A commenter wondered whether listing M0530 (when does urinary incontinence occur?) rather than M0520 (urinary incontinence or urinary catheter presence) in the clinical dimension was a typographical error.

Response: No, it is not. As we noted in the proposed rule, we avoided M0520 because of concern that using it might promote negative practice patterns. M0530 is a stronger measure of the impact of incontinence on home care because it takes timed voiding into account.

Comment: A couple of commenters stated that the case-mix adjuster should identify patients with urostomy because services and teaching requirements exceed those for bowel ostomy patients.

Response: OASIS does not currently allow identification of urostomy patients. We will consider this suggestion for future OASIS studies.

Comment: A commenter asked why hearing status is not included, while vision status is.

Response: We tested hearing problems as part of a set of neurological, cognitive, sensory, and behavioral impairments during our development of the case-mix system. Few of these variables contributed meaningfully to the case-mix model, and for some types of clinically severe patients these impairments were inversely related to resource cost. We were ultimately able to include both vision problems (M0390) and behavioral problems (M0610) in the clinical dimension as statistically significant variables positively related to resource cost.

Comment: One commenter suggested that we change OASIS item M0390 on vision status to identify patients who have difficulty accommodating to distance.

Response: We will consider testing this change in research on modifications to OASIS.

Comment: A commenter requested clarification of the definition in the vision status item (M0390).

Response: All OASIS items, including this item, are discussed in the OASIS Implementation Manual available on the HCFA Web site.

Comment: A commenter stated that OASIS functional items are not sensitive to patient progression, so that the patient who improves is still rated at the same level after improvement. The commenter cited the case of the patient who is dependent in bathing in bed, and progresses to independent in bathing in bed.

Response: This comment appears to address the use of OASIS items for outcome measurement. During the testing of outcome measures for use in home health care, it was necessary to balance several competing demands. One of these demands was for sufficient ''rigor'' in the outcome measures and data items, including the data item's likelihood of consistent application by the clinicians making the assessment. Another demand was a more practical one—would the home health agency's staff be able to use the item in its day-to-day functioning? Because every OASIS item that now has several levels of a scale could most likely be expanded to many more scale levels, several questions must be asked as part of the evaluation of OASIS items. For example, would the item be perceived as practical for use by clinicians? Would the resulting outcome measures be valuable in evaluating quality of care across agencies? Would the item have a high incidence of consistent application? These are among the evaluation criteria we would apply as the outcome measures and the OASIS items continue to evolve over time.

Comment: A commenter said the system should recognize medically underserved patients.

Response: The OASIS assessment does not clearly identify medically underserved patients. However, a variable relating to Medicaid status is reported on the OASIS assessment and can be considered a proxy indicator. During our system development work on the Abt sample we tested the Medicaid variable (which indicates whether Medicaid was among the patient's payment sources). We found that it did not contribute to explaining variation in resource use.

Comment: A commenter stated that home health aide supervisory visits should be included in the case rates, and the agency should be able to bill for those visits.

Response: Time spent in the home, including time spent on supervisory visits, was recorded in the visit log data submitted to Abt Associates by agencies participating in the case-mix research. This means that the case-mix relative weights should reflect any case-mix group differences in supervisory time. Supervisory visits are also in the cost base for the average cost per-visit computations used in the PPS episode rates. We are making no changes in payment policy regarding billing for supervisory visits.

Comment: A commenter, stating that the case-mix system inadequately accounts for costs of behavioral patients, asked how well such patients were represented in the Abt sample.

Response: We believe these patients were adequately represented. Approximately 4.5 percent of the Abt sample had a primary diagnosis code of a mental disorder. Approximately 2.6 percent received psychiatric nursing services at home. About 14 percent were classifiable as having chronic cognitive, mental, or behavioral problems. Approximately one-quarter of the sample had current problems due to one or more of the behaviors listed in OASIS M0610.

Comment: A commenter suggested that refinement activities include examining outliers to see whether the case-mix categories involved are improperly weighted.

Response: We plan to examine the data as suggested.

Comment: One commenter questioned whether we examined the validity of the relative weights. A related recommendation was to validate the relative weights on a large national data set after the first year of PPS.

Response: We examined various measures of fit of the case-mix model to episode-cost data to judge the model's performance and, by implication, the validity of the relative case-mix weights derived from it. Most of these fit measures are reported and discussed in the Abt Associates Second Interim Report (September 24, 1999). As explained in the proposed rule, we derived the relative weights from a straightforward regression equation that estimates the average addition to resource cost due to each severity level above the lowest-severity case-mix group (C0F0S0). This regression equation, estimated from the Abt sample data, performed well. We used case-mix-group means estimated from the coefficients of the regression equation to compute the relative case-mix weights. We plan to re-examine the accuracy of the relative weights periodically.

Comment: A commenter asked whether the mean or median was used to calculate the relative case-mix weights.

Response: We used the mean estimated from the regression equation described in the previous response.

Comment: A commenter requested that we disclose the computations for independent review.

Response: In the section of the rule regarding the calculation of the case-mix relative weights, we show the regression equation coefficients and the mean resource cost calculated for each case-mix group from the regression coefficients.

Comment: A commenter stated that we should release data showing the incidence of cases in the groups used to define the relative weights.

Response: Appendix C in the Abt Associates Second Interim Report (available on the HCFA website) shows the incidence of cases in each case-mix group in the sample.

Comment: A commenter questioned whether hospital-based agencies were adequately represented in the sample used to develop the case-mix system.

Response: We believe that hospital-based agencies were adequately represented in the sample. About one-third of the 90 agencies participating in the Abt study were hospital-based and one-third of the episodes in the Abt analytic sample came from hospital-based agencies. The hospital-based agencies were distributed across the four census regions, urban and rural locations, and represented varying practice patterns. The total development sample included more than 9,000 episodes (Abt Associates Second Interim Report, September 24, 1999). The sample for deriving case-mix weights in the final rule included more than 26,500 episodes.

Phase II Per-Episode PPS Demonstration

Comment: One commenter asked whether demonstration agencies deliberately avoided higher-acuity patients while participating in the demonstration project.

Response: The demonstration evaluation study examined this question. Analyses suggested that PPS agencies were no less likely than non-PPS agencies to admit a patient with a serious medical condition, limitations in activities of daily living, or other conditions predictive of higher-than-average service needs. Furthermore, the demonstration did not appear to affect the admission of patients expected to have relatively high costs per visit.

Comment: A commenter wanted to know why data on pages 58143 and 58150 in the proposed rule showed different percentages of discharges at 60 days and 120 days. Page 58143 cites completion rates of 60 percent and 73 percent in 60 and 120 days, respectively. Page 58150 cites completion rates of 46 percent and 62 percent, respectively.

Response: Data cited on page 58143 were completion rates for 39 agencies paid prospectively under the Phase II per-episode prospective payment demonstration in the first year of the demonstration (1995-96). Data cited on page 58150 are national averages from an episode file constructed from 1997 paid claims. Research would suggest that the differences stem mainly from the incentives of prospective payment.

L. Episode Rate Methodology

Comment: Several commenters suggested that we include the amounts for new billing and financial systems in the PPS episode rate.

Response: We do not foresee any major changes to the billing and financial systems for home health agencies that would justify an increase in the rate amount. Home health agencies will still use and submit the same claim forms that are currently being used under IPS. With only minimal changes in bill content we will be furnishing free grouping software to all HHAs. If an HHA elects to purchase different or more deluxe software from its vendors, that would be an individual business decision of the HHA. It is primarily the fiscal intermediaries systems that will require changes in order to process home health claims under PPS. We will not reimburse agencies for modifications to their internal billing and financial systems beyond what is already included as overhead costs reported on the cost report.

Comment: Several commenters requested that we not use the most current data for developing the home health PPS episode rates in order to avoid incorporating the effects of IPS.

Response: In developing the final PPS episode payment rate, the primary influence for the final amount is the budget neutrality target. The statute requires that the total amounts payable under HHA PPS be equal to the total amount that would have been made if HHA PPS had not been in effect. This numeric value is based on actuarial estimates of future home health spending and utilization in the aggregate. Since the projected spending

is based on historical trends derived using the most recent data available, IPS cannot be ignored. Using data prior to the implementation of IPS would not reflect current home health utilization and spending.

Comment: One commenter suggested that we revise the computations of the average cost per visit to only apply the cost limit adjustment factor to those disciplines that were over the per-visit cost limits.

Response: The per-visit cost limit has been applied on an aggregate basis, not on a per-discipline basis. Separating the disciplines proved too difficult to achieve and would be of questionable worth. The cost limit adjustment factor was determined by dividing the aggregate cost limit amount by the aggregate reasonable cost amount. If the factor was less that 1.0, then the factor was applied across all disciplines. If we had only applied it to the disciplines that were over the limits, then we would not have recognized the actual impact of the cost limits.

M. Audited Cost Report Sample

Comment: Several commenters questioned the accuracy and use of the statutorily required most current audited cost report data available to the Secretary to calculate the PPS rates. Commenters questioned whether better, more accurate data may exist than the 1997 audited cost report data set forth in the proposed rule.

Response: For the proposed rule, data from audited cost reports received by an HCFA determined deadline date were used for the calculation of the proposed HHA PPS rates. Even though all audited cost reports were not available (for reasons such as, suspensions, investigations, natural disasters, etc.), HCFA had to set a cut-off date to meet the stringent time constraints for completing the proposed rule. Any additional audited cost report data files that were received by HCFA Central Office (CO) beyond the deadline were not included in the rate calculations for the proposed rule. Since then, audited cost reports from the sample may have been appealed, reopened, and revised resulting in an updated version of the cost report data available for calculation of the rates for the final rule. Even after the publication of the proposed rule, we required fiscal intermediaries to resubmit any reopened audited cost reports and have that more recent, accurate data available for final rule calculations through the first week of January, 2000. This process resulted in an additional seven providers for which we now have audited cost reports for FY 1997. Additionally, during the above-described additional time period, we received 23 reopened audited cost reports with newer and more accurate data for use in the final rule calculations.

Comment: Commenters were concerned with pre-IPS cost data being used and that 1997 data may not be an adequate time period to reflect the cost of providing care today.

Response: HCFA is required, in its development of a PPS for home health agencies, to use the most current audited cost report data available. At present, 1997 audited cost reports are the most current audited cost reports available of a representative sample of HHAs. The 1997 audited cost data is updated by the market basket in order to make it more reflective of the cost of providing care today.

Comment: Commenters were concerned that not all types of HHAs, with respect to their being considered large, small, urban, rural, for profit, not-for-profit, for example, were adequately represented in the audited cost report sample used to construct the PPS rates.

Response: The sample was designed to be representative of the home health industry, including census region, urban versus rural location, and large versus small agencies. The sample included each provider type (freestanding not-for-profit, freestanding for-profit, freestanding governmental, and provider-based), which are referred to as strata in sampling terms. The design of the sample then took into account the number of providers and the variation in cost and beneficiaries in each stratum, resulting in a representative sample of the home health industry.

Comment: A few commenters were concerned with the sample design which excluded ''very small'' agencies.

Response: Agencies with fewer than 50 Medicare beneficiaries were excluded from the sample list of agencies for development of the home health PPS. These agencies were judged to be atypical in their costs and utilization. This would particularly be the case if the agency is a large agency that happens to have only a small Medicare business. Prior PPS demonstrations also excluded these low-volume providers from participation for similar reasons.

Comment: Commenters raised concern about rebasing for FY 2002 based on a 100 percent sample of cost reports. Commenters further recommended that if the future PPS data varies from the FY 2001 base year or their proposed revised approach to rebase for FY 2002, that adjustments be made to the standards on which the system is based.

Response: HCFA has no statutory authority to rebase the home health PPS on 100 percent cost report data. We will continue to monitor the effects of the policies governing the PPS system.

N. Cost Outlier Payments

Comment: Commenters generally supported the outlier policy but often disagreed with specific aspects of the proposed policy. Many commenters stated that protection from the financial risk of catastrophic cases was important. These commenters frequently identified severe wound care patients and non-self injecting diabetics as the types of patients that pose the greatest financial risk because of the concern that the HHRG system may not adequately recognize their costs. In addition, commenters tended to support greater financial protection against large losses, favoring a greater concentration of outlier payments on the most expensive cases, which can be accomplished by using a higher fixed dollar loss amount and a higher loss sharing ratio. Several commenters wanted provisions totally incompatible with the statutory constraint that total outlier payments be no greater than 5 percent of total payments including outliers, such as no fixed dollar loss and a higher loss sharing ratio, or even full cost reimbursement of outlier cases. However, several commenters argued that if greater catastrophic protection could not be provided, 5 percent higher episode payments for all episodes would be preferable to the proposed outlier policy.

Response: As stated in the proposed rule, the provision for outlier payments is optional under section 1895(b)(5) of the Act. However, if outlier payments are included in the PPS, the statute requires that total outlier payments be no more than 5 percent of total payments, including outlier payments. Section 1895(b)(3)(C) of the Act also requires that the episode payment amounts be adjusted to effectively pay for outlier payments within the same level of estimated total spending. These statutory requirements place rather strict limits upon the additional payments that can be directed to unusually expensive cases.

Before deciding to exercise our discretionary authority to include a home health PPS outlier policy in this final rule, we carefully considered the arguments presented in the public comments. We have decided that the benefit to the home health community of adopting an outlier policy consistent with the statute outweighs no outlier policy. However, based on the majority of public comments, we have decided to

increase the loss sharing ratio from the 60 percent set forth in the proposed rule to 80 percent, the same ratio that is used in the inpatient hospital PPS.

Accordingly, the fixed dollar loss amount has also been changed. Our preliminary estimates reported in the proposed rule indicated that a loss-sharing ratio of .80 was consistent with a fixed dollar loss amount equal to 1.35 times the standard episode amount. However, estimates based on the most recent data indicate that the fixed dollar loss amount should be changed to 1.13 times the standard episode amount. Among the commenters supporting a higher loss sharing ratio, while no one suggested a loss sharing ratio lower than .75; some stated that the ratio should be the same as in the inpatient hospital PPS (.80), and others stated that the ratio should be .80 or even .90.

Comment: Several commenters argued that the proposed outlier policy was not sufficient to cover the costs of patients with intensive service needs and would result in inadequate home care being provided to patients with the greatest needs. Some commenters cited the effects of the fixed dollar loss and the loss sharing ratio in severely limiting the additional payment that would be made to outlier cases. Another commenter stated that the outlier threshold should be based on medical necessity without any qualifying financial loss being suffered by the provider, and others stated, in effect, that there should be no fixed dollar loss. Yet another commenter questioned the sufficiency of 5 percent for these types of cases.

Response: As noted above, section 1895(b)(5) of the Act limits the total amount of outlier payments that can be targeted to outlier cases to no more than 5 percent of estimated total payments. It is impossible to eliminate the fixed dollar loss and to pay the full estimated cost in excess of the episode payment. To do so would result in outlier payments far in excess of the 5 percent allowed by the statute. It is also inconsistent with a basic premise of the episode based payment, which is based on average episode costs, and anticipates that ''underpayment'' of some episodes will tend to be balanced by ''overpayment'' of other episodes.

Given the constraint on total outlier payments, we were presented with determining how to beneficially distribute the limited amount of additional payments among the expensive cases. If only the very most expensive of the costly cases qualify for outlier payments, a higher proportion of the total costs of those cases can be paid. Alternatively, if a larger number of costly cases qualify for outlier payments, it is necessary to pay a lower proportion of their total costs. If the fixed dollar loss were eliminated, so that all cases whose estimated costs exceeded the episode amount qualified for outlier payments, the amount of the outlier payment per case would of necessity be so small that there would be little or no benefit for the expensive cases.

As discussed in another comment, we have chosen a loss-sharing ratio of .80 for the final rule instead of the .60 set forth in the proposed rule. We believe that a loss-sharing ratio of 1.00 would go too far in concentrating outlier payments on the most expensive cases. It would further limit the number of cases that could receive any outlier payment and would provide no incentive for agencies to attempt to provide care cost-effectively for outlier cases.

Comment: A number of commenters raised concerns regarding the method used to estimate the cost of an episode in determining outlier payments. Several commenters stated that the ''outlier-standardized per-visit rates'' do not reflect the real cost of visits. Another commenter appeared to misunderstand that we would use per-visit costs for each of the six home health disciplines.

Response: In this final rule, we are revising proposed § 484.240 to modify the per-visit rate used to estimate per-visit costs. We will now use the average cost per visit from the PPS audit sample including the average cost for nonroutine medical supplies and the average OASIS adjustment costs. The only standardization applied to these per-visit costs will be the wage index standardization factor. See Table 6 of the proposed rule (64 FR 58169) and Table 6 in section IV.C. of this final rule.

The wage index standardization factor is included in the per-visit cost because the estimated episode cost will be adjusted by the wage index, just as is the episode payment amount. As a result of these changes from the proposed rule, our estimated cost of an episode will be higher, and more episodes will qualify for higher outlier payments than would have occurred under the originally proposed method. This change in cost methodology will require increasing the fixed dollar loss in order to stay within the 5 percent constraint.

The estimated cost of an episode will be calculated by multiplying the per-visit cost of each discipline by the number of visits in the discipline and computing the total cost for all disciplines.

We understand that the estimated cost will not necessarily accurately measure the actual cost of any individual episode or the actual costs of any single agency. Our method of cost estimation will measure differences among episodes in three factors: the total number of visits, the skill mix of those visits, and the wage costs of the geographical area where the care was provided. This methodology will assume an equitable and timely application of outlier payments among HHAs without introducing the complex and idiosyncratic elements of individual agency cost finding using cost report analysis.

Comment: Several commenters suggested that we consider reimbursing reasonable costs for outlier cases. Other commenters stated that the estimated cost does not include the cost of non-routine medical supplies provided during each outlier episode, and that if we estimated costs in the same manner that is used in the inpatient hospital PPS, we could include the costs of non-routine medical supplies.

Response: It is correct that while the total costs of non-routine medical supplies were included in the episode payment amount, the non-routine medical supplies of an individual episode are not accounted for in calculating the payment for an episode or in outlier calculations. In the inpatient hospital PPS, costs of outlier cases are estimated by multiplying total charges for the services provided during the hospital stay by a hospital-specific cost-to-charge ratio that is determined from the Medicare hospital cost report. Applying this method to the home health PPS would provide a means of including the cost of non-routine medical supplies in the estimated cost of an episode. However, there are two major reasons why we believe that using the estimated visit cost method is necessary. First, we do not have charges for non-routine medical supplies or agency cost-to-charge ratios in the Abt case-mix data that we are using to estimate the outlier policy for the first year of the PPS. Therefore, we are unable to use the cost-to-charge ratio method at this time. Second, we would like to avoid making the Medicare cost report a necessary part of determining an agency's payments under the home health PPS. In particular, we would like to make the new system independent of the burdensome and idiosyncratic cost-finding process of the previous, reasonable cost-based payment system.

Comment: Some commenters indicated a misunderstanding about the application of the wage index in calculating outlier payments. The

confusion was whether the fixed dollar loss was adjusted by the wage index.

Response: The fixed dollar loss amount is wage-adjusted in exactly the same manner that the standard episode payment is wage-adjusted. As a result, the fixed dollar loss will be the same proportion of the episode payment in all wage index areas. In nominal dollars, the outlier threshold for an episode in a low wage index area is lower than the outlier threshold for an episode in the same HHRG in a high wage index area. The outlier payment is also wage-adjusted. Hence, the outlier payment for an episode will be the same proportion of the total payment for that episode whether the episode of care is provided in a low or a high wage index area.

Comment: Several commenters asked operational questions about the outlier policy and how outlier payments would actually be made. For example, one commenter asked us to clarify how and when outlier payments would be made. Another asked who initiates an outlier request and whether it would be automated. Others asked how the 5 percent would be determined and how information on outlier payments would be communicated to agencies. Another commenter asked what our policy would be if total outlier payments are significantly different than the 5 percent amount. Another commenter asked how outlier payments would be tracked and capped nationally and how agencies would know when the outlier pool had been exhausted. Finally, there was the question whether the 5 percent applied to individual agencies or all agencies in the aggregate.

Response: Outlier payments will be made automatically by RHHI through the normal claims processing system. When the RHHI determines the final episode payment based on the claim submitted by the agency, as part of determining the appropriate payment for the episode, the RHHI system estimates the imputed cost of the episode under the outlier methodology. If the cost exceeds the outlier threshold for the HHRG to which the episode is assigned, then an outlier payment will automatically be calculated for the episode. The agency will know when it receives an outlier payment for an episode because it will be part of the final payment for the episode and noted on the remittance advice.

It is important to understand that, according to section 1895(b)(5) of the Act, the 5 percent constraint applies to estimated total payments, not actual total payments. Each year, we will establish, the loss-sharing ratio and the fixed dollar loss values that will be used throughout the next fiscal year to calculate outlier payments. There will be no reconciliation of actual outlier payments to the 5 percent target either during a current fiscal year or in any subsequent fiscal years. If actual outlier payments during a given year exceed 5 percent of actual total payments, there will be no attempt to recoup the difference. Similarly, if total outlier payments in a year fall short of 5 percent of actual total payments, there will be no additional payments made to agencies. Such information will, however, be part of the analysis conducted for setting the appropriate threshold in subsequent years.

Finally, there is no direct relationship between the 5 percent limit on total outlier payments and the percent of outlier payments that an individual agency may receive. Depending on the agency's caseload during the year, the percentage of outlier payment to its total payments as outlier payments will likely vary. The 5 percent constraint applies to all agencies in the aggregate and not to individual agencies.

Comment: One commenter questioned why we have no outlier policy for LUPA episodes.

Response: No additional payments will be made for LUPA episodes beyond the LUPA payment. However, it should be noted that in this final rule, we have changed the per-visit costs to be used in computing the LUPA payment so that the same per-visit amounts will be used for the LUPA payment as that used in estimating the cost of a regular 60-day episode.

Comment: A commenter stated that we should implement a payment ceiling for outlier cases (such as 175 percent of the HHRG payment) and use a 15 percent adjustment to fund the outlier pool.

Response: Since a basic objective of outlier payments is to increase payments to the most costly cases, we do not think that outlier payments should be limited to some percent of the HHRG payment. The effect of such a ceiling would be to allow other less costly cases to receive higher relative outlier payments. As to the latter comment, a 15 percent outlier adjustment is not permitted by the statute, which sets 5 percent of total estimated payments as the maximum amount of outlier payments.

Comment: One commenter suggested that we eliminate outliers and recalculate the case-mix to include long stay cases as part of the HHRG system.

Response: ''Long stay'' cases are as much a part of the HHRG system as shorter term cases, and will not necessarily become outlier cases. As the system provides for unlimited 60-day periods, provided that patients continue to be eligible for Medicare home health services for each 60-day period, HHAs will receive additional episode payments based on the assigned HHRG for each episode. Thus, length of stay is not a factor leading to underpayments. The purpose of the outlier policy is to provide additional payments to cases requiring unusually intensive services within a 60-day episode.

Comment: One commenter stated that a transition policy would be a preferable alternative to the proposed outlier policy.

Response: As discussed previously, we have decided against implementing a transition policy. However, we note that a transition policy could serve some of the same purposes as an outlier policy early in system implementation. For example, a transition policy bases a proportion of the episode payment on the estimated cost (using the same method as we apply in the outlier policy) and the rest of the episode payment on the case-mix and wage adjusted episode amount. Such a policy could provide higher total payments to episodes whose estimated cost exceeds the episode payment. However, for all cases whose estimated cost is less than the episode payment, this blended payment would be lower than the episode payment. Because it would potentially change the payment to all episodes, a transition policy has a greater impact on total payments than that of the outlier policy. Whereas the outlier policy is self-financing under the terms of the statute, a broader transition policy would require a different and possibly greater adjustment for budget neutrality. Finally, a transition policy is, as the name indicates, intended to be temporary, and intended to allow providers time to adjust to a new system. In contrast, we intend the outlier policy to be a permanent feature of the payment system.

Comment: One commenter urged us to carefully monitor the impact of the outlier policy and stressed the importance of maintaining an appropriate balance between the total number of outlier patients and the payment per outlier case. Another commenter expressed a preference for refinement of the case-mix system as an alternative to the outlier policy.

Response: We fully agree with the suggestion of both commenters. We will monitor the impact of the outlier policy with the intention of refining it where possible. We will also explore case-mix refinements as we gather the data needed to support the necessary analyses. We are also hopeful that, over time, case-mix refinement may reduce

the need for an outlier policy. We will examine the issue in the future when more information is available.

Comment: Three commenters raised concern about the impact of outliers on specific types of home health agencies. They expressed concern for financial losses that would be incurred by rural agencies, a provider of ''last resort'' whose cases are in need of intensive services, and agencies in States where there are no other publicly funded home and community based services. In addition, a commenter stated that the wage adjusted per-visit costs would be significantly less than the actual per-visit costs in a particular geographical area.

Response: These comments suggest that the outlier policy might be tailored to increase outlier payments for specific agencies on the basis of their location or case-mix. The outlier policy set forth in this rule provides greater compensation for agencies based on the imputed cost of an agency's episodes. There is no data available to us which objectively identifies providers for whom, on some basis, additional payments would be warranted. We believe the PPS system with its various adjustments provides a sound basis for distributing payment in accordance with patient need.

Comment: Some commenters suggested that we apply different outlier criteria to different types of cases. For example, one commenter stated that the outlier payments should be restricted to the 40 non-therapy HHRGs.

Response: We believe that estimated total cost is the best measure we have for identifying outlier cases. The fact that the fixed dollar loss is the same for all cases means that the estimated loss that must be incurred is the same for all cases and thus achieves equity. Even though a therapy case receives a higher episode payment than a non-therapy case, the estimated loss that must be incurred before it qualifies for outlier payments will be the same.

Comment: One commenter recommended a lower fixed dollar loss for wound care cases than for other outlier cases.

Response: We note that a lower fixed dollar loss for wound care cases than for other cases would direct a greater proportion of outlier payments to wound care cases. We have decided against adopting such a policy at this time. As indicated in a previous response, we believe that it is more equitable to let the estimated cost of each episode determine the amount of outlier payments without singling out specific types of cases for special treatment.

Comment: One commenter seemed to argue that a fixed dollar loss equal to or greater than the episode payment amount was impossible empirically and resulted from assumptions we made about episode costs and payments.

Response: This commenter seemed to misunderstand the method we used to estimate the fixed dollar loss amount and the loss-sharing ratio. The estimates of fixed dollar loss amounts and loss-sharing ratios presented in the proposed rule and in this final rule were not based on any assumptions about internal data relationships. As described in the proposed rule, the estimates were derived from modeling simulated payments and estimated costs for the episodes included in the Abt case-mix data set. For this final rule, we conducted the simulations again using an updated Abt data set. We were unable to perform simulations using early OASIS data from the OASIS national repository, because data lags prevented us from linking OASIS data to claims such that they could be included in this final rule. However, we were able to perform a variety of case-mix comparisons between the national OASIS data and the Abt sample data. These comparisons indicated a high degree of conformity between the two data sources. Further, we were able to compare the 1998 episode file developed from Medicare claims and the Abt data to determine how well the distribution of expensive cases matched in the two files. This analysis also supported the use of the Abt data.

O. Budget Neutrality

Comment: A number of commenters raised concerns regarding the budget neutrality target. A few commenters were concerned about the budget target of IPS limits reduced by 15 percent. Another felt expenditures should be based on the Congressional Budget Office projection of expenditures.

Response: Section 302 of BBRA of 1999 amended the statute to delay the 15 percent reduction in spending until one year after the implementation of PPS and further requires the Secretary to report to Congress within 6 months after implementation of PPS on the need for the 15 percent reduction. The statute also requires the budget target to be based on the Secretary's estimate of spending in FY 2001, not the Congressional Budget Office estimate.

Comment: Some commenters asked if we intend to re-evaluate the budget neutrality factor in the future.

Response: Re-evaluating the experience over the next few years and adjusting the rates accordingly could be beneficial. However, the statute does not provide for any adjustment in the budget neutrality factor nor an adjustment to change the program budget target.

Comment: Several commenters were concerned about our projection of the number of episodes in FY 2001. Some mentioned specific reasons for declining episodes such as the changes in venipuncture rules.

Response: Since the time we published the preliminary notice, we have obtained more meaningful data about home health spending and utilization changes. We now have two consecutive year's episode files and have clarified issues related to spending projections such as unsubmitted claims and sequential billing. We are no longer projecting the same number of episodes as we had in CY 1997. Utilization has dropped substantially since that time. However, the reasons for the drop, such as venipuncture changes, cannot be quantified. We have a two-year comparison relating the drop in episodes to the drop in visits within an episode. Based upon the most recent data, we are dropping the projected number of episodes substantially.

Comment: Several commenters took issue with the data to be used as the basis for the rate setting. They felt that we should not use the 1998 data to establish rates as the low utilization associated with IPS would be built into this analysis.

Response: Because the law requires us to establish a PPS that is budget neutral to what would have been paid under IPS, we need the most recent data to help us develop a model of what would have happened under IPS in 2001. Since utilization did drop so dramatically, we feel that it is important to know how the mix of services changed. Use of 1997 data or 1998 data does not necessarily have a direct effect on the level of payment because of the budget neutrality requirement. For example, using 1998 data, with a lower number of visits in an episode than 1997 data, will result in less of an adjustment to obtain budget neutrality to reach projected FY 2001 spending.

Comment: Some commenters suggested that we increase the budget target to reflect the cost of Part B therapies that were provided outside the home health benefit that will now be covered by the PPS rate.

Response: We determined how much of this type of therapy is being provided to current beneficiaries receiving home health services. We added this amount to the target for spending.

Comment: One commenter believed that we should have performed an impact study for rural areas because

such an analysis would have shown the need for separate budget neutrality factors for rural versus urban areas.

Response: We did look at costs per visits in several different types of rural areas versus urban areas. There was no significant difference, therefore we did not create distinct rates for urban versus rural.

Comment: Several commenters argued that we did not provide support for the behavioral adjustment assumed about the percentage of LUPA payments.

Response: Analysis of the 1998 episode file showed that when home health services were broken into 60-day blocks, for 16 percent of the time either a beneficiary had 1 to 4 visits extending outside a continuous period of service or that a beneficiary simply had only 1 to 4 visits within a 60-day period. Of this 16 percent, only 26 percent or 4 percent of the total were cases where only 1 to 4 visits were provided in a single 60-day, non-contiguous period. This four percent would clearly classify as LUPA episodes. It is not clear that those visits simply falling outside the 60 days would, under PPS, qualify as an episode. A plan of care would probably simply include those straggler visits with the preceding episode in many cases. The episode file was created to help us determine the average number of visits and the mix of visits in an episode. The file was not meant to fully reflect a system where payments are made prospectively. The incentives and the management of care under the prospective system we have designed have many differences from a cost-based reimbursement system. Our assumption about the percentage of LUPA episodes is not so much a reflection of a behavioral change but a clarification of how the episode file was constructed. It would not be reasonable to assume that the distribution of visits under PPS will replicate that of IPS. Our assumption that 5 percent of episodes will be LUPA is based on the actuaries' best estimate of what will actually happen under PPS.

Comment: One commenter suggested that we include appropriate assumptions regarding the PEP in the budget neutrality adjustment.

Response: We developed the PEP and the SCIC to benefit both agencies and beneficiaries. The SCIC was created so that beneficiaries whose condition had changed since the start of the episode could continue to be cared for by the same agency. There is a cost to the payment system in allowing this change in condition. Because we do not have adequate data to estimate this cost, our rate setting assumptions could not incorporate the increased cost of changing to a higher case-mix mid-episode. There are some slight savings from using an end date to the PEP which does not equal the start date of the next episode. Again, we did not specifically account for this in determining the budget neutrality factor because as in the case of the SCIC, we do not have concrete data on which to base any cost estimate. We feel that the cost of the SCIC will outweigh any savings from the PEP. This being the case, the rates are not lower than they should be because of assumptions about the PEP.

P. Discharge Issues

Comment: Several commenters raised concern over possible impacts of discharge policies under the new PPS. Commenters requested clarification of our policy governing the situations of patients who are discharged because they are no longer homebound and therefore ineligible for the Medicare home health benefit during the 60-day episode, the patient refuses services or is discharged because of safety, abuse, non-compliance concerns, or dies.

Response: We believe the documented and legitimate event of a patient's death would result in a full episode payment for the HHA. Therefore, if a patient dies on day 35 of an episode, the HHA would receive a full episode payment for that individual. There would be no proportional payment adjustments to the full episode payment. If a patient is discharged because he or she becomes no longer homebound and therefore ineligible for the home health benefit, refuses services, or becomes a documented safety, abuse or non-compliance discharge during the 60-day episode, the HHA would receive a full 60-day episode payment unless the patient became subsequently eligible for the home health benefit during the same 60-day episode and later transferred to another HHA or returned to the same HHA, then the latter situation would result in a PEP adjustment.

Comment: Commenters requested clarification of discharge policies governing an intervening hospital, SNF or hospice admission.

Response: We believe that HHAs should be given the option to discharge the patient within the scope of its own operating policies; however, an HHA discharging a patient as a result of hospital admission during the 60-day episode will not be recognized by Medicare as a discharge for billing and payment purposes. An intervening hospital stay will result in either an applicable SCIC adjustment or, if the Resumption of Care OASIS assessment upon return to home health does not indicate a change in case-mix level, a full 60-day episode payment will be provided spanning the home health episode start of care date prior to the hospital admission, through and including the days of the hospital admission, and ending with the 59th day from the original start of care date.

Comment: Several commenters asked whether a patient could be discharged before the end of the 60-day episode and whether the final bill could be submitted upon discharge before the end of the 60-day episode.

Response: The claim may be submitted upon discharge before the end of the 60-day episode. However, subsequent adjustments to any payment based on the claim may be made due to an intervening event resulting in a PEP adjustment, such as a transfer to another HHA prior to the end of the 60-day episode or discharge and return to the same HHA prior to the end of the 60-day episode.

Comment: A commenter requested clarification of the situation where an HMO fails to notify the HHA of a transfer of coverage, asking whether the HHA would be responsible for that portion of the PPS payment deducted by Medicare.

Response: The common working file data base includes enrollment data that should inform the HHA of the enrollment status of patients under a home health plan of care with their agency. If the beneficiary becomes HMO eligible mid-episode, the 60-day episode payment will be proportionally adjusted with a PEP adjustment. The episode payment will be proportionally adjusted using the span of days based on the billable visit date that the beneficiary was under the care of the HHA prior to the beneficiary transfer to an HMO.

Q. Consolidated Billing

Comment: Several commenters requested clarification of the services governed by the statutorily required consolidated billing requirements under sections 1842(b)(6)(F) and 1862(a) of the Act as amended by section 305 of BBRA. Some commenters were concerned with possible False Claims Act violations.

Response: Section 1842(b)(6)(F) of the Act, enacted by the BBA , and amended by the BBRA, requires the consolidated billing of all covered home health services listed in section 1861(m) of the Act, except for DME covered as a Medicare home health service. Section 305 of BBRA revised the statute to exclude DME covered under the Medicare home health benefit from the consolidated billing requirements. Under PPS, HHAs will be required to bill and receive payment for all covered

home health services listed in section 1861(m) of the Act, except DME during the 60-day episode. Under the current system, issues concerning the False Claims Act are within the purview of the Inspector General who will review any possible claims violation.

Comment: Commenters requested reassurance that parenteral and enteral nutrition was not included in the consolidated billing requirements governing home health PPS.

Response: Perenteral and enteral nutrition services are currently not a covered home health service. Therefore, perenteral and enteral nutrition services are not subject to the consolidated billing requirements and are not included in the PPS episode rate.

Comment: Several commenters requested the elimination of non-routine medical supplies, osteoporosis drugs and the therapies from the consolidated billing requirements governing PPS.

Response: The statute requires all covered home health services listed in section 1861(m) of the Act, except for DME, to be governed by the consolidated billing requirements. HHAs cannot unbundle non-routine medical supplies that are currently covered as a Medicare home health service that may coincidentally have a duplicate Part B payment code for payment. In addition, HHAs cannot unbundle the osteoporosis drug or therapies covered under the Medicare home health benefit. Although the osteoporosis drug covered under the Medicare home health benefit is not included in the PPS rate, it is still governed by the statutorily required consolidated billing requirements.

Comment: Commenters suggested that we remove the requirement for consolidated billing of intern and resident services unless it is a choice of the hospital and the HHAs. Commenters suggested a separate payment amount to those HHAs that will bill for their intern and resident services.

Response: To the extent these services were paid on a reasonable cost basis and covered under the home health benefit, there cannot be separate payment for these services under home health PPS. These services will be subject to the consolidated billing requirements. However, the HHA PPS rates and consolidated billing requirements do not affect Medicare payments to hospitals for graduate medical education or billing requirements.

Comment: Commenters suggested that we establish, at a minimum, a partial episode payment to a nonprimary HHA that can demonstrate they followed the recommended Common Working File (CWF) procedures for CWF verification of home health status before providing care, but received incorrect information about the episode status of the beneficiary.

Response: We believe that HCFA systems will provide the appropriate information in a timely manner so that HHAs may establish primacy for purposes of consolidated billing and corresponding payment. In future refinements to the system we will certainly not rule out the feasibility of this proposal if the data shows that this situation occurs frequently.

Comment: Commenters requested clarification of the procedures HHAs and other providers will follow to communicate the necessary charges of DME and the osteoporosis drug.

Response: The current communication level that is necessary to effectively meet the DME and osteoporosis drug needs of home health patients will continue under PPS. Both DME and the osteoporosis drug are paid outside of the PPS rates. As DME covered as a home health service, is no longer subject to the consolidated billing requirements governing home health PPS, the status quo for the provision of DME will continue under PPS. The osteoporosis drug is subject to the consolidated billing provisions although it is paid outside of the PPS rates. HHAs will no longer be able to unbundle the osteoporosis drug to a Part B supplier. The HHA will have to bill Medicare directly for the osteoporosis drug and any applicable supplier will have to look to the HHA for payment.

Comment: Commenters requested clarification of consolidated billing requirements governing billings and payments for services at hospitals, skilled nursing facilities, and rehabilitation centers when they include equipment too cumbersome to bring to the home.

Response: Payments for services at hospitals, SNFs, and rehabilitation centers when they include equipment too cumbersome to bring to the home have been incorporated into the baseline cost data used to develop the PPS rates and are included in those rates. Those services are also subject to the consolidated billing requirements. Therefore, the HHA cannot unbundle the services to a Part B supplier. The HHA must provide the services either directly or under arrangement and bill Medicare directly for payment.

R. Physician Certification of the HHRG (§ 484.22)

Comment: Several commenters requested the elimination of the proposed requirement governing physician certification of the HHRG. In general, commenters objected to the burden associated with this requirement and questioned its logic. Commenters also argued that physicians would not be able to comply with the requirement of certification of the HHRG.

Response: We proposed to require the physician to certify the appropriate case-mix weight/HHRG as part of the required physician certification of the plan of care. This was an attempt to have the physician more involved in the decentralized delivery of home health services. However, based on the number of negative responses from commenters and our reevaluation of this issue, we have decided to eliminate this requirement and focus our attention on physician certification efforts and education in order to better involve the physician in the delivery of home health services. In this final rule, we are deleting proposed § 424.22(a)(1)(v) to remove this requirement from our regulations.

S. Small Rural Providers

Comment: Several commenters suggested that we recognize several small rural exceptions to the national episode payment rate and LUPA policy that would more appropriately recognize the special needs of small rural providers. Commenters suggested that the payment rates are inadequate to meet the special travel needs and potential economy of scale challenges that commenters believe small rural HHAs encounter. Commenters believed the data used to develop the PPS did not include or adequately reflect the behavior of small rural HHAs, and therefore believed it would be difficult to predict the impact of PPS on small rural HHAs. Conversely, other commenters specifically recommended no exception for small rural HHAs.

Response: In our re-examination of the small rural impact issue, we did not find data to support the rural differentiation suggested in the comments submitted. Our analysis included the subcategorization of data into increasing degrees of rural remoteness. As demonstrated in the analysis below, the subcategories did not yield a significant differentiation in costs associated with resource needs and service delivery in rural areas. We do not believe that rural providers will be disadvantaged under HHA PPS. However, we will continue to look at alternatives regarding beneficiary access to Medicare home health services in remote areas. We will continue to analyze this complex issue with new data under HHA PPS. If and when an adjustment is justified, we will refine the system accordingly.

RURAL CONTINUUM CODE STATUS TABLE

Provider type	Continuum code [1]	Average cost per beneficiary 1997 [2]	Average cost per beneficiary 2001 [3]
Free Standing For Profit Agencies	0	$6,622	$4,079
Free Standing For Profit Agencies	1	12,632	3,939
Free Standing For Profit Agencies	2	7,367	5,397
Free Standing For Profit Agencies	3	7,965	6,577
Free Standing For Profit Agencies	4	6,400	5,330
Free Standing For Profit Agencies	5	7,014	5,997
Free Standing For Profit Agencies	6	6,367	4,230
Free Standing For Profit Agencies	7	7,671	4,333
Free Standing For Profit Agencies	8	5,838	4,971
Free Standing For Profit Agencies	9	4,871	4,266
Free Standing Governmental Agencies	0	3,758	2,589
Free Standing Governmental Agencies	1	2,325	2,370
Free Standing Governmental Agencies	2	4,117	2,938
Free Standing Governmental Agencies	3	4,054	3,407
Free Standing Governmental Agencies	4	3,683	2,975
Free Standing Governmental Agencies	5	4,459	3,495
Free Standing Governmental Agencies	6	3,204	2,375
Free Standing Governmental Agencies	7	3,905	3,253
Free Standing Governmental Agencies	8	3,046	2,572
Free Standing Governmental Agencies	9	3,170	2,477
Free Standing Non-Profit Agencies	0	5,341	3,035
Free Standing Non-Profit Agencies	1	4,258	3,871
Free Standing Non-Profit Agencies	2	4,897	2,991
Free Standing Non-Profit Agencies	3	4,069	3,162
Free Standing Non-Profit Agencies	4	3,279	2,810
Free Standing Non-Profit Agencies	5	6,124	4,630
Free Standing Non-Profit Agencies	6	5,730	3,320
Free Standing Non-Profit Agencies	7	5,146	3,638
Free Standing Non-Profit Agencies	8	3,620	3,692
Free Standing Non-Profit Agencies	9	6,546	4,899
Provider Based Agencies	0	5,488	3,233
Provider Based Agencies	1	4,049	3,498
Provider Based Agencies	2	4,553	3,845
Provider Based Agencies	3	4,418	3,015
Provider Based Agencies	4	2,834	2,757
Provider Based Agencies	5	4,358	3,322
Provider Based Agencies	6	3,973	3,212
Provider Based Agencies	7	4,221	2,938
Provider Based Agencies	8	2,355	1,496
Provider Based Agencies	9	4,553	3,580

[1] Source: Bureau of Census' urban and rural classification of populations.
[2] Source: Audited Cost Report Sample Data.
[3] Source: Audited Cost Report Sample Data updated to FY 2001.

CODE DEFINITIONS*
0 Central counties of metro areas of 1 million population or more
1 Fringe counties of metro areas of 1 million population or more
2 Counties in metro areas of 250,000 to 1 million population
3 Counties in metro areas of fewer than 250,000 population
4 Urban population of 20,000 or more, adjacent to a metro area
5 Urban population of 20,000 or more, not adjacent to a metro area
6 Urban population of 2,500 to 19,999, adjacent to a metro area
7 Urban population of 2,500 to 19,999, not adjacent to a metro area
8 Completely rural or fewer than 2,500 urban population, adjacent to a metro area
9 Completely rural or fewer than 2,500 urban population, not adjacent to a metro area

RURAL FRONTIER STATUS TABLE

Provider type	Frontier status [1]	Average cost per beneficiary 1997 [2]	Average cost per beneficiary 2001 [3]
Free Standing For Profit Agencies	No	$6,858	$4,664
Free Standing For Profit Agencies	Yes	4,179	4,620
Free Standing Governmental Agencies	No	3,579	2,803
Free Standing Governmental Agencies	Yes	2,450	1,758
Free Standing Non-Profit Agencies	No	4,921	3,118
Free Standing Non-Profit Agencies	Yes	6,926	2,785
Provider Based Agencies	No	4,500	3,344
Provider Based Agencies	Yes	3,999	2,942

[1] Frontier Status is defined as 6 or fewer persons per square mile.
Source: ''Definitions of Rural: A Handbook for Health Policy Makers and Researchers (HRSA).''
[2] Source: Audited Cost Report Sample Data.
[3] Source: Audited Cost Report Sample Data updated to FY 2001.

T. Wage Index

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 by HHAs. Many commenters suggested the development of a home health specific wage index. Several of the commenters that suggested the home health specific wage index believed the hospital wage index did not adequately represent the cost of rural wages. A few commenters expressed concern with our proposed approach that continues to apply the wage index adjustment based on the site of service of beneficiaries rather than the location of the parent office. Several commenters suggested that a few wage index values included in Table 4 of the proposed rule were incorrect. A commenter suggested the application of the latest hospital wage index with exclusion of physician and resident costs and hours from the calculation. Several commenters were concerned with the application of the wage index when the patient transfers mid-episode or relocates during the episode.

Response: As indicated in the proposed rule, we are using the latest pre-floor and pre-reclassified hospital wage index. We used the latest pre-floor and pre-reclassified hospital wage index that was available at the time of publication of the proposed rule.

While we appreciate the intent of a home health specific wage index, we want to point out that our previous efforts in developing such an index resulted in weights that the industry immediately repudiated because it was viewed less favorable than the pre-floor and pre-reclassified hospital wage index. The industry had concerns with the methodology used to develop a home health specific wage index. These concerns coupled with our lack of applicable home health specific data resulted in our adoption of the hospital wage index in our approach to adjusting the labor portion of the formulas. In future refinements to the PPS we will certainly not rule out the feasibility of this recommendation.

We have decided to continue basing the application of the wage index on the site of service of the beneficiary under PPS. We believe this is the most equitable recognition of the wage component for service delivery. Based on commenters concerns with incorrect values included in Table 4 of the proposed rule, we re-examined our data. Based on the data available at the time of publication of the proposed rule, both Tables 4A and B in the proposed rule are correct. We use, and will continue to use the pre-floor and pre-reclassified hospital wage index values which are not published in the annual inpatient hospital PPS notice. We believe this may be the source of some confusion reflected in the comments.

If there is a PEP adjustment, whether it is a transfer or discharge and return to the same HHA during the 60-day episode, the patients site of service is the location of application of the appropriate wage index value. The wage index based on the beneficiary site of service adjusts the labor portion of the original proportional payment and will also adjust the labor portion of the new 60-day episode payment resulting from the intervening event. The PEP adjustment is viewed as two discrete situations: (1) The labor adjustment of the original proportional payment and (2) the labor adjustment of the new 60-day episode payment resulting from the intervening event. If a beneficiary changes locations during the episode (for example, moves in with a family member), then the MSA or non-MSA at the start of the episode governs the labor adjustment of the episode payment for the balance of the episode. The new MSA or non-MSA corresponding to the new location would begin with the subsequent episode.

U. Market Basket

Comment: One commenter requested further clarification of the market basket used to update the cost data for inflation.

Response: We believe the market basket update was adequately described in the proposed rule (64 FR 58149). See section IV.B.2. of this rule for further clarification on the home health market basket. We are available to answer specific questions any commenters may have on an individual basis.

V. Alternative Methods of Care

Comment: Some commenters suggested the need to recognize alternative methods of care under PPS such as telemedicine or other innovations. Commenters recommended such alternative methods as a way to improve service delivery to patients and promote efficiencies.

Response: While we appreciate the intent of this comment, at this point the modality of telemedicine has not been adequately defined nor are there established safety and effectiveness standards across the continuum of products. Thus, we do not intend to change the current definition of a visit governed by § 409.48(c) which states, ''A visit is an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA for the purpose of providing a covered service.'' There is nothing to preclude an HHA from adopting telemedicine or other technologies that they believe promote efficiencies, but those untested technologies will not be specifically recognized and reimbursed by Medicare under the home health benefit.

W. Discrimination

Comment: A few commenters argued that the PPS as proposed discriminates

against States, provider types, classes of patients, and the impoverished and poorly educated due to their disproportionate numbers in certain States and regions of the country.

Response: The PPS was developed based on national norms and is intended to eliminate previous patterns of care that never related to patient need. We believe the case-mix methodology, significant change in condition adjustment, and cost outlier payments as developed in the system, treats all patients across the country equitably in relation to their condition.

X. Other Federal Requirements

Comment: A few commenters suggested that HHAs should not be required to comply with new Occupational Safety and Health Administration standards or any other new Federal requirements prior to PPS implementation.

Response: While we appreciate the concerns of the commenters, it is beyond the scope of our authority to place a moratorium on the application of regulations from other Federal agencies or other statutory Medicare requirements.

Y. OASIS Assessment and Plan of Care Certification Transition Concerns

Comment: Several commenters requested clarification of requirements governing OASIS assessments and plan of care certifications for implementation October 1, 2000. Commenters raised concerns regarding burden and costs associated with complying with the requirement that all patients be grouped into appropriate case-mix classifications and plan of care certifications for the October 1, 2000 implementation date.

Response: We addressed this concern in the proposed rule. We proposed to provide a one-time grace period in order to ease the transition to PPS for patients under an established OASIS assessment and certified plan of care prior to PPS implementation on October 1, 2000. We proposed if a beneficiary is under a home health plan of care before October 1, 2000 and the HHA has completed a Start of Care or Follow-Up OASIS assessment earlier than September 1, 2000, the HHA must complete a one-time additional Follow-up OASIS assessment using the modified OASIS B–1(8/2000) at least 5 days before October 1, 2000 for purposes of case-mix classification. The modified OASIS B–1(8/2000) is available on the HCFA Internet site at: http://www.hcfa.gov. If a beneficiary is under an established home health plan of care before October 1, 2000, and the HHA completed a Start of Care or Follow-Up OASIS assessment using the modified OASIS data set B–1(8/2000) on or after September 1, 2000 and does not wish to do a one-time OASIS at the inception of PPS, the HHA may use the earlier OASIS assessment.

We proposed a similar one-month grace period for physician certifications of the plan of care. In the October 28, 1999 proposed rule (64 FR 58195), we proposed, ''If a beneficiary is under an established home health plan of care before October 1, 2000 and the certification date is on or after September 1, 2000 and the HHA in conjunction with a certifying physician does not wish to do a one-time additional recertification of the plan of care at the inception of PPS, the HHA may use the recertification date (September 1, 2000 through September 30, 2000) from the earlier version of the plan of care. This is a one time grace period.'' We believe it is important to allow a one time grace period for plan of care certifications to ease transition concerns.

A beneficiary under an established plan of care as of September 1, 2000, may have a one-time implementation grace period for the plan of care certification requirements for a maximum period of up to 90 days (September 1, 2000 through and including November 29, 2000). This one-time grace period to alleviate implementation burden must be done in conjunction with a certifying physician. The regulatory requirements governing the Medicare home health benefit before implementation of PPS would apply to the certification period up to and including September 30, 2000. Home health agencies in conjunction with a certifying physician will have to document a break in ordered services for the pre-PPS physician ordered services (September 1, 2000 through and including September 30, 2000) and all post-PPS physician ordered services as of PPS implementation on October 1, 2000. The documented break in services during the one-time implementation grace period for the plan of care certification requirements for a maximum period of up to 90 days is required in order to ensure the alignment of all certified episodes and OASIS assessments as of PPS implementation on October 1, 2000.

For example, a Medicare home health eligible patient is under a physician's plan of care and the first billable visit date/start of care date in the plan of care is September 15, 2000. The one-time implementation grace period would reflect a plan of care that specifies physician orders for services furnished both before and after implementation of HHA PPS. The physician orders in the plan of care would reflect services from September 15, 2000 through and including September 30, 2000. All current coverage and payment rules would apply to the services provided on September 15, 2000 through and including September 30, 2000. The plan of care would also specify any services ordered on October 1, 2000 through and including November 29, 2000. The plan of care would reflect the break in services both before and after implementation of HHA PPS. The start of care date/first billable visit date for this patient under PPS in the plan of care is October 1, 2000. The one-time implementation grace period would require the documentation of services in the plan of care that were furnished both before and after implementation of HHA PPS and the documentation of the new PPS start of care date under PPS.

Many commenters raised concern about the potential burden associated with patients who are under a plan of care prior to October 1, 2000, but due to timing, their OASIS schedule did not fall in the post September 1, 2000 grace period time frame. These patients would require OASIS reassessment during the last 5 days of September in order to group the patients for purposes of case-mix classification for the October 1, 2000 PPS effective date. For some HHAs, this could potentially pose a significant implementation burden. Thus, we are revising our proposed approach to permit the completion of the next scheduled OASIS follow-up assessment for those patients under an established home health plan of care prior to September 1, 2000, but on or after August 1, 2000, to be completed at the HHA's discretion during the month of September. Therefore, if the patient is under a home health plan of care that overlaps the month of August 2000, the HHA will have the discretion to complete the next scheduled Follow-Up OASIS Assessment during the month of September. Under the one-time transition grace period, we are not requiring that the OASIS assessment be completed during the required time frame during the last 5 days of the episode certification requirement for August and September 2000. The requirement that the OASIS assessment must be completed during the last 5 days of the certification period in order to case-mix adjust the patient for a subsequent episode certification will resume with PPS implementation effective October 1, 2000. If the patient is under an established certified home health plan of care as of August 1, 2000 through and including August 31, 2000, then the HHA may complete the next

scheduled OASIS follow-up assessment anytime during the month of September 2000. For patients under an established home health plan of care on September 1, 2000 through and including September 30, 2000, then the HHA may use the most recent start of care or follow-up assessment on file for the month of September 2000 to group patients for purposes of case-mix PPS implementation on October 1, 2000.

Z. Billing Issues

Comment: Several commenters requested clarification regarding the billing instructions governing the new PPS.

Response: Due to the highly technical nature of these comments, we will not address those comments in this final rule. However, we will release operational billing instructions to accompany the publication of this final rule.

AA. Cost Reporting Under PPS

Comment: Several commenters recommended that the requirement for an HHA cost report end with PPS implementation.

Response: Cost reporting requirements for HHAs will not end with PPS. As with all other PPS systems there is continued demand for this data. Importantly, the data may be used to monitor, refine, and improve PPS in the future.

Comment: Several commenters requested clarification of the cost reporting requirements governing the October 1, 2000 PPS implementation date. Commenters were concerned with cost reporting periods that do not parallel the implementation date of PPS, October 1, 2000.

Response: All providers will file a full 12-month cost report regardless of their specific cost reporting year. There will be a statistical break in the cost report based on Medicare statistics up through and including September 30, 2000. Under PPS, the cost report will capture all statistical data for both costs and statistics for all subsequent periods. A provider's cost reporting year will not be affected by the implementation of PPS. We will provide more detailed instructions on PPS cost reporting instructions in subsequent program instructions and revisions to the Provider Reimbursement Manual.

Comment: Commenters requested clarification of the application of the interim payment system cost limits for the period of a cost reporting period that may overlap the date of implementation of PPS. Commenters wanted clarification on whether or not the interim payment system cost limits will be prorated.

Response: The interim payment system cost limits (per-visit limit and per-beneficiary limit) will not be prorated. Full application of the limits will apply to the cost reporting year subject to the interim payment system limits.

Comment: A commenter suggested a cost reporting mechanism for the identification of nontraditional home health services and their costs.

Response: Currently, there is no cost reporting mechanism for the separate identification of non-traditional Medicare costs. At their own option, providers may accumulate detailed statistics within their own accounting system.

BB. OASIS Data and Grouper Issues

Many of the OASIS comments were highly technical or not within the parameters of this final rule. Interested parties can get assistance with their queries on an individual basis as well as through the RHHIs and on HCFA's home page. We have provided general responses to the following OASIS data comments:

Comment: A few commenters reported that State OASIS personnel are stating that payments to HHAs under PPS will be based upon actual bills submitted.

Response: This information is incorrect. We have provided State OASIS Educational Coordinators (OEC) with the authority and responsibility to educate HHA providers about the implementation of the clinical aspects of the OASIS data set in their agency, and with the reporting and transmission requirements of the data set needed to go from the agency to the State system. They are not trained to answer questions about reimbursement. The RHHIs have the background and knowledge to educate HHA providers on the reimbursement aspect of HHA PPS. HHAs are free to contact their RHHI on questions concerning reimbursement under HHA PPS.

Comment: One commenter requested that we use the criteria of hospitalization as an indicator for a PEP adjustment due to concerns with the impact on outcome tracking.

Response: As discussed previously in our response to comments concerning the PEP adjustment, we have re-examined our approach due to intervening hospitalizations and potential discharge concerns. We have provided consistency to the extent possible to ensure adequate payment levels and corresponding outcome tracking for quality purposes.

Comment: A few commenters requested clarification of the payment approach for pre- and post-partum Medicare disability patients who are not required to have an OASIS assessment.

Response: While the OASIS data set was not designed for the assessment of the clinical needs of the maternity patient, and the maternity patient is excluded by regulation from the collection of the data set, the reimbursement system will require a home health resource group (HHRG) to be submitted on the claim. In the rare case of a pre-or post-partum Medicare maternity patient, the HHA will need to complete the comprehensive assessments at the specified time points, which are required for production of the HHRG. The HHA can place that HHRG group case-mix number on the claim to receive payment. The HHA is not required to transmit the assessments to the State Agency, but must include those assessments in the clinical record at the agency.

We believe the majority of this type of maternity patient will be held at the LUPA level. If, in the rare instance the patient requires more than four visits, we would suggest the HHA complete an OASIS in order to ensure adequate payment levels. We believe this would be true for the Medicare disabled population under 18. If the patient was at the LUPA level, in all likelihood he or she would be classified into the lowest HHRG level and ultimately paid at the LUPA level at the end of the episode.

Comment: A few commenters requested clarification on the proper OASIS schedule that should be used for a private pay or Medicaid patient who is in a current OASIS assessment period that becomes eligible for Medicare home health benefits during that period.

Response: All Medicare cases require a new Start of Care OASIS assessment to group the patient for payment purposes and assess the patient for care planning at the time the patient becomes Medicare eligible.

Comment: Several commenters requested access to the grouper prior to the publication of the final rule.

Response: We provided draft grouper software on the HHA PPS HCFA website during the comment period of the proposed rule. Providers could download the grouper software in a PC EXCEL format. We plan to also provide the final grouper on the HCFA HHA PPS website.

Comment: Some commenters questioned the affect untimely reporting of OASIS date or the absence of it would have on payment.

Response: An HHRG cannot be generated without a completed OASIS. The RHHI will not accept a billed HHRG unless the OASIS that supports the billed case-mix classification is encoded by the agency, electronically transmitted and accepted by the State's OASIS repository.

Comment: A few commenters were concerned with potential implementation costs associated with the OASIS schedules used to group patients for case-mix purposes.

Response: In section IV.C. of this rule, we set forth the payment methodology for the first year of PPS one-time adjustment reflecting implementation costs associated with revised OASIS schedules needed to classify patients into appropriate categories for payment. We have provided clarification of the proper OASIS assessment schedule used to group patients for case-mix based on the patient's episode status. Further clarification will be provided in subsequent program instructions.

Type of episode or adjustment	OASIS assessment: M0100 & M0825 response selection
1. Initial, whether first or new 60-day episode resulting from PEP Adjustment.	Start of Care: (M0100) RFA 1 and (M0825) select 0—No or 1—Yes*
2. SCIC *with* intervening Hospital Stay during current episode	Resumption of Care: (M0100) RFA 3 and (M0825) is 0—No or 1—Yes* If a patient was transferred to the hospital without agency discharge during the current episode, the required assessment upon return to home is the Resumption of Care assessment (RFA 3). The Resumption of Care assessment is required within 48 hours of the patient's return from the inpatient facility. The Resumption of Care assessment (RFA 3) also serves to determine the appropriate new case-mix assignment for the SCIC adjustment.
3. SCIC *with* intervening Hospital Stay at the end of an episode	Resumption of Care: (M0100) RFA 3 and (M0825) is 0—No or 1—Yes* and Follow up (M0100) RFA4 and (M0825) is 0—No or 1—Yes* If a patient was transferred to the hospital without agency discharge, the required assessment upon return to home is the Resumption of Care assessment (RFA 3). The Resumption of Care assessment is required within 48 hours of the patient's return from the inpatient facility. The recertification (Follow-up, RFA 4) comprehensive assessment is required in the last five days of the certification period; for payment purposes, this assessment is used to determine the case-mix assignment for the subsequent 60-day period. If the second part of the SCIC adjustment occurs in the last five days of the certification period, two comprehensive assessments are required. One assessment will be done for the resumption of care (RFA 3) and (M0825) select 0—No or 1—Yes; the other will be done for the re-certification (Follow-up) assessment (RFA4) and (M0825) select 0—No or 1—Yes.* The reason two assessments are required is that therapy need must be predicted and reported on the OASIS record for each discrete 60 day episode.
4. SCIC *without* intervening Hospital Stay	Other Follow-Up Assessment: (M0100) RFA 5 and (M0825) select 0—No or 1—Yes*
5. Subsequent 60-day episode due to the need for continuous home health care after an initial 60-day episode.	Recertification (Follow-up): (M0100) RFA 4 and (M0825) select 0—No or 1—Yes*

* (M0825) = NA is applicable only when response (M0150)—response 1 (traditional Medicare fee-for-service) is not selected.

CC. Medical Review Under PPS

Comment: A number of commenters expressed concerns pertaining to the initiation of medical review activities for home health claims under the prospective payment system and suggested there should be a moratorium on or a delay of medical review. Others proposed a limit on the amount of and/or the kind of medical review performed.

Response: We believe it is important to implement medical review activities at the start-up of the new prospective payment system. As problems with specific home health claims are identified, contractors will be able to educate the home health agencies to prevent future billing errors. We have been working hard to develop an effective medical review strategy that will guard against program vulnerabilities unique to the PPS environment, be fair to home health providers, and meet the goal of paying claims correctly.

Comment: Commenters asked that we clarify the medical review process. One commenter asked if the RHHIs will change the case-mix assignment based on the medical review determination, and if so, asked what appeals process will be available to the agencies.

Response: For the most part, medical reviewers will continue to perform the same types of reviews that were conducted prior to implementation of PPS. For example, they will review to ensure that the beneficiary meets the requirements for Medicare home health coverage, and that services provided were reasonable and necessary and appropriately documented. One additional aspect of the review strategy will focus on the OASIS information and whether it is supported by documentation in the medical record. If the RHHI determines that a case-mix assignment is not appropriate, they will adjust the case-mix group accordingly. Agencies will continue to have all appeal rights currently associated with home health claims.

Comment: A commenter suggested that we impose time limits on contractors to complete medical review activities within a prescribed amount of time after receiving requested medical documentation.

Response: We have not prescribed specific contractor medical review time frames. We agree that this may be an issue that warrants further consideration; however, it is beyond the scope of this regulation and we will revisit this issue if warranted.

Comment: Several commenters expressed concerns about cash flow

issues if providers are placed on focused medical review and recommended that we prohibit sequential billing. Other commenters asked how medical review of an episode would affect subsequent episodes.

Response: We are sensitive to provider cash flow concerns and desires to balance legitimate provider concerns with Medicare's stewardship responsibilities. Sequential billing is not a requirement in the home health PPS, therefore medical review of one episode will not automatically delay payment for subsequent episodes. However, we may reduce or disapprove requests for anticipated payments in those situations in which protecting Medicare program integrity warrants these actions.

Comment: Several commenters expressed concerns about vulnerabilities presented by the prospective payment system.

Response: We recognize that there are unique program vulnerabilities related to the prospective payment environment. However, we believe we have identified possible vulnerabilities and random review will assist us in assessing vulnerabilities and problems on an ongoing basis. We are working with the RHHIs and home health providers to address them as we develop the medical review strategy.

Comment: A commenter recommended that RHHIs review the patient's plan of care (POC) and all visit documentation before determining whether or not patients qualify for full episode payments or therapy thresholds.

Response: We agree, and for claims selected for medical review, RHHIs will consider all available information from the agency for the episode billed in determining payment. That information may include all visit information such as nursing and therapy notes, treatment and flow charts, and vital sign records, weight charts, and medication records. In addition, the solicited information may also include the OASIS, the patient's POC, physician orders, hospital discharge summaries and transfer forms.

Comment: One commenter asked if HCFA expects significant changes in the numbers of denials under PPS.

Response: It is our goal to reduce payment errors. Because this is a new payment methodology, it is difficult to predict whether there will be changes in the denial rate for home health claims. We believe that education and early intervention is key to ensure proper billing under the new payment methodology, and can help reduce both denials and errors by increasing compliance.

DD. Quality Under PPS

Comment: We received a few comments requesting clarification of the quality improvement approach proposed under PPS.

Response: Efforts are currently underway to develop systems to generate outcome based quality improvement reports based on the OASIS that can be used to assess the quality of care at home health agencies, assist the States in their survey and certification responsibility, and provide information to home health agencies to assist them in ongoing quality improvement. Part of this effort is the implementation of the Home Health Outcome Based Quality Improvement System pilot project where the Peer Review Organizations (PROs) will act in a supportive role to assess and support quality improvement efforts in home health agencies. The Home Health Outcome Based Quality Improvement (HH OBQI) System is being implemented as a pilot project in five States through the PRO program. The HH OBQI system will explore the feasibility of providing assistance to HHAs in their efforts to implement and manage new programs for quality improvement. After a competitive solicitation to all PROs, HCFA selected the Maryland PRO, the Delmarva Foundation for Medical Care, Inc., as the lead or Home Health PRO (HH PRO). As the HH PRO, Delmarva will oversee the implementation of the project, coordinate the efforts of the four pilot PROs, and also serve as the fifth pilot PRO. The PROs for Michigan, New York, Rhode Island, and Virginia have also been selected as pilot PROs. The HH PRO will distribute information and guidance to the pilot PROs based on OASIS outcome reports, and its own analysis of OASIS data obtained from the national OASIS repository. The pilot PROs will, in turn, provide education and consultation to home health agencies to assist them in developing and managing their outcome based quality improvement programs. The pilot PROs will also provide consultation to State agencies, RHHIs and HCFA components in interpreting and using the outcome reports to assess home health quality.

EE. Medicare Secondary Payor (MSP) Under PPS

Comment: A few commenters raised concerns regarding the treatment of MSP under home health PPS.

Response: The statute governing home health PPS was silent regarding the treatment of MSP. The current requirements governing MSP will continue under the home health PPS environment. If warranted, further technical clarification will be provided in operational program instructions.

FF. Appeal Rights Under PPS

Comment: Several commenters requested clarification of provider appeal rights under home health PPS.

Response: Under the home health PPS, HHAs will have appeal rights comparable to the current environment. They will not be able to appeal the request for anticipated payment of the initial percentage payment for the episode, but they will be able to appeal a denial or down-coding by the intermediary where items or services were found as to be noncovered custodial care or were not reasonable and necessary AND where the intermediary finds that the beneficiary or provider should have known that they were excluded from coverage under the program (42 CFR § 405.704(c)).

Comment: Some commenters asked about beneficiary appeal rights under home health PPS, specifically demand billing procedures.

Response: We are currently reviewing demand billing procedures to determine whether they must be modified to take into account differences between HHA reasonable cost billing and the HHA PPS.

GG. Suggestions for HCFA

Comment: Several commenters sent comments on other regulations that were outside the scope of this rule. In addition, some commenters requested changes to the current statutorily required eligibility requirements, plan of care certification requirements, other coverage requirements that were not set forth in the proposed rule and the request to publish aspects of the final regulation on a faster publication track.

Response: These comments cannot be addressed in this rule, as this rule does not pertain to current law governing eligibility or plan of care certification requirements and therefore, we cannot amend these requirements as requested by the commenters. Due to tight timeframes for publication of this rule, we were unable to publish any portion of this rule in a separate rule under a quicker timeframe.

Comment: Several commenters recommended that we review all regulations and manual instructions for consistency.

Response: We have reviewed and will continue to review all current instructions and provide corresponding manual revisions and operational

instructions that reflect the final policies set forth in this rule.

Comment: Several commenters suggested the need for formal quarterly meetings with industry representatives or other industry groups to develop the final rule and provide a forum of open communication.

Response: We will continue to strive to keep the lines of communication open with our external environment. There are several requirements that govern the rulemaking process that inhibit consultation with outside groups. However, we will continue to ensure that we are available to clarify concerns and listen to our stakeholders throughout the process.

IV. Overview of Final Regulation

This final rule sets forth the methodology for the national PPS applicable to all Medicare home health services covered under both Part A and Part B. This final rule incorporates a national 60-day episode payment for all of the reasonable costs of services furnished to an eligible beneficiary under a Medicare home health plan of care. This section describes the components of the national 60-day episode payment and the methodology and data used in computation.

A. Costs and Services Covered by the Payment

The prospective payment applies to all home health services set forth in section 1861(m) of the Act that are covered and paid on a reasonable cost basis under the Medicare home health benefit (except osteoporosis drugs as defined in 1861(kk) which are paid outside PPS) as of the date of the enactment of the BBA, including medical supplies. DME is a covered home health service that is not currently paid on a reasonable cost basis, but is paid on a fee schedule basis when covered as a home health service under the Medicare home health benefit. Under the HHA PPS, DME covered as a home health service as part of the Medicare home health benefit will continue to be paid under the DME fee schedule. A separate payment amount in addition to the prospective payment amount for home health services will be made for DME currently covered as a home health service under the PPS. Although the covered osteoporosis drug under the home health benefit is currently paid on a reasonable cost basis, section 4603(c)(2)(A) of the BBA amended section 1833(a)(2)(A) of the Act to specifically exclude it from the prospective payment rate. In addition, unlike DME which is now excluded from the statutorily required consolidated billing requirement, the osteoporosis drug is included in the consolidated billing requirements.

B. Data Sources Used for the Development of the Payment

1. Audited Cost Report Data

Audit Sample Methodology: As discussed in the response to comments section, we provided an additional time period for intermediaries serving providers in the audited sample to resubmit audited cost reports ending in FY 1997 if the cost reports had been appealed and reopened. This provided us with the opportunity to include revised data in the calculation of the final rates if any of the audited cost reports in the original sample had been appealed, reopened or revised as of January 2000. The result was that we added an additional seven providers from whom we have audited cost report data for FY 1997, resulting in a total of 574 cost reports that have been used in the final rate calculations in this rule. The ''window of opportunity'' resulted in an additional seven audited cost reports. Although the new total number of audited cost reports increased to 574, however, we used only 563 of the 574 providers in the developing of the impacts. From 1997 to 1998, 11 of the 574 providers either closed or merged with another provider. As stated above, we are using CY 1998 utilization data in the PPS rate calculation. There was not 1998 utilization data to match to the audited cost report data for the 11 providers that closed or merged.

- Updating to September 30, 2001. Before computing the average cost per visit for each discipline that would be used to calculate the prospective payment rate, we adjusted the costs from the audit sample by the latest available market basket factors to reflect expected cost increases occurring between the cost reporting periods ending in FY 1997 to September 30, 2001. Multiplying nominal dollars for a given FY end by their respective inflation adjustment factor will express those dollars in the dollar level for the FY ending September 30, 2001. Therefore, we multiplied the total costs for each provider by the appropriate inflation factor shown in the table below. See section IV.B.2. of this regulation for a detailed description of the market basket.
- Nonroutine Medical Supplies Paid on a Reasonable Cost Basis Under a Home Health Plan of Care. Before computing the average cost per episode for non-routine medical supplies paid on a reasonable cost basis under a home health plan of care, we also adjusted the audited cost report data for nonroutine medical supplies using the latest market basket factors to reflect expected cost increases occurring between the cost reporting periods ending in FY 1997 to September 30, 2001.
- Adjusting Costs for Providers Impacted by the Per-Visit Limits. For cost reporting periods ending in FY 1997, Medicare recognized reasonable costs as the lower of the provider's actual costs or the per-visit limit applied in the aggregate for the six disciplines. Because some providers' costs were higher than the per-visit limits applied in the aggregate for the six disciplines, it was necessary to adjust their costs in order to reflect only those costs on which the provider's payment was based. The adjustment factor was calculated by dividing a provider's total visit limit by the total Medicare costs, but only if the total visit limit was less than the total Medicare costs. For those providers who were not impacted by the visit limit, (that is, those subject to their actual reasonable costs) no adjustment was necessary and the adjustment factor was set equal to one. The adjustment factor was applied to each provider's total costs for each discipline. Summing each provider's updated, weighted, and adjusted total costs by the sum of visits for each discipline results in the non-standardized, updated, weighted, and visit limit adjusted average cost per visit by discipline.

2. Home Health Agency Market Basket Index

The data used to develop the HHA PPS payments were adjusted using the latest available market basket factors to reflect expected cost increases occurring between cost reporting periods contained in our database and September 30, 2001. The following inflation factors were used in calculating the HHA PPS:

FACTORS FOR INFLATING DATABASE DOLLARS TO SEPTEMBER 30, 2001

FY end	1996	1997
October 31	1.15736	.....
November 30	1.15468	.....
December 31	1.15203	.....
January 31	.....	1.14946
February 28	.....	1.14697
March 31	.....	1.14451
April 30	.....	1.14203
May 31	.....	1.13952
June 30	.....	1.13693
July 31	.....	1.13420
August 31	.....	1.13132
September 30	.....	1.12841

For each of fiscal years 2002 and 2003, section 1895(b)(3)(B)(ii) of the Act

requires the standard prospective payment amounts to be increased by a factor equal to the home health market basket minus 1.1 percentage points. In addition, for any subsequent fiscal years, the statute requires that the rates be increased by the applicable home health market basket index change.

3. Claims Data

We also conducted analysis on an episode database created from the 1997 and 1998 National Claims History Files using 60-day episodes to define episode lengths. These data were based on use of home health services under the current system. We built a CY 1998 episode data base parallel to the construction of the CY 1997 episode data base set forth in the proposed rule at 64 FR 58149.

Table 1 illustrates the comparison of the distribution of consecutive 60-day episodes that occurred in calendar years 1997 and 1998.

Total number of consecutive 60-day episodes	Distribution based on only 60-day episodes that occurred in the CY 1997 period (percent)	Distribution based on only 60-day episodes that occurred in the CY 1998 period (percent)
1	51	59.5
2	18	19.3
3	8	7.7
4	5	4.1
5	4	2.5
6	3	1.7
7	10	5.2

Table 2 is a comparison of the average number of visits per episode for each discipline for CY 1997 and CY 1998 and Episodes in CY 1997 and CY 1998 with five or more visits.

Average number of visits by discipline	Average based on only 60-day episodes that fell into the CY 1997 period	Average based on only 60-day episodes that fell into the CY 1997 period with visit >4	Average based on only 60-day episodes that fell into the CY 1998 period	Average based on only 60-day episodes that fell into the CY 1998 period with visit >4
Skilled Nursing Services	12.55	14.69	12.1	14.08
Physical Therapy Services	2.35	2.74	2.59	3.05
Occupational Therapy Services	0.41	0.48	0.45	0.53
Speech Pathology Services	0.15	0.18	0.15	0.18
Medical Social Services	0.31	0.36	0.28	0.32
Home Health Aide Services	14.59	17.59	11.28	13.4
Total for all Disciplines	30.36	36.04	26.85	31.56

Table 3 provides analysis of the distribution of disciplines across a series of 60-day episodes in CY 1998.

Total number of 60-day episodes	Episode number within series of 60-day episodes	Percent of skilled nursing services	Percent of home health aide services	Percent of occupational therapy services	Percent of speech pathology services	Percent of medical social services	Percent of physical therapy services
1	1	50	24	3	1	2	20
2	1	46	34	3	1	1	15
2	2	46	37	2	1	1	13
3	1	46	38	2	1	1	11
3	2	45	41	2	1	1	10
3	3	46	42	2	1	1	9
4	1	45	43	2	1	1	8
4	2	45	46	1	1	1	7
4	3	45	46	1	0	1	7
4	4	46	45	1	0	1	6
5	1	45	46	1	0	1	6
5	2	44	48	1	0	1	5
5	3	44	49	1	0	1	5
5	4	44	49	1	0	1	5
5	5	45	47	1	0	1	5
6	1	44	48	1	0	1	6

Total number of 60-day episodes	Episode number within series of 60-day episodes	Percent of skilled nursing services	Percent of home health aide services	Percent of occupational therapy services	Percent of speech pathology services	Percent of medical social services	Percent of physical therapy services
6	2	43	50	1	0	1	5
6	3	43	51	1	0	1	4
6	4	43	51	1	0	1	4
6	5	44	50	1	0	1	4
6	6	45	49	1	0	1	4
7	1	40	56	1	0	1	3
7	2	41	55	0	0	1	3
7	3	41	56	0	0	1	3
7	4	41	56	0	0	1	2
7	5	41	55	0	0	1	2
7	6	42	55	0	0	1	2
7	7	42	55	0	0	0	2
8	1	42	53	1	0	1	4
8	2	42	54	1	0	1	3
8	3	42	53	0	0	1	3
8	4	43	54	0	0	1	3
8	5	43	54	0	0	0	3
8	6	43	53	0	0	0	3
8	7	44	53	0	0	0	3
8	8	44	52	0	0	0	3

National Part B Claims History File—Medical Supplies. Nonroutine medical supplies are also a covered home health service listed in section 1861(m)(5) of the Act. The law governing PPS requires medical supplies to be included in the prospective payment rate and to be subject to the consolidated billing requirements. As discussed in the proposed rule, before PPS implementation, HHAs were not required to bundle all home health services. Specifically, nonroutine medical supplies that have a duplicate Part B code could have been furnished by a supplier rather than the HHA and paid under Part B prior to PPS. Under the current IPS, some HHAs may have chosen to unbundle those non-routine medical supplies that had a corresponding Part B payment. In order to determine the scope of the non-routine medical supplies that could have been unbundled under the current system, we identified 199 HCPCs codes representing those items that would fall into the possible ''unbundled nonroutine medical supply'' category.

As discussed in the response to comment section of this rule, based on several comments we re-examined our approach to the original list of 199 codes. Our analysis yielded a payment approach to non-routine medical supplies included in the PPS rates that uses 178 Part B codes that could have possibly been unbundled to Part B before PPS. We performed the same data analysis on the CY 1998 claims data and the revised list of 178 Part B codes to develop the appropriate payment adjustment amount for non-routine medical supplies that could possibly be unbundled to Part B before PPS that is added to the non-standardized episode payment.

We pulled all claims with the corresponding HCPCs codes from the Part B national claims history file. In order to determine whether the HCPCs codes were related to the beneficiary receiving home health services under a home health plan of care, we linked every Part B claim with one or more of the 199 HCPCs codes to home health episodes from our episode database for both CY 1997 and CY 1998 by beneficiary and dates of service. If a beneficiary received home health services during a 60-day episode and there was a corresponding Part B claim with one of the 178 HCPCs codes that was billed during the same 60-day episode, we identified the item as related to the home health stay. We proposed an additional payment amount of $6.08 to the 60-day episode base rate for those nonroutine medical supplies with corresponding Part B codes that may have been unbundled under the interim payment system.

National Part B Claims History File—Therapies. As discussed above in section III. of this final rule. *Analysis and Responses to Public Comments,* we conducted a parallel analysis of Part B therapy claims that could possibly be related to a home health stay during CY 1997 and CY 1998. Prior to consolidated billing requirements governing PPS, HHAs may have unbundled therapy services to Part B. We believe that this was a rare occurrence. Under PPS, HHAs will be responsible for providing physical therapy, speech language pathology services and occupational therapy either directly or under arrangement. Under subsequent analysis, based upon comments received, we believe that there is a need to recognize these therapy services that could have been unbundled to Part B before PPS in the PPS rates. We conducted claims analysis similar to our approach to identify those non-routine medical supplies that could have been unbundled to Part B. We identified the three therapy services in both Part B outpatient and Part B physician/supplier claims data.

HCFA identified 54 HCPCs codes that represent those services that could fall into the possible ''unbundled therapy related services'' category under Part B Physician/Supplier claims for patients under a home health plan of care before implementation of PPS. We also identified under Part B, therapy services that could have been unbundled and provided in an hospital outpatient setting to patients under a home health plan of care before implementation of PPS. We identified the 17 revenue center code ranges for physical, occupational, and speech therapy services that could have been billed under Part B in a hospital outpatient setting for patients under a home health plan of care before implementation of PPS. HCFA pulled all claims from the Part B Physician/Supplier claims with the corresponding 54 codes above and all claims from the Part B hospital outpatient claims with the corresponding 17 revenue center code ranges. As with our analysis of nonroutine medical supplies that could have been unbundled to Part B before implementation of PPS, HCFA matched

claims for a beneficiary receiving home health services under a home health plan of care by linking the Part B claims to home health episodes from our 1998 episode database, by beneficiary and dates of service. If a beneficiary received home health services during a 60-day episode and there was a corresponding part B claim with either one of the 54 HCPCs or a revenue center code within one of the 17 revenue center code ranges for therapy services, we identified the Part B service as related to the home health stay.

As a result of our therapy analysis, we are recognizing an additional adjustment to the 60-day non-standardized episode amount for therapy services that could have been unbundled to Part B before implementation of PPS. The per episode possible unbundled therapy related service amounts billed under Part B included in the PPS rate were calculated by summing the allowed charges for the 54 HCPCs for physician/supplier and the costs for the 17 therapy revenue center code ranges for hospital outpatient in calendar year 1998 for beneficiaries under a home health plan of care. That total was divided by the total number of episodes in calendar year 1998 from the episode database. The methodology for the adjustment is set forth in section IV.C. of this regulation.

4. Hospital Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act, require the Secretary to establish area wage adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of health services and to provide appropriate adjustments to the episode payment amounts under PPS to account for area wage differences. The wage adjustment factors may be the factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act. The statute allows the Secretary to use the area where the services are furnished or such area as the Secretary may specify for the wage index adjustment. To be consistent with the wage index adjustment under the current interim payment system, we proposed and will retain applying the appropriate wage index value to the labor portion of the PPS rates based on the geographic area in which the beneficiary received home health services.

In addition, section 1895(b)(3)(A)(i) of the Act requires the Secretary to standardize the cost data used in developing the PPS payment amount for wage levels among different HHAs in a budget-neutral manner. The wage index adjustment to the PPS rates must be made in a manner that does not result in aggregate payments that are greater or less than those that would have otherwise been made if the PPS rates were not adjusted by the wage index.

Each HHA's labor market area is determined based on definitions of Metropolitan Statistical Areas (MSAs) issued by the Office of Management and Budget (OMB). In establishing the final HHA PPS rates, we used the most recent pre-floor and pre-reclassified hospital wage index without regard to whether these hospitals have been classified to a new geographic area by the Medicare Geographic Reclassification Board. As stated in the response to comments, we believe the use of the pre-floor and pre-reclassified hospital wage index data results in an appropriate adjustment to the labor portion of costs as required by law.

TABLE 4A.—FY 2000 WAGE INDEX FOR RURAL AREAS—PRE-FLOOR AND PRE-RECLASSIFIED

Nonurban area	Wage Index
Alabama	0.7391
Alaska	1.2058
Arizona	0.8545
Arkansas	0.7236
California	0.9952
Colorado	0.8814
Connecticut	1.2414
Delaware	0.9167
Florida	0.8987
Georgia	0.8095
Guam	0.7268
Hawaii	1.0728
Idaho	0.8652
Illinois	0.8048
Indiana	0.8397
Iowa	0.7927
Kansas	0.7461
Kentucky	0.8043
Louisiana	0.7382
Maine	0.8640
Maryland	0.8632
Massachusetts	1.1370
Michigan	0.8815
Minnesota	0.8670
Mississippi	0.7307
Missouri	0.7724
Montana	0.8396
Nebraska	0.8008
Nevada	0.9098
New Hampshire	0.9906
New Jersey [1]	.....
New Mexico	0.8379
New York	0.8637
North Carolina	0.8290
North Dakota	0.7648
Ohio	0.8650
Oklahoma	0.7256
Oregon	0.9868
Pennsylvania	0.8525
Puerto Rico	0.4249
Rhode Island [1]	.....
South Carolina	0.8264

TABLE 4A.—FY 2000 WAGE INDEX FOR RURAL AREAS—PRE-FLOOR AND PRE-RECLASSIFIED—Continued

Nonurban area	Wage Index
South Dakota	0.7577
Tennessee	0.7651
Texas	0.7471
Utah	0.8907
Vermont	0.9408
Virginia	0.7904
Virgin Islands	0.6389
Washington	1.0447
West Virginia	0.8069
Wisconsin	0.8760
Wyoming	0.8860

[1] All counties within the State are classified as urban.

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED

MSA	Urban area (constituent counties)	Wage index
0040	Abilene, TX	0.8180
	Taylor, TX	
0060	Aguadilla, PR	0.3814
	Aguada, PR	
	Aguadilla, PR	
	Moca, PR	
0080	Akron, OH	1.0164
	Portage, OH	
	Summit, OH	
0120	Albany, GA	1.0373
	Dougherty, GA	
	Lee, GA	
0160	Albany-Schenectady-Troy, NY.	0.8755
	Albany, NY	
	Montgomery, NY	
	Rensselaer, NY	
	Saratoga, NY	
	Schenectady, NY	
	Schoharie, NY	
0200	Albuquerque, NM	0.8500
	Bernalillo, NM	
	Sandoval, NM	
	Valencia, NM	
0220	Alexandria, LA	0.7870
	Rapides, LA	
0240	Allentown-Bethlehem-Easton, PA.	1.0228
	Carbon, PA	
	Lehigh, PA	
	Northampton, PA	
0280	Altoona, PA	0.9343
	Blair, PA	
0320	Amarillo, TX	0.8381
	Potter, TX	
	Randall, TX	
0380	Anchorage, AK	1.2860
	Anchorage, AK	
0440	Ann Arbor, MI	1.1484
	Lenawee, MI	
	Livingston, MI	
	Washtenaw, MI	
0450	Anniston, AL	0.8463
	Calhoun, AL	
0460	Appleton-Oshkosh-Neenah, WI.	0.8913

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
	Calumet, WI	
	Outagamie, WI	
	Winnebago, WI	
0470	Arecibo, PR	0.4815
	Arecibo, PR	
	Camuy, PR	
	Hatillo, PR	
0480	Asheville, NC	0.8885
	Buncombe, NC	
	Madison, NC	
0500	Athens, GA	0.9705
	Clarke, GA	
	Madison, GA	
	Oconee, GA	
0520	Atlanta, GA	1.0051
	Barrow, GA	
	Bartow, GA	
	Carroll, GA	
	Cherokee, GA	
	Clayton, GA	
	Cobb, GA	
	Coweta, GA	
	DeKalb, GA	
	Douglas, GA	
	Fayette, GA	
	Forsyth, GA	
	Fulton, GA	
	Gwinnett, GA	
	Henry, GA	
	Newton, GA	
	Paulding, GA	
	Pickens, GA	
	Rockdale, GA	
	Spalding, GA	
	Walton, GA	
0560	Atlantic-Cape May, NJ ..	1.1311
	Atlantic, NJ	
	Cape May, NJ	
0580	Auburn-Opelka, AL	0.9619
	Lee, AL	
0600	Augusta-Aiken, GA–SC	0.9014
	Columbia, GA	
	McDuffie, GA	
	Richmond, GA	
	Aiken, SC	
	Edgefield, SC	
0640	Austin-San Marcos, TX	0.9082
	Bastrop, TX	
	Caldwell, TX	
	Hays, TX	
	Travis, TX	
	Williamson, TX	
0680	Bakersfield, CA	0.9531
	Kern, CA	
0720	Baltimore, MD	0.9892
	Anne Arundel, MD	
	Baltimore, MD	
	Baltimore City, MD	
	Carroll, MD	
	Harford, MD	
	Howard, MD	
	Queen Anne's, MD	
0733	Bangor, ME	0.9610
	Penobscot, ME	
0743	Barnstable-Yarmouth, MA.	1.3303
	Barnstable, MA	
0760	Baton Rouge, LA	0.8708
	Ascension, LA	

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
	East Baton Rouge, LA	
	Livingston, LA	
	West Baton Rouge, LA	
0840	Beaumont-Port Arthur, TX.	0.8624
	Hardin, TX	
	Jefferson, TX	
	Orange, TX	
0860	Bellingham, WA	1.1395
	Whatcom, WA	
0870	Benton Harbor, MI	0.8458
	Berrien, MI	
0875	Bergen-Passaic, NJ	1.2029
	Bergen, NJ	
	Passaic, NJ	
0880	Billings, MT	1.0039
	Yellowstone, MT	
0920	Biloxi-Gulfport-Pascagoula, MS.	0.7868
	Hancock, MS	
	Harrison, MS	
	Jackson, MS	
0960	Binghamton, NY	0.8751
	Broome, NY	
	Tioga, NY	
1000	Birmingham, AL	0.8995
	Blount, AL	
	Jefferson, AL	
	St. Clair, AL	
	Shelby, AL	
1010	Bismarck, ND	0.7759
	Burleigh, ND	
	Morton, ND	
1020	Bloomington, IN	0.8593
	Monroe, IN	
1040	Bloomington-Normal, IL	0.8994
	McLean, IL	
1080	Boise City, ID	0.9060
	Ada, ID	
	Canyon, ID	
1123	Boston-Worcester-Lawrence-Lowell-Brockton, MA–NH.	1.1359
	Bristol, MA	
	Essex, MA	
	Middlesex, MA	
	Norfolk, MA	
	Plymouth, MA	
	Suffolk, MA	
	Worcester, MA	
	Hillsborough, NH	
	Merrimack, NH	
	Rockingham, NH	
	Strafford, NH	
1125	Boulder-Longmont, CO	0.9945
	Boulder, CO	
1145	Brazoria, TX	0.8517
	Brazoria, TX	
1150	Bremerton, WA	1.1012
	Kitsap, WA	
1240	Brownsville-Harlingen-San Benito, TX.	0.9213
	Cameron, TX	
1260	Bryan-College Station, TX.	0.8510
	Brazos, TX	
1280	Buffalo-Niagara Falls, NY.	0.9605
	Erie, NY	

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
	Niagara, NY	
1303	Burlington, VT	1.0559
	Chittenden, VT	
	Franklin, VT	
	Grand Isle, VT	
1310	Caguas, PR	0.4561
	Caguas, PR	
	Cayey, PR	
	Cidra, PR	
	Gurabo, PR	
	San Lorenzo, PR	
1320	Canton-Massillon, OH ...	0.8772
	Carroll, OH	
	Stark, OH	
1350	Casper, WY	0.9200
	Natrona, WY	
1360	Cedar Rapids, IA	0.9019
	Linn, IA	
1400	Champaign-Urbana, IL ..	0.9164
	Champaign, IL	
1440	Charleston-North Charleston, SC.	0.8989
	Berkeley, SC	
	Charleston, SC	
	Dorchester, SC	
1480	Charleston, WV	0.9096
	Kanawha, WV	
	Putnam, WV	
1520	Charlotte-Gastonia-Rock Hill, NC–SC.	0.9434
	Cabarrus, NC	
	Gaston, NC	
	Lincoln, NC	
	Mecklenburg, NC	
	Rowan, NC	
	Stanly, NC	
	Union, NC	
	York, SC	
1540	Charlottesville, VA	1.0575
	Albemarle, VA	
	Charlottesville City, VA	
	Fluvanna, VA	
	Greene, VA	
1560	Chattanooga, TN–GA ...	0.9732
	Catoosa, GA	
	Dade, GA	
	Walker, GA	
	Hamilton, TN	
	Marion, TN	
1580	Cheyenne, WY	0.8176
	Laramie, WY	
1600	Chicago, IL	1.0874
	Cook, IL	
	DeKalb, IL	
	DuPage, IL	
	Grundy, IL	
	Kane, IL	
	Kendall, IL	
	Lake, IL	
	McHenry, IL	
	Will, IL	
1620	Chico-Paradise, CA	1.0391
	Butte, CA	
1640	Cincinnati, OH–KY–IN ..	0.9419
	Dearborn, IN	
	Ohio, IN	
	Boone, KY	
	Campbell, KY	
	Gallatin, KY	

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
	Grant, KY	
	Kenton, KY	
	Pendleton, KY	
	Brown, OH	
	Clermont, OH	
	Hamilton, OH	
	Warren, OH	
1660	Clarksville-Hopkinsville, TN–KY.	0.8090
	Christian, KY	
	Montgomery, TN	
1680	Cleveland-Lorain-Elyria, OH.	0.9689
	Ashtabula, OH	
	Cuyahoga, OH	
	Geauga, OH	
	Lake, OH	
	Lorain, OH	
	Medina, OH	
1720	Colorado Springs, CO ..	0.9218
	El Paso, CO	
1740	Columbia, MO	0.8905
	Boone, MO	
1760	Columbia, SC	0.9358
	Lexington, SC	
	Richland, SC	
1800	Columbus, GA–AL	0.8511
	Russell, AL	
	Chattahoochee, GA	
	Harris, GA	
	Muscogee, GA	
1840	Columbus, OH	0.9908
	Delaware, OH	
	Fairfield, OH	
	Franklin, OH	
	Licking, OH	
	Madison, OH	
	Pickaway, OH	
1880	Corpus Christi, TX	0.8702
	Nueces, TX	
	San Patricio, TX	
1890	Corvallis, OR	1.1088
	Benton, OR	
1900	Cumberland, MD–WV ...	0.8802
	Allegany, MD	
	Mineral, WV	
1920	Dallas, TX	0.9607
	Collin, TX	
	Dallas, TX	
	Denton, TX	
	Ellis, TX	
	Henderson, TX	
	Hunt, TX	
	Kaufman, TX	
	Rockwall, TX	
1950	Danville, VA	0.9062
	Danville City, VA	
	Pittsylvania, VA	
1960	Davenport-Moline-Rock Island, IA–IL.	0.8707
	Scott, IA	
	Henry, IL	
	Rock Island, IL	
2000	Dayton-Springfield, OH	0.9461
	Clark, OH	
	Greene, OH	
	Miami, OH	
	Montgomery, OH	
2020	Daytona Beach, FL	0.8988
	Flagler, FL	
	Volusia, FL	
2030	Decatur, AL	0.8680
	Lawrence, AL	
	Morgan, AL	
2040	Decatur, IL	0.8322
	Macon, IL	
2080	Denver, CO	1.0190
	Adams, CO	
	Arapahoe, CO	
	Denver, CO	
	Douglas, CO	
	Jefferson, CO	
2120	Des Moines, IA	0.8755
	Dallas, IA	
	Polk, IA	
	Warren, IA	
2160	Detroit, MI	1.0422
	Lapeer, MI	
	Macomb, MI	
	Monroe, MI	
	Oakland, MI	
	St. Clair, MI	
	Wayne, MI	
2180	Dothan, AL	0.7799
	Dale, AL	
	Houston, AL	
2190	Dover, DE	0.9336
	Kent, DE	
2200	Dubuque, IA	0.8521
	Dubuque, IA	
2240	Duluth-Superior, MN–WI	1.0166
	St. Louis, MN	
	Douglas, WI	
2281	Dutchess County, NY ...	1.0553
	Dutchess, NY	
2290	Eau Claire, WI	0.8958
	Chippewa, WI	
	Eau Claire, WI	
2320	El Paso, TX	0.8948
	El Paso, TX	
2330	Elkhart-Goshen, IN	0.9380
	Elkhart, IN	
2335	Elmira, NY	0.8534
	Chemung, NY	
2340	Enid, OK	0.7954
	Garfield, OK	
2360	Erie, PA	0.9024
	Erie, PA	
2400	Eugene-Springfield, OR	1.0604
	Lane, OR	
2440	Evansville-Henderson, IN–KY.	0.8304
	Posey, IN	
	Vanderburgh, IN	
	Warrick, IN	
	Henderson, KY	
2520	Fargo-Moorhead, ND–MN.	0.8621
	Clay, MN	
	Cass, ND	
2560	Fayetteville, NC	0.8495
	Cumberland, NC	
2580	Fayetteville-Springdale-Rogers, AR.	0.7774
	Benton, AR	
	Washington, AR	
2620	Flagstaff, AZ–UT	1.0349
	Coconino, AZ	
	Kane, UT	
2640	Flint, MI	1.1021
	Genesee, MI	
2650	Florence, AL	0.7928
	Colbert, AL	
	Lauderdale, AL	
2655	Florence, SC	0.8619
	Florence, SC	
2670	Fort Collins-Loveland, CO.	1.0303
	Larimer, CO	
2680	Ft. Lauderdale, FL	1.0173
	Broward, FL	
2700	Fort Myers-Cape Coral, FL.	0.8951
	Lee, FL	
2710	Fort Pierce-Port St. Lucie, FL.	0.9999
	Martin, FL	
	St. Lucie, FL	
2720	Fort Smith, AR–OK	0.7844
	Crawford, AR	
	Sebastian, AR	
	Sequoyah, OK	
2750	Fort Walton Beach, FL ..	0.8714
	Okaloosa, FL	
2760	Fort Wayne, IN	0.9097
	Adams, IN	
	Allen, IN	
	DeKalb, IN	
	Huntington, IN	
	Wells, IN	
	Whitley, IN	
2800	Forth Worth-Arlington, TX.	0.9836
	Hood, TX	
	Johnson, TX	
	Parker, TX	
	Tarrant, TX	
2840	Fresno, CA	1.0263
	Fresno, CA	
	Madera, CA	
2880	Gadsden, AL	0.8689
	Etowah, AL	
2900	Gainesville, FL	1.0103
	Alachua, FL	
2920	Galveston-Texas City, TX.	0.9733
	Galveston, TX	
2960	Gary, IN	0.9391
	Lake, IN	
	Porter, IN	
2975	Glens Falls, NY	0.8607
	Warren, NY	
	Washington, NY	
2980	Goldsboro, NC	0.8334
	Wayne, NC	
2985	Grand Forks, ND–MN ...	0.9098
	Polk, MN	
	Grand Forks, ND	
2995	Grand Junction, CO	0.9189
	Mesa, CO	
3000	Grand Rapids-Muskegon-Holland, MI.	1.0136
	Allegan, MI	
	Kent, MI	
	Muskegon, MI	
	Ottawa, MI	
3040	Great Falls, MT	1.0460

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
	Cascade, MT	
3060	Greeley, CO	0.9723
	Weld, CO	
3080	Green Bay, WI	0.9133
	Brown, WI	
3120	Greensboro-Winston-Salem-High Point, NC.	0.9038
	Alamance, NC	
	Davidson, NC	
	Davie, NC	
	Forsyth, NC	
	Guilford, NC	
	Randolph, NC	
	Stokes, NC	
	Yadkin, NC	
3150	Greenville, NC	0.9501
	Pitt, NC	
3160	Greenville-Spartanburg-Anderson, SC.	0.9189
	Anderson, SC	
	Cherokee, SC	
	Greenville, SC	
	Pickens, SC	
	Spartanburg, SC	
3180	Hagerstown, MD	0.8843
	Washington, MD	
3200	Hamilton-Middletown, OH.	0.8947
	Butler, OH	
3240	Harrisburg-Lebanon-Carlisle, PA.	0.9918
	Cumberland, PA	
	Dauphin, PA	
	Lebanon, PA	
	Perry, PA	
3283	Hartford, CT[1 2]	1.1716
	Hartford, CT	
	Litchfield, CT	
	Middlesex, CT	
	Tolland, CT	
3285	Hattiesburg, MS	0.7634
	Forrest, MS	
	Lamar, MS	
3290	Hickory-Morganton-Lenoir, NC.	0.9113
	Alexander, NC	
	Burke, NC	
	Caldwell, NC	
	Catawba, NC	
3320	Honolulu, HI	1.1477
	Honolulu, HI	
3350	Houma, LA	0.7837
	Lafourche, LA	
	Terrebonne, LA	
3360	Houston, TX	0.9388
	Chambers, TX	
	Fort Bend, TX	
	Harris, TX	
	Liberty, TX	
	Montgomery, TX	
	Waller, TX	
3400	Huntington-Ashland, WV–KY–OH.	0.9758
	Boyd, KY	
	Carter, KY	
	Greenup, KY	
	Lawrence, OH	
	Cabell, WV	
	Wayne, WV	
3440	Huntsville, AL	0.8823
	Limestone, AL	
	Madison, AL	
3480	Indianapolis, IN	0.9793
	Boone, IN	
	Hamilton, IN	
	Hancock, IN	
	Hendricks, IN	
	Johnson, IN	
	Madison, IN	
	Marion, IN	
	Morgan, IN	
	Shelby, IN	
3500	Iowa City, IA	0.9608
	Johnson, IA	
3520	Jackson, MI	0.8841
	Jackson, MI	
3560	Jackson, MS	0.8387
	Hinds, MS	
	Madison, MS	
	Rankin, MS	
3580	Jackson, TN	0.8601
	Madison, TN	
	Chester, TN	
3600	Jacksonville, FL	0.8958
	Clay, FL	
	Duval, FL	
	Nassau, FL	
	St. Johns, FL	
3605	Jacksonville, NC	0.7853
	Onslow, NC	
3610	Jamestown, NY	0.7858
	Chautauqua, NY	
3620	Janesville-Beloit, WI	0.9657
	Rock, WI	
3640	Jersey City, NJ	1.1676
	Hudson, NJ	
3660	Johnson City-Kingsport-Bristol, TN–VA.	0.8854
	Carter, TN	
	Hawkins, TN	
	Sullivan, TN	
	Unicoi, TN	
	Washington, TN	
	Bristol City, VA	
	Scott, VA	
	Washington, VA	
3680	Johnstown, PA	0.8641
	Cambria, PA	
	Somerset, PA	
3700	Jonesboro, AR	0.7232
	Craighead, AR	
3710	Joplin, MO	0.7679
	Jasper, MO	
	Newton, MO	
3720	Kalamazoo-Battlecreek, MI.	0.9982
	Calhoun, MI	
	Kalamazoo, MI	
	Van Buren, MI	
3740	Kankakee, IL	0.8599
	Kankakee, IL	
3760	Kansas City, KS–MO	0.9322
	Johnson, KS	
	Leavenworth, KS	
	Miami, KS	
	Wyandotte, KS	
	Cass, MO	
	Clay, MO	
	Clinton, MO	
	Jackson, MO	
	Lafayette, MO	
	Platte, MO	
	Ray, MO	
3800	Kenosha, WI	0.9034
	Kenosha, WI	
3810	Killeen-Temple, TX	0.9933
	Bell, TX	
	Coryell, TX	
3840	Knoxville, TN	0.9200
	Anderson, TN	
	Blount, TN	
	Knox, TN	
	Loudon, TN	
	Sevier, TN	
	Union, TN	
3850	Kokomo, IN	0.8919
	Howard, IN	
	Tipton, IN	
3870	La Crosse, WI–MN	0.8934
	Houston, MN	
	La Crosse, WI	
3880	Lafayette, LA	0.8340
	Acadia, LA	
	Lafayette, LA	
	St. Landry, LA	
	St. Martin, LA	
3920	Lafayette, IN	0.8810
	Clinton, IN	
	Tippecanoe, IN	
3960	Lake Charles, LA	0.7967
	Calcasieu, LA	
3980	Lakeland-Winter Haven, FL.	0.8816
	Polk, FL	
4000	Lancaster, PA	0.9256
	Lancaster, PA	
4040	Lansing-East Lansing, MI.	0.9978
	Clinton, MI	
	Eaton, MI	
	Ingham, MI	
4080	Laredo, TX	0.8323
	Webb, TX	
4100	Las Cruces, NM	0.8591
	Dona Ana, NM	
4120	Las Vegas, NV–AZ	1.1259
	Mohave, AZ	
	Clark, NV	
	Nye, NV	
4150	Lawrence, KS	0.8900
	Douglas, KS	
4200	Lawton, OK	09533
	Comanche, OK	
4243	Lewiston-Auburn, ME ...	0.8900
	Androscoggin, ME	
4280	Lexington, KY	0.8532
	Bourbon, KY	
	Clark, KY	
	Fayette, KY	
	Jessamine, KY	
	Madison, KY	
	Scott, KY	
	Woodford, KY	
4320	Lima, OH	0.8906
	Allen, OH	
	Auglaize, OH	
4360	Lincoln, NE	0.9671

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
	Lancaster, NE	
4400	Little Rock-North Little Rock, AR.	0.8615
	Faulkner, AR	
	Lonoke, AR	
	Pulaski, AR	
	Saline, AR	
4420	Longview-Marshall, TX	0.8739
	Gregg, TX	
	Harrison, TX	
	Upshur, TX	
4480	Los Angeles-Long Beach, CA.	1.2052
	Los Angeles, CA	
4520	Louisville, KY–IN	0.9382
	Clark, IN	
	Floyd, IN	
	Harrison, IN	
	Scott, IN	
	Bullitt, KY	
	Jefferson, KY	
	Oldham, KY	
4600	Lubbock, TX	0.8412
	Lubbock, TX	
4640	Lynchburg, VA	0.8815
	Amherst, VA	
	Bedford, VA	
	Bedford City, VA	
	Campbell, VA	
	Lynchburg City, VA	
4680	Macon, GA	0.8531
	Bibb, GA	
	Houston, GA	
	Jones, GA	
	Peach, GA	
	Twiggs, GA	
4720	Madison, WI	0.9730
	Dane, WI	
4800	Mansfield, OH	0.8476
	Crawford, OH	
	Richland, OH	
4840	Mayaguez, PR	0.4675
	Anasco, PR	
	Cabo Rojo, PR	
	Hormigueros, PR	
	Mayaguez, PR	
	Sabana Grande, PR	
	San German, PR	
4880	McAllen-Edinburg-Mission, TX.	0.8121
	Hidalgo, TX	
4890	Medford-Ashland, OR ...	1.0493
	Jackson, OR	
4900	Melbourne-Titusville-Palm Bay, FL.	0.9297
	Brevard, FL	
4920	Memphis, TN–AR–MS ..	0.8245
	Crittenden, AR	
	DeSoto, MS	
	Fayette, TN	
	Shelby, TN	
	Tipton, TN	
4940	Merced, CA	1.0278
	Merced, CA	
5000	Miami, FL	1.0234
	Dade, FL	
5015	Middlesex-Somerset-Hunterdon, NJ.	1.1123
	Hunterdon, NJ	
	Middlesex, NJ	
	Somerset, NJ	
5080	Milwaukee-Waukesha, WI.	0.9846
	Milwaukee, WI	
	Ozaukee, WI	
	Washington, WI	
	Waukesha, WI	
5120	Minneapolis-St. Paul, MN–WI.	1.0930
	Anoka, MN	
	Carver, MN	
	Chisago, MN	
	Dakota, MN	
	Hennepin, MN	
	Isanti, MN	
	Ramsey, MN	
	Scott, MN	
	Sherburne, MN	
	Washington, MN	
	Wright, MN	
	Pierce, WI	
	St. Croix, WI	
5140	Missoula, MT	0.9086
	Missoula, MT	
5160	Mobile, AL	0.8268
	Baldwin, AL	
	Mobile, AL	
5170	Modesto, CA	1.0112
	Stanislaus, CA	
5190	Monmouth-Ocean, NJ ...	1.1259
	Monmouth, NJ	
	Ocean, NJ	
5200	Monroe, LA	0.8222
	Ouachita, LA	
5240	Montgomery, AL	0.7704
	Autauga, AL	
	Elmore, AL	
	Montgomery, AL	
5280	Muncie, IN	1.0835
	Delaware, IN	
5330	Myrtle Beach, SC	0.8530
	Horry, SC	
5345	Naples, FL	0.9840
	Collier, FL	
5360	Nashville, TN	0.9450
	Cheatham, TN	
	Davidson, TN	
	Dickson, TN	
	Robertson, TN	
	Rutherford, TN	
	Sumner, TN	
	Williamson, TN	
	Wilson, TN	
5380	Nassau-Suffolk, NY	1.4076
	Nassau, NY	
	Suffolk, NY	
5483	New Haven-Bridgeport-Stamford-Waterbury-Danbury, CT.	1.2357
	Fairfield, CT	
	New Haven, CT	
5523	New London-Norwich, CT.	1.2429
	New London, CT	
5560	New Orleans, LA	0.9090
	Jefferson, LA	
	Orleans, LA	
	Plaquemines, LA	
	St. Bernard, LA	
	St. Charles, LA	
	St. James, LA	
	St. John The Baptist, LA	
	St. Tammany, LA	
5600	New York, NY	1.4519
	Bronx, NY	
	Kings, NY	
	New York, NY	
	Putnam, NY	
	Queens, NY	
	Richmond, NY	
	Rockland, NY	
	Westchester, NY	
5640	Newark, NJ	1.1647
	Essex, NJ	
	Morris, NJ	
	Sussex, NJ	
	Union, NJ	
	Warren, NJ	
5660	Newburgh, NY–PA	1.0910
	Orange, NY	
	Pike, PA	
5720	Norfolk-Virginia Beach-Newport News, VA–NC.	0.8441
	Currituck, NC	
	Chesapeake City, VA	
	Gloucester, VA	
	Hampton City, VA	
	Isle of Wight, VA	
	James City, VA	
	Mathews, VA	
	Newport News City, VA	
	Norfolk City, VA	
	Poquoson City, VA	
	Portsmouth City, VA	
	Suffolk City, VA	
	Virginia Beach City, VA	
	Williamsburg City, VA	
	York, VA	
5775	Oakland, CA	1.5059
	Alameda, CA	
	Contra Costa, CA	
5790	Ocala, FL	0.9616
	Marion, FL	
5800	Odessa-Midland, TX	0.8874
	Ector, TX	
	Midland, TX	
5880	Oklahoma City, OK	0.8588
	Canadian, OK	
	Cleveland, OK	
	Logan, OK	
	McClain, OK	
	Oklahoma, OK	
	Pottawatomie, OK	
5910	Olympia, WA	1.0933
	Thurston, WA	
5920	Omaha, NE–IA	1.0456
	Pottawattamie, IA	
	Cass, NE	
	Douglas, NE	
	Sarpy, NE	
	Washington, NE	
5945	Orange County, CA	1.1591
	Orange, CA	
5960	Orlando, FL	0.9796
	Lake, FL	
	Orange, FL	

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
	Osceola, FL	
	Seminole, FL	
5990	Owensboro, KY	0.8105
	Daviess, KY	
6015	Panama City, FL	0.9170
	Bay, FL	
6020	Parkersburg-Marietta, WV–OH.	0.8415
	Washington, OH	
	Wood, WV	
6080	Pensacola, FL	0.8443
	Escambia, FL	
	Santa Rosa, FL	
6120	Peoria-Pekin, IL	0.8350
	Peoria, IL	
	Tazewell, IL	
	Woodford, IL	
6160	Philadelphia, PA–NJ	1.1161
	Burlington, NJ	
	Camden, NJ	
	Gloucester, NJ	
	Salem, NJ	
	Bucks, PA	
	Chester, PA	
	Delaware, PA	
	Montgomery, PA	
	Philadelphia, PA	
6200	Phoenix-Mesa, AZ	0.9465
	Maricopa, AZ	
	Pinal, AZ	
6240	Pine Bluff, AR	0.7698
	Jefferson, AR	
6280	Pittsburgh, PA	0.9635
	Allegheny, PA	
	Beaver, PA	
	Butler, PA	
	Fayette, PA	
	Washington, PA	
	Westmoreland, PA	
6323	Pittsfield, MA	1.0256
	Berkshire, MA	
6340	Pocatello, ID	0.8974
	Bannock, ID	
6360	Ponce, PR	0.4971
	Guayanilla, PR	
	Juana Diaz, PR	
	Penuelas, PR	
	Ponce, PR	
	Villalba, PR	
	Yauco, PR	
6403	Portland, ME	0.9476
	Cumberland, ME	
	Sagadahoc, ME	
	York, ME	
6440	Portland-Vancouver, OR–WA.	1.0976
	Clackamas, OR	
	Columbia, OR	
	Multnomah, OR	
	Washington, OR	
	Yamhill, OR	
	Clark, WA	
6483	Providence-Warwick-Pawtucket, RI.	1.0691
	Bristol, RI	
	Kent, RI	
	Newport, RI	
	Providence, RI	
	Washington, RI	

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
6520	Provo-Orem, UT	0.9819
	Utah, UT	
6560	Pueblo, CO	0.8854
	Pueblo, CO	
6580	Punta Gorda, FL	0.9509
	Charlotte, FL	
6600	Racine, WI	0.9217
	Racine, WI	
6640	Raleigh-Durham-Chapel Hill, NC.	0.9545
	Chatham, NC	
	Durham, NC	
	Franklin, NC	
	Johnston, NC	
	Orange, NC	
	Wake, NC	
6660	Rapid City, SD	0.8364
	Pennington, SD	
6680	Reading, PA	0.9537
	Berks, PA	
6690	Redding, CA	1.1265
	Shasta, CA	
6720	Reno, NV	1.0656
	Washoe, NV	
6740	Richland-Kennewick-Pasco, WA.	1.1225
	Benton, WA	
	Franklin, WA	
6760	Richmond-Petersburg, VA.	0.9546
	Charles City County, VA	
	Chesterfield, VA	
	Colonial Heights City, VA	
	Dinwiddie, VA	
	Goochland, VA	
	Hanover, VA	
	Henrico, VA	
	Hopewell City, VA	
	New Kent, VA	
	Petersburg City, VA	
	Powhatan, VA	
	Prince George, VA	
	Richmond City, VA	
6780	Riverside-San Bernardino, CA.	1.1211
	Riverside, CA	
	San Bernardino, CA	
6800	Roanoke, VA	0.8139
	Botetourt, VA	
	Roanoke, VA	
	Roanoke City, VA	
	Salem City, VA	
6820	Rochester, MN	1.1430
	Olmsted, MN	
6840	Rochester, NY	0.9185
	Genesee, NY	
	Livingston, NY	
	Monroe, NY	
	Ontario, NY	
	Orleans, NY	
	Wayne, NY	
6880	Rockford, IL	0.8784
	Boone, IL	
	Ogle, IL	
	Winnebago, IL	
6895	Rocky Mount, NC	0.8735
	Edgecombe, NC	
	Nash, NC	

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
6920	Sacramento, CA	1.2285
	El Dorado, CA	
	Placer, CA	
	Sacramento, CA	
6960	Saginaw-Bay City-Midland, MI.	0.9287
	Bay, MI	
	Midland, MI	
	Saginaw, MI	
6980	St. Cloud, MN	0.9422
	Benton, MN	
	Stearns, MN	
7000	St. Joseph, MO	0.8944
	Andrew, MO	
	Buchanan, MO	
7040	St. Louis, MO–IL	0.9053
	Clinton, IL	
	Jersey, IL	
	Madison, IL	
	Monroe, IL	
	St. Clair, IL	
	Franklin, MO	
	Jefferson, MO	
	Lincoln, MO	
	St. Charles, MO	
	St. Louis, MO	
	St. Louis City, MO	
	Warren, MO	
7080	Salem, OR	0.9950
	Marion, OR	
	Polk, OR	
7120	Salinas, CA	1.4711
	Monterey, CA	
7160	Salt Lake City-Ogden, UT.	0.8855
	Davis, UT	
	Salt Lake, UT	
	Weber, UT	
7200	San Angelo, TX	0.7846
	Tom Green, TX	
7240	San Antonio, TX	0.8318
	Bexar, TX	
	Comal, TX	
	Guadalupe, TX	
	Wilson, TX	
7320	San Diego, CA	1.1931
	San Diego, CA	
7360	San Francisco, CA	1.4002
	Marin, CA	
	San Francisco, CA	
	San Mateo, CA	
7400	San Jose, CA	1.3610
	Santa Clara, CA	
7440	San Juan-Bayamon, PR	0.4658
	Aguas Buenas, PR	
	Barceloneta, PR	
	Bayamon, PR	
	Canovanas, PR	
	Carolina, PR	
	Catano, PR	
	Ceiba, PR	
	Comerio, PR	
	Corozal, PR	
	Dorado, PR	
	Fajardo, PR	
	Florida, PR	
	Guaynabo, PR	
	Humacao, PR	
	Juncos, PR	

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
	Los Piedras, PR	
	Loiza, PR	
	Luguillo, PR	
	Manati, PR	
	Morovis, PR	
	Naguabo, PR	
	Naranjito, PR	
	Rio Grande, PR	
	San Juan, PR	
	Toa Alta, PR	
	Toa Baja, PR	
	Trujillo Alto, PR	
	Vega Alta, PR	
	Vega Baja, PR	
	Yabucoa, PR	
7460	San Luis Obispo-Atascadero-Paso Robles, CA.	1.0471
	San Luis Obispo, CA	
7480	Santa Barbara-Santa Maria-Lompoc, CA.	1.0820
	Santa Barbara, CA	
7485	Santa Cruz-Watsonville, CA.	1.3929
	Santa Cruz, CA	
7490	Santa Fe, NM	1.0438
	Los Alamos, NM	
	Santa Fe, NM	
7500	Santa Rosa, CA	1.3001
	Sonoma, CA	
7510	Sarasota-Bradenton, FL	0.9906
	Manatee, FL	
	Sarasota, FL	
7520	Savannah, GA	0.9954
	Bryan, GA	
	Chatham, GA	
	Effingham, GA	
7560	Scranton—Wilkes-Barre—Hazleton, PA.	0.8373
	Columbia, PA	
	Lackawanna, PA	
	Luzerne, PA	
	Wyoming, PA	
7600	Seattle-Bellevue-Everett, WA.	1.1291
	Island, WA	
	King, WA	
	Snohomish, WA	
7610	Sharon, PA	0.8284
	Mercer, PA	
7620	Sheboygan, WI	0.8203
	Sheboygan, WI	
7640	Sherman-Denison, TX	0.9330
	Grayson, TX	
7680	Shreveport-Bossier City, LA.	0.9050
	Bossier, LA	
	Caddo, LA	
	Webster, LA	
7720	Sioux City, IA–NE	0.8549
	Woodbury, IA	
	Dakota, NE	
7760	Sioux Falls, SD	0.8777
	Lincoln, SD	
	Minnehaha, SD	
7800	South Bend, IN	0.9794
	St. Joseph, IN	
7840	Spokane, WA	1.0800
	Spokane, WA	

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
7880	Springfield, IL	0.8689
	Menard, IL	
	Sangamon, IL	
7920	Springfield, MO	0.7992
	Christian, MO	
	Greene, MO	
	Webster, MO	
8003	Springfield, MA	1.0678
	Hampden, MA	
	Hampshire, MA	
8050	State College, PA	0.9139
	Centre, PA	
8080	Steubenville-Weirton, OH–WV.	0.8815
	Jefferson, OH	
	Brooke, WV	
	Hancock, WV	
8120	Stockton-Lodi, CA	1.0519
	San Joaquin, CA	
8140	Sumter, SC	0.8239
	Sumter, SC	
8160	Syracuse, NY	0.9413
	Cayuga, NY	
	Madison, NY	
	Onondaga, NY	
	Oswego, NY	
8200	Tacoma, WA	1.1479
	Pierce, WA	
8240	Tallahassee, FL	0.8485
	Gadsden, FL	
	Leon, FL	
8280	Tampa-St. Petersburg-Clearwater, FL.	0.9045
	Hernando, FL	
	Hillsborough, FL	
	Pasco, FL	
	Pinellas, FL	
8320	Terre Haute, IN	0.8571
	Clay, IN	
	Vermillion, IN	
	Vigo, IN	
8360	Texarkana, AR-Texarkana, TX.	0.8136
	Miller, AR	
	Bowie, TX	
8400	Toledo, OH	0.9816
	Fulton, OH	
	Lucas, OH	
	Wood, OH	
8440	Topeka, KS	0.9327
	Shawnee, KS	
8480	Trenton, NJ	1.0103
	Mercer, NJ	
8520	Tucson, AZ	0.8743
	Pima, AZ	
8560	Tulsa, OK	0.8087
	Creek, OK	
	Osage, OK	
	Rogers, OK	
	Tulsa, OK	
	Wagoner, OK	
8600	Tuscaloosa, AL	0.8065
	Tuscaloosa, AL	
8640	Tyler, TX	0.9370
	Smith, TX	
8680	Utica-Rome, NY	0.8299
	Herkimer, NY	
	Oneida, NY	

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
8720	Vallejo-Fairfield-Napa, CA.	1.3347
	Napa, CA	
	Solano, CA	
8735	Ventura, CA	1.1456
	Ventura, CA	
8750	Victoria, TX	0.8379
	Victoria, TX	
8760	Vineland-Millville-Bridgeton, NJ.	1.0518
	Cumberland, NJ	
8780	Visalia-Tulare-Porterville, CA.	1.0412
	Tulare, CA	
8800	Waco, TX	0.8076
	McLennan, TX	
8840	Washington, DC–MD–VA–WV.	1.1055
	District of Columbia, DC	
	Calvert, MD	
	Charles, MD	
	Frederick, MD	
	Montgomery, MD	
	Prince Georges, MD	
	Alexandria City, VA	
	Arlington, VA	
	Clarke, VA	
	Culpeper, VA	
	Fairfax, VA	
	Fairfax City, VA	
	Falls Church City, VA	
	Fauquier, VA	
	Fredericksburg City, VA	
	King George, VA	
	Loudoun, VA	
	Manassas City, VA	
	Manassas Park City, VA	
	Prince William, VA	
	Spotsylvania, VA	
	Stafford, VA	
	Warren, VA	
	Berkeley, WV	
	Jefferson, WV	
8920	Waterloo-Cedar Falls, IA	0.8518
	Black Hawk, IA	
8940	Wausau, WI	0.9446
	Marathon, WI	
8960	West Palm Beach-Boca Raton, FL.	1.0013
	Palm Beach, FL	
9000	Wheeling, WV–OH	0.7644
	Belmont, OH	
	Marshall, WV	
	Ohio, WV	
9040	Wichita, KS	0.9422
	Butler, KS	
	Harvey, KS	
	Sedgwick, KS	
9080	Wichita Falls, TX	0.7653
	Archer, TX	
	Wichita, TX	
9140	Williamsport, PA	0.8450
	Lycoming, PA	
9160	Wilmington-Newark, DE–MD.	1.1275
	New Castle, DE	
	Cecil, MD	
9200	Wilmington, NC	0.9708
	New Hanover, NC	

TABLE 4B.—WAGE INDEX FOR URBAN AREAS—FY 2000 PRE-FLOOR AND PRE-RECLASSIFIED—Continued

MSA	Urban area (constituent counties)	Wage index
	Brunswick, NC	
9260	Yakima, WA	1.0333
	Yakima, WA	
9270	Yolo, CA	0.9720
	Yolo, CA	
9280	York, PA	0.9310
	York, PA	
9320	Youngstown-Warren, OH.	0.9997
	Columbiana, OH	
	Mahoning, OH	
	Trumbull, OH	
9340	Yuba City, CA	1.0663
	Sutter, CA	
	Yuba, CA	
9360	Yuma, AZ	0.9925
	Yuma, AZ	

C. Methodology Used for the Calculation of the 60-Day Episode Payment Amount

The methodology used to compute the standardized national 60-day episode payment rates was a multistep process combining each of the data sources described above. As stated above, section 1895(b)(3)(A)(i) of the Act requires that—(1) the computation of a standard prospective payment amount that includes all costs of home health services covered and paid for on a reasonable-cost basis be initially based on the most recent audited cost report data available to the Secretary, and (2) the prospective payment amounts be standardized to eliminate the effects of case-mix and wage levels among HHAs. The budget neutrality provision, with the 15-percent reduction and contingency reduction to IPS, originated from the BBA, was delayed by OCESAA, and further amended by BBRA to delay the 15 percent reduction by one year, while eliminating the contingency reduction to IPS. The data used to develop the HHA PPS rates were adjusted using the latest available market basket increases occurring between the cost reporting periods contained in our database and September 30, 2001.

With data described above, we calculated the standard average prospective payment amount for the 60-day episode using the following formula:

• We multiply the national mean cost per visit updated for inflation for each of the six disciplines (skilled nursing, physical therapy, occupational therapy, speech-language pathology services, medical social services, and home health aide services) in a 60-day episode by the national mean utilization for each of the six disciplines in a 60-day episode summed in the aggregate. We add to the figure derived from the above calculation, amounts for—

++ Nonroutine medical supplies paid on a reasonable-cost basis under a home health plan of care;

++ Nonroutine medical supplies that could have been unbundled to Part B that will be included under the PPS rate;

++ Therapy services that could have been unbundled to Part B that will be included under the PPS rate;

++ An OASIS adjustment to pay HHAs for estimated ongoing OASIS assessment reporting costs; and

++ A one-time implementation adjustment to pay HHAs for estimated costs associated with implementing the revisions to the OASIS assessment schedules in order to classify patients into the appropriate case-mix categories for payment for the first year of PPS.

• Nonroutine Medical Supplies. The per-episode nonroutine medical supply amounts, paid on a reasonable cost basis under a home health plan of care, were calculated by summing the nonroutine medical supply costs for all of the providers in the audited cost report sample weighted to represent the national population and updated to FY 2001. That total was divided by the number of episodes for the providers in the audited cost report sample weighted to represent the national population and updated to FY 2001.

The per-episode possible unbundled nonroutine medical supply amounts billed under Part B included in the PPS rate were calculated by summing the allowed charges for the revised 178 HCPCs codes (described in sections II.B and IV.) in calendar year 1998 for beneficiaries under a home health plan of care. That total was divided by the total number of episodes in calendar year 1998 from the episode database.

• Possible unbundled therapies billed to Part B that will be included under the PPS Rate. As discussed in the response to comments and section III. of this regulation, prior to consolidated billing requirements governing PPS, HHAs may have been unbundled therapy services to Part B. Although this was a rare occurrence, we re-examined our approach to calculating the PPS rate. There is an additional therapy adjustment to the nonstandardized 60-day episode. For further detail, see section IV.B.3. The rate methodology is provided in Table 5 below.

• Ongoing OASIS Cost Adjustments. In the August 11, 1998 IPS Per-Visit and Per-Beneficiary Limitations notice (63 FR 42912) HCFA discussed a proposed adjustment for HHAs for the agency collection of the Outcome Assessment Information Set (OASIS) Data. Collecting and reporting OASIS is a condition of Medicare participation for HHAs. As we stated in the August 11, 1998 IPS notice, we believe there will be no permanent ongoing incremental costs associated with OASIS collection. Additionally, we believe that there will be no further one-time, start-up, OASIS reporting costs beyond those recognized at the inception of OASIS collection under IPS. However, we do believe that ongoing costs are associated with reporting OASIS data. Our proposed adjustment for the ongoing costs associated with OASIS reporting is based on information from the ongoing Medicare Quality and Improvement Demonstration, as well as the OASIS demonstration data. We assume, for purposes of deriving the OASIS proposed adjustment, that the typical HHA has 486 admissions and 30,000 visits per year and an 18 person staff. OASIS reporting adjustments are unlike the one-time OASIS collection adjustments published in the August 11, 1998 **Federal Register** which were based only on the number of skilled visits. These reporting adjustments are based on total Medicare visits. The following are HCFA's estimates of costs that a typical HHA will incur for OASIS reporting which form the basis of the per-visit OASIS reporting adjustment and the per-episode OASIS adjustment. The first descriptive chart below shows the base OASIS reporting costs for an HHA which include the following: audits to ensure data accuracy; data entry, editing and auditing; supplies; and telephone costs. We estimate these ongoing OASIS costs to total $.101228 per visit. The second descriptive chart shows the OASIS personal computer costs for those HHAs that are unable to run OASIS because they lack the requisite hardware needed to support automation of the assessment tool. We estimate this percentage to be 50 percent (64 FR 3759). These costs consist of the depreciation of a personal computer and printer. For years one through three, HHAs are able to depreciate both their personal computer and printer. We estimate this OASIS cost to be $.026778 per visit. For years four and five, HHAs can only depreciate their printer. We estimate this OASIS cost to be $.004 per visit. In order for HHAs to keep pace with the ever evolving computing standards, to include enhancements to computer hardware and software, as well as future versions of Haven's OASIS software, this process of the depreciation of computer hardware is one that would repeat itself every five

years. Similarly, a yearly average computer hardware depreciation adjustment was computed to yield an OASIS adjustment for each of the five years. This was accomplished by multiplying the first three years' computer hardware depreciation adjustment of $.026778 by 3, multiplying the following two years' computer hardware depreciation adjustment of $.004 by 2, summing those two factors, and dividing that sum by the total number of depreciable years (five), to get a yearly average for the computer hardware depreciation adjustment of $.017667. This yearly average for computer hardware depreciation adjustments ($.017667), when added to the base OASIS adjustment ($.101228), results in a total OASIS adjustment of $.118895 rounded to $.12 per visit.

For purposes of calculating the ongoing OASIS adjustment for the 60-day episode payment, we multiplied the average number of visits per 60-day episode (36 visits) by the total rounded per-visit OASIS adjustment ($.12 per visit). The calculation resulted in a per-episode OASIS adjustment of $4.32 for each 60-day episode under HHA PPS. The home health prospective payment calculation is provided in Table 5.

We calculated the ongoing OASIS adjustment for the low utilization payment adjustments by adding the total rounded per-visit OASIS adjustment ($.12 per visit) to the national standardized average cost per visit by discipline for each of the four or fewer visits provided in the episode. The low utilization payment adjustment calculation is provided in Table 6.

CONTINUOUS OASIS ADJUSTMENT: BASE

[For data reporting]

Type of adjustment	Source	Formula	Cost per visit
Audits to ensure data accuracy	University of Colorado (CHPR), BLS Occupational Employment Survey (1996), 1994 & 1995 HCFA Cost Report Data.	(((((10 records per month * 12 months)) * .25 hrs) * $25.42) / 30,000 avg visits)...professional staff.	$.02542
Data entry, editing, & auditing	University of Colorado(CHPR), Estimated average salary for clerical staff, 1994 & 1995 HCFA Cost Report Data.	((((8.5 hrs per month * 12) + (5 hrs per month * 12) + (1 hr per month * 12) + (5 hrs per year)) * $10 per hour) / 30,000 avg visits).	.059667
Supplies	HCFA–3006–IFC OASIS Reporting (64 FR 3748), 1994 & 1995 HCFA Cost Report Data.	$250 avg cost / 30,000 avg visits	.008333
Ongoing telephone costs	Bell Atlantic, 1994 & 1995 HCFA Cost Report Data (for average size HHA).	((($13.14 per month, per line) + ($ 6.38 per month subscriber fee)) * 12 months) / 30,000 avg visits).	.007808
Total			.101228

CONTINUOUS OASIS ADJUSTMENT: 5 YEAR DEPRECIATION AVERAGING

[For data reporting]

Type of adjustment	Source	Formula	Cost per visit
Computer Hardware	American Hospital Association's, Health Data & Coding Standards Group's, Estimated Useful Lives of Depreciable Hospital Assets {revised 1998}.		
Computer	Average cost for PC with minimal acceptable standards 1994 & 1995 HCFA Cost Report Data.	$2050 computer depreciated over 3 years (($2050/3) / 30,000 avg visits.	$.022778
Printer	Average cost for printer with minimal acceptable standards 1994 & 1995 HCFA Cost Report Data.	$600 printer cost depreciated over 5 years (($600/5) / 30,000 avg visits.	.004
	First 3 Year's Adjustment	*Note: computer & printer depreciation	.026778
	Next 2 Year's Adjustment	*Note: printer ONLY depreciation	.004
	5-Year Average Adjustment	(((($.026777 * 3) + ($.004 * 2)) / 5)	.017667

PERSONAL COMPUTER MINIMAL SPECIFICATIONS

Description	Minimal specifications
Warranty	Minimum 3 year.
Processor	Pentium II Processor running at 400 MHz w/512 Cache.
Operating System	32-bit operating system with Graphical User Interface.
Hard Drive	3 Gb Hard drive minimum.
Memory	32 MB minimum.
CD ROM	14–32 X, IDE, integrated sound.
Floppy Drive	3.5″ 1.44 MB diskette drive.
Fax Modem	56K v.90 Data/Fax.
Monitor	17″ Color Monitor.
Graphics	MB AGP.

PERSONAL COMPUTER MINIMAL SPECIFICATIONS—Continued

Description	Minimal specifications
Mouse	Wheel mouse.
Keyboard	104 key ergonomic keyboard.
Anti Virus	Anti Virus Software.
Management Software	System management client software/license.
Printer	600 dpi Laser printer with cable.

OASIS ADJUSTMENT: ''ONE-TIME''

[For data reporting]

Type of adjustment	Source	Formula	Cost per visit
Training of Data Entry Staff	BLS Employer Provided Training (Hrs of Training 1995) & an estimated average salary for clerical personnel 1994 & 1995 HCFA Cost Report Data.	(24 hrs * $10)/30,000 avg visits	$.008
Telephone installation	Bell Atlantic Bell Atlantic 1994 & 1995 HCFA Cost Report Data.	($28 processing fee) + ($40 per line connect fee)/30,000 avg visits.	.002266
Total One Time Adjustment			.010266

• First Year of PPS One-Time Adjustment Reflecting Implementation Costs Associated with Revised OASIS Assessment Schedules needed to Classify Patients into Appropriate Case-Mix Categories for Payment.

As set forth in the home health PPS proposed rule published in the **Federal Register** on October 28, 1999, (64 FR 58134) all data necessary to classify a patient to one of the 80 HHRG categories are contained in the OASIS–B supplemented, as applicable, by one additional item regarding projected therapy use in a given 60-day episode. Under PPS, HHAs are required to use the collection and reporting requirements for the OASIS data elements published in the **Federal Register** on January 25, 1999, supplemented by one additional therapy item as applicable. We set forth the proposed changes to the OASIS schedules in the home health PPS proposed rule. We also stated that we expect that the software programs, called grouper software, that use the OASIS–B supplemented by the projected therapy variable and assign patients to the appropriate groups, will be available from many software vendors. The version we use will be available at no cost from our HCFA website on PPS. We proposed the option to build the grouper logic into the HAVEN software, which is currently used for the transmission of OASIS data for purposes of quality via the State system.

As stated in the Interim Payment System Notice published in the **Federal Register** on August 11, 1998, (63 FR 42912) we set forth the methodology for the one-time offset adjustment for the implementation of the home health OASIS. The one-time offset adjustment methodology provided financial relief to HHAs for costs associated with integrating the OASIS collection into their overall approach to comprehensive assessment of patients. The costs recognized in the one-time offset adjustment methodology included three types of costs associated with training staff, increases in assessment time during the initial implementation, and staff to revise assessment forms and integrate OASIS elements.

In response to commenters concern with costs associated with implementing the OASIS-based case-mix methodology, we believe there will be a modified one-time adjustment for HHAs to implement the revised schedules for the start of care and follow up assessments for PPS implementation. We are providing a refined methodology for the one-time adjustment for OASIS scheduling changes required by the case-mix adjustment methodology for the first year of PPS implementation. This is a one-time one year implementation adjustment. This methodology is a refined version of the offset adjustment set forth in the August 11, 1998 Interim Payment System Notice. The total offset adjustment described in the August 11, 1998 notice was applied by—

• First, multiplying the labor portion of the per-visit limitation for skilled nursing, physical therapy, speech language pathology, and occupational therapy by the factor of 1.003513 for training and forms revision;

• Secondly, adding the non-labor portion to the adjusted labor portion; and

• Thirdly, adding one cent for printing costs.

Under PPS, we are applying the same formula to the non-standardized average number and average cost per-visit amounts for episodes containing 5 or more visits for skilled nursing services, physical therapy services, speech-language pathology services, and occupational therapy services. That aggregate non-standardized amount will then be adjusted by an OASIS scheduling adjustment factor.

As part of the formal OMB clearance process (see section VI. of this regulation for OMB approval number), we requested the following modifications to the current Version Start of Care/Resumption of Care Version Form HCFA–R245A approved 6/99, Follow-Up Version Form HCFA–R245B approved 6/99 for purposes of case-mix adjusting patients under home health PPS.

• Modification to the Version Start of Care/Resumption of Care Version Form HCFA–R245A approved 6/99.

(1) New Therapy Threshold Question discussed in the background section of this package.

MO825 Therapy Need: Does the care plan of the Medicare payment period for which this assessment will define a case-mix group indicate a need for therapy (physical, occupational, or speech

therapy) that meets the threshold for a Medicare high-therapy case-mix group?

0—No

1—Yes

NA—not applicable

• Modification to the Follow-Up Version Form HCFA–R245B approved 6/99.

(1) Must add the following already approved OASIS items to the Follow-Up schedule:

MO230 Home Care Diagnosis

M0240 Other Diagnosis

MO390 Vision

(2) Must modify and add the current approved OASIS item MO170 regarding hospital discharge or nursing home care discharge within the past 14 days.

(3) Must add the therapy threshold variable (M0825) to the Follow-Up OASIS Form and Schedule.

We believe there will be a modified one-time adjustment for HHAs to implement the revised schedules for the start of care and follow up assessments as follows:

Visit by discipline	Average number of visits (A)	Average cost per visit (B)	Aggregate total ((A) * (B))
SK Nursing	14.08	$94.96	$1,337.04
PT	3.05	104.05	317.35
SPL	.18	113.26	20.39
OT	.53	104.76	55.52
Total			1730.30

Approach:

(1) Total = $1730.30

(2) Labor Portion = 1730.30 × .77668 = 1343.89, Non-Labor Portion = 1730.30 × .22332 = 386.41

(3) Adjusted Labor Portion = 1343.89 × 1.003513 = 1348.61

(4) Adjusted Labor Portion 1348.61 + Non-Labor Portion 386.41 = 1735.02

(5) .01 for printing + 1735.02 = $1735.03

(6) 1735.03/80 (80 OASIS items) = $21.69

(7) 21.69/4 (4 types of OASIS Schedules) = $5.42

(8) We believe $5.42 reflects the cost for a new item added to a new schedule. Therefore, $5.42 is the figure used to reflect the need to add the new therapy variable to Start of Care/Resumption of Care Assessment Schedules to case-mix adjust the initial episodes as part of the implementation adjustment to the 60-day non-standardized episode amount.

We must then add the cost of adding the new therapy variable to the Follow-Up Assessment Schedule as well as three already approved OASIS items. As set forth in the approach on the previous page, adding the new therapy variable to an assessment schedule is projected to cost $5.42 for the first year of implementation. In addition to the new therapy variable, three of the already approved OASIS items need to be added to the Follow-up OASIS. We estimated that adding a new item to the OASIS schedule would cost $5.42. We are applying an adjustment factor to that amount to account for the three additional already approved OASIS items to the Follow-Up Assessment schedule. We multiply the 5.42 for the new therapy variable by 3/80 (3 of the total 80 OASIS items). (We are applying a scheduling adjustment factor of 3/80 to the $5.42 amount to recognize that the three OASIS items are already approved and are only added to a new assessment schedule.) The Follow-Up Assessment schedule will now include the new therapy variable ($5.42) and the three already approved OASIS items ($5.42 * 3/80). The formula for the costs associated with the one-time first year implementation of the Scheduling Changes to the Follow-Up Assessment is as follows: $5.42 for the new therapy variable plus an additional $0.20 ($ 5.42 × .0375 or (3/80)) = $5.62 per patient per Follow-Up assessment used to case-mix adjust subsequent episodes for continuing home health care.

The non-standardized 60-day episode amount for each Start of Care 60-day episode will be adjusted to offset the one-time implementation cost and burden associated with the OASIS scheduling modifications required to implement the case-mix methodology for the first year of HHA PPS. The non-standardized 60-day episode amount for each follow-up assessment used to case-mix adjust subsequent episodes will also be adjusted. These adjustments will be combined and reflected as proportional adjustments.

Our research upon which we are basing the national PPS rate indicates that about 60 percent of episodes are completed within 60-days. We are using the following approach to reflect the one time transition:

Start of Care Assessments used for initial episodes (.60 × $5.42) + Follow-Up Assessments used for subsequent episodes (.40 × $5.62) = an adjustment of $5.50 for each non-standardized 60-day episode for the first year of PPS.

The nonstandardized average prospective payment amount must be then standardized to eliminate the effects of case-mix and wage levels among HHAs. The standard average prospective payment amount for the 60-day episode equals the nonstandardized average prospective payment amount for a 60-day episode divided by the standardization factor. The standardization factor is discussed in section IV.C.4 of this regulation. Once the payment rate is standardized, that amount is multiplied by the budget-neutrality factor. The budget-neutrality factor is discussed in section IV.C.5 of this regulation. The standardized budget-neutral amount is divided by 1.05 to account for outlier payments capped at 5 percent of total estimated outlays under PPS.

The actual national 60-day episode payment amount that will be paid to HHAs incorporates the standard average prospective payment amount adjusted to account for case-mix and wage index. All of the elements incorporated into the national 60-day episode payment amounts (the standard average prospective payment amount adjusted to account for case-mix and wage index) must be budget neutral to the interim payment system limitation amounts. Table 5 illustrates the home health prospective payment calculation.

TABLE 5.—HOME HEALTH PROSPECTIVE PAYMENT CALCULATION

Home health discipline type	Total costs for all providers in the PPS audit sample (weighted, updated to FY 2001, and visit limit adjusted)	Total visits for all providers in the PPS audit sample (weighted)	Average cost per visit from the PPS audit sample	Average number of visits for episodes with >4 visits from the CY 1998 episode file	Home health prospective payment rate
Home Health Aide Services	5,915,395,602	141,682,907	$41.75	13.4	$559.45
Medical Social Services	458,571,353	2,985,588	153.59	.32	49.15
Occupational Therapy Services	444,691,130	4,244,901	104.76	.53	55.52
Physical Therapy Services	2,456,109,303	23,605,011	104.05	3.05	317.35
Skilled Nursing Services	12,108,884,714	127,515,950	94.96	14.08	1,337.04
Speech Pathology Services	223,173,331	1,970,399	113.26	.18	20.39

Total Non Standardized Prospective Payment Amount Per 60-Day Episode For FY 2001	2,338.90
Average Cost per Episode for Non Routine Medical Supplies included in the home health benefit and reported as costs on the Cost Report	43.54
Average Payment per Episode for Non Routine Medical Supplies possibly unbundled and billed separately to Part B	6.08
Average Payment per Episode for Part B Therapies	17.67
Average Payment per Episode for OASIS One Time Adjustment for form changes	5.50
Average Payment per Episode for Ongoing OASIS Adjustment Costs	4.32
Total Non Standardized Prospective Payment Amount Per 60-Day Episode For FY 2001 Plus Medical Supplies & Ongoing OASIS	2,416.01

Total non standardized prospective payment amount per 60-day episode for FY 2001	Standardization factor for wage index and case-mix [1]	Budget neutrality factor [2]	Outlier adjustment factor [3]	Final standardized and budget neutral prospective payment amount per 60-day episode for FY 2001
$2,416.01	.96184	.88423	1.05	$2115.30

[1] (Based on 100% episode wage indicies with therapy/nontherapy factors based on ABT data).
[2] (Budget neutral to current IPS).
[3] (Adjustment to PPS rate to account for 5% of total payments to outlier episodes).

CALCULATION FOR NON ROUTINE MEDICAL SUPPLIES PER EPISODE AMOUNT INCLUDED IN THE HOME HEALTH BENEFIT

Non routine medical supplies included in the home health benefit and reported as costs on the cost report [1]	Total number of episodes for those providers in the audited cost report sample [2]	Average cost per episode for non routine medical supplies included in the home health benefit and reported as costs on the cost report	Market basket update factor to FY 2001 [3]	Average cost per episode for non routine medical supplies included in the home health benefit and reported as costs on the cost report
$234,547,615	5,733,010	$40.91	1.0643	$43.54

[1] Source: Audited Cost Report Data from the audit sample updated to FY 2001 and weighted to National Totals.
[2] Source: Calendar Year 1998 Episode file.
[3] Cumulative Market Basket Update Factor for years 1999–2001.

CALCULATION FOR NON ROUTINE MEDICAL SUPPLIES POSSIBLY UNBUNDLED AND BILLED UNDER PART B

Non routine medical supplies possibly unbundled and billed separately to part B and reimbursed on the fee schedule [1]	Total number of episodes for all providers in the calendar year 1998 file adjusted for estimated total episodes in FY 2001 [2]	Average payment per episode for non routine medical supplies possibly unbundled and billed separately to part B	DME fee schedule update to FY 2001 [3]	Updated average payment per episode for non routine medical supplies possibly unbundled and billed separately to part B
$37,526,132.26	6,170,887	$6.08	1.0	$6.08

[1] Source: 1998 National Claims History Part B file extract for 178 codes matched to the 60-day episode file by beneficiary and dates of service.
[2] Source: Calendar Year 1998 Episode file.
[3] There exists no update to the DME Fee Schedule affecting Non Routine Medical Supplies for years 1999–2001.

CALCULATION FOR THE PART B THERAPIES

Therapy services billed separately to part B	Total number of episodes for all providers in the calendar year 1998 file adjusted for estimated total episodes in FY 2001 [2]	Average payment per episode for part B therapies	Physician fee schedule updates to FY 2001 [3]	Updated average payment per episode for part B therapies
$94,200,316.08	6,170,887	$15.27	1.157	$17.67

[1] Source: 1998 National Claims History Part B extract file for 57 CPT therapy codes for Physician/Supplier claims and for the physical therapy, occupational therapy, and speech therapy revenue center codes matched to the 60 Day episode file by beneficiary and dates of service.

[2] Source: Calendar Year 1998 Episode file.
[3] Cumulative Update Factor for Part B Therapies based on Physician Fee Schedule Updates for years 1999–2001.

Each component of the methodology is discussed below.

1. Cost Data—60-Day Episode Payment

The audited cost data is discussed above in detail in section IV. of this regulation. The data source used in developing the national mean cost per visit for a 60-day episode is the audited cost report sample database. We calculated the national mean cost per visit for each of the six disciplines (skilled nursing, physical therapy, occupational therapy, speech-language pathology services, medical social services, and home health aide services) used in a 60-day episode. The data source in developing the average cost per episode for nonroutine medical supplies paid on a reasonable-cost basis under a home health plan of care is the audited cost report sample database also discussed in section III. this regulation.

2. Utilization Data—60-Day Episode Payment

As discussed above, developing the national mean number of visits for each of the six disciplines in a 60-day episode resulted from the thorough analysis of the national claims history.

3. Updating the Data

The HHA market basket index reflects changes over time in the prices of an appropriate mix of goods and services included in covered HHA services. The HHA market basket index is used to develop the national 60-day episode payment rates. The data used to develop the HHA PPS rates were adjusted using the latest available market basket increases occurring between the cost reporting periods contained in our database and September 30, 2001. For each of fiscal years 2002 and 2003, section 1895(b)(3)(B)(ii) of the Act requires the standard prospective payment amounts be increased by a factor equal to the home health market basket minus 1.1 percentage points. In addition, for any subsequent fiscal years, the statute further requires the rates to be increased by the applicable home health market basket index change. A complete discussion concerning the design and application of the HHA market basket index and the factors used in developing the 60-day episode payment rates is discussed in section IV.B.2. of the regulation.

4. Standardization Factor

Section 1895(b)(3)(A)(i) of the Act requires that the prospective payment amounts be standardized to eliminate the effects of variation in wage levels and case-mix among HHAs. The objective of standardization is to ensure that the wage-index and case-mix adjustments to the episode payment amount do not alter the aggregate payments that would occur in the absence of these adjustments. All the estimates described in this section are based on episodes with more than four visits since only those episodes will be paid on a per-episode basis.

Several types of information are required for standardization. To account for wage differences, the proportion of labor and nonlabor components of HHA costs must be identified. These proportions are based on the relative importance of the different components of the HHA market basket index. As calculated, the labor-related portion of cost is 77 percent and the nonlabor-related portion is 23 percent. Wage differences are measured using the hospital wage index. In standardizing the episode payment amount, we used the pre-floor and pre-reclassified FY 2000 hospital wage index, which is based on FY 1996 hospital wage data. For application of the wage index, the statute allows us to use the service area or any other area we specify. As noted in the proposed rule, to be consistent with the current interim payment system, the wage index value that will be applied to the labor portion of the episode amount will be the appropriate wage index for the geographic area where the beneficiary received home health services. The best source of data on wage-index variation among 60-day episodes that was available for standardization was the episode data set that we constructed from 1998 Medicare home health claims.

To account for case-mix differences, it is necessary to have information on the distribution of 60-day home health episodes among the 80 groups of the HHRG case-mix system. For this final rule, we were able to examine more data on case-mix variation than was available for the proposed rule. For the proposed rule, the only available data on episodes classified by HHRG was the Abt data set that was used to develop the HHRG case-mix classification system. For the final rule, we had access to an updated (and larger) Abt data set, early data from the OASIS national repository, and the 1998 episode file constructed from Medicare claims to which we were able to assign average therapy and non-therapy HHRG weights.

We first compared the Abt data to the data from the OASIS national repository. We compared the distributions of the responses to the OASIS items used in constructing the HHRGs. In addition, we compared the distributions of the HHRGs for both of these data sets. This comparison had to be made using only 40 of the 80 HHRGs as therapy assignments could not be made from the national OASIS data. (Time lags in the receipt of claims for episodes corresponding to the OASIS from the national repository prevented us from making therapy assignments for the national OASIS data.) Despite this limitation, the comparisons we were able to make showed a high degree of similarity between the two data sources and increased our confidence that the Abt data set is representative of national case-mix variation.

We next compared the Abt data to the 1998 episode data set derived from Medicare claims. In particular, we compared the distributions of estimated cost for the two data sets. Cost was estimated by multiplying the national per-visit costs for each discipline by the number of visits in each discipline and summing the total. Cost distributions were constructed for the Abt data using both samples, with and without applying the population weights described in the proposed rule. We found that the cost distribution of the unweighted Abt data matched the 1998 episode data much more closely than did the weighted Abt data. From this analysis, we concluded that the unweighted Abt data provided a good basis for comparison of standardization factors.

To make full use of the available data, we developed the following strategy for standardizing the episode amount:

- First, we estimated three standardization factors using the Abt data set. The first one accounts only for variation in wage index values; the second accounts for wage index and case-mix variation, using all 80 HHRGs; the third accounts for wage index and case-mix variation, using HHRG weights collapsed to therapy and non-therapy averages. All three Abt standardization factors are very similar: .97510, .97945, and .97888, respectively.
- Then, we estimated two standardization factors using the 1998 national claims episode data: a wage-only factor and a wage and two case-mix groups factor. The wage-only standardization factor was .95808, compared to .97510 for the

corresponding factor using the Abt data. The wage index and two case-mix groups standardization factor was .96183, compared to .97887 for the corresponding factor from the Abt data.

For several reasons, we decided to use the wage index and two case-mix groups factor from the 1998 national claims data as the final standardization factor for this rule.

- First, the national claims data provides the most reliable estimate of the effects of wage index variation;
- Second, there was hardly any difference in the wage and case-mix standardization factors based on the Abt data using either 80 HHRGs or the collapsed two-groups;
- Third, overall there was a high degree of similarity of values obtained from all of the various methods.

Each of the estimates of the standardization factor was calculated in the following manner:

- For each episode (or in the case of the Abt data, the number of episodes represented by each sample episode), the appropriate wage index value was multiplied by the labor-related proportion of cost (.77668) and added to the nonlabor-related proportion (.22332) to obtain a wage-adjustment factor;
- In turn, the wage-adjustment factor was multiplied by the HHRG relative weight;
- The product of the wage and case-mix factors was summed over all episodes in the database, yielding a case-mix and wage-adjusted episode sum;
- Dividing the case-mix and wage-adjusted episode sum by the total number of episodes (the unadjusted episode sum) yields the standardization factor, a ratio that indicates how the combined effects of wage and case-mix variation impact aggregate payments;
- If the standardization factor is greater than one, the unstandardized episode cost must be reduced to account for the aggregate payment effect of the case-mix and wage index payment adjustments;
- If the factor is less than one, then the unstandardized episode cost must be increased to accomplish the same objective. The standardized episode amount is equal to the unstandardized episode cost divided by the standardization factor. Note that all three of our estimates were less than one, which implies that the standardization factor increases the standard episode amount. Our final standardization factor produces an increase of about 4.7 percent.

5. Budget-Neutrality Factor

To determine the budget neutrality adjustment, we use our most current estimate of incurred costs for home health expenditures in FY 2001 under the interim payment system (IPS). Under the President's FY 2001 Budget assumptions, we are projecting this amount to be $11,273 million. This amount includes the medical supplies which were billed separately under IPS but will be bundled under PPS. Our best estimate of what would be spent in FY 2001 on Part B therapies not currently included in the home health benefit but which will be covered by the benefit under PPS is $109 million. We did not include this in the home health spending for the FY 2001 budget because we had not yet determined it needed to be added to the spending target. We are adding $109 million to the $11,273 million to determine the total spending target for home health PPS spending, $11,382 million. We are estimating that there would have been 137,271,000 visits incurred in FY 2001. The following table outlines the variables used to determine the adjustment:

Period (1)	Visits (2)	Visits/per episode (3)	Number of episodes (4)
CY 1997	280,569,000	30.99	9,054,000
CY 1998	163,208,000	26.88	6,072,000
FY 2001	137,271,000	.....	.....

Column (2) represents the actuaries' best estimate of the number of visits incurred in each of the time periods. These numbers differ from the number of visits in the episode files. The episode files were created to analyze visits per episode and were not meant to be the basis for the actual number of visits incurred in calendar years 1997 and 1998.

Column (3) was determined from the episode files we had created. Column (4) was determined by dividing Column (2) by Column (3) and rounding to the nearest thousand. From these numbers we need to determine the number of visits per episodes we would have if we had an episode file created for 2001. This would then allow us to determine the number of episodes there will be in 2001.

From the table, we can see that the number of visits declined by about 42 percent from CY 1997 to CY 1998. The episode file analysis showed that one-third of this decline was due to a decline in the number of visits per episode. Between CY 1998 and FY 2001, we are projecting a further 16 percent decline in the number of visits. We are assuming that one-third of this decline will be attributable to the decline in the number of visits per episode. This results in number of visits per episode of 25.5. Dividing 137,271,000 visits by 25.5 results in 5,383,000 episodes. This would be the number of expected episodes if episodes were not all starting on October 1, 2001. Because all patients being served at the beginning of the fiscal year will be starting a new episode on October 1, we will be making more episode payments in that first year. We will be paying for an increased number of episodes in FY 2001 compared to what would have been paid if patients entered PPS only after their current period of home health care ended. To account for this first-year anomaly, we increased the number of episodes by 3.66 percent over the 5,383,000 determined above. This results in a projected number of episodes of 5,580,000 incurred in FY 2001. In fiscal years 2002 and later we will be adding $79 to the episode payment since this anomaly will no longer exist in those years.

These 5,580,000 episodes need to be split into full episodes and LUPA episodes since our current number of projected visits includes both. We estimate that 5 percent of episodes will be ones with four or fewer visits. Therefore, 95 percent will receive a full episode payment. The 1998 episode file showed that 16 percent of episodes would have received a LUPA payment. Of this 16 percent, only 26 percent or 4 percent of the total were cases where only 1 to 4 visits were provided in a single 60-day, non-contiguous period. These cases would clearly receive LUPA payments under PPS. Twelve percent of total episodes have less than five visits but were episodes which fell at the end of a series of prior episodes. Under a plan of care established for PPS these ''episode end'' visits may not exist. Because of the nature of how the episode file created LUPA episodes, we

feel that LUPA payments will make up a smaller portion of payments than was shown in the episode file. The determination of this adjustment factor to the episode payment is as follows:

Number of LUPA episodes	Average LUPA payment	Number of full episodes (non-LUPA)	Average full episode (non-LUPA) payment
5,580,000 × .05 = 279,000	$205.20	5,580,000 × .95 = 5,301,000	$2,416.01

	LUPA	Full episode
Projected Payments Before Neutrality	(279,000 × $205.20) + (5,301,000 × $2,416.01)	
	= $57.25 million	= $12,807 million

Projected Incurred Spending in FY 2001: $11,382 million

Budget Neutrality Adjustment Factor = (11,382–57.25)/ 12,807 = 0.88423

After applying this adjustment to the full episode payments, we expect to have the following incurred payments in FY 2001: $57.25 million for LUPA payments plus 5,301 × $2,416.01 × .88423 = $11,325 million in full episode payments, totaling $11,382 million.

D. Methodology Used for Low-Utilization Payments

As discussed above, section 1895(b)(1) of the Act requires the development of the definition of the unit of payment or episode to take into consideration the number, type, duration, mix, and cost of visits provided within the unit of payment. As a result of our analysis, we determined the need to also recognize a low-utilization payment under HHA PPS. Low-utilization payment would reduce the 60-day episode payments, PEP adjustment or the SCIC adjustment to those HHAs that provide minimal services to patients during a 60-day episode.

Payments for low-utilization episodes will be made on a per-visit basis using the cost per-visit rates by discipline determined from the audited cost report sample for calculation of the standard episode amount. Included in these per-visit amounts are amounts for (1) nonroutine medical supplies paid under a home health plan of care, (2) nonroutine medical supplies possibly unbundled to Part B, (3) a per-visit ongoing OASIS reporting adjustment as discussed above, and (4) a one-time one year adjustment reflecting costs associated with OASIS assessment schedule refinements needed to implement the case-mix methodology in section IV.G. of this regulation. We did not add a per-visit rate adjustment for therapies possibly unbundled to Part B as we did for the per-episode payments. Based on the analysis of the Part B therapy date, we found that blending the higher and lower therapy per-visit amounts creates an anomalous result. We know the per-visit amounts provided in Table 6 are appropriate. These per-visit ''prices'' would be updated in the same manner as the standard episode amount. However, as discussed in the responses to comment section, we have revised our approach to the calculation of the amount paid for each visit price per discipline. We are retaining the four or fewer visit threshold for the LUPA, but are increasing the proposed amount by using the standardized wage adjusted national average cost per visit by discipline amounts updated by the market basket to FY 2001. See the response to comment in section III. of this rule for further clarification.

For low-utilization payments, they would be adjusted by the wage index in the same manner as the standard episode amount. However, the low-utilization payments are not case-mix adjusted. The standardization factor used to adjust the LUPAs was calculated using national claims data for episodes containing four or fewer visits. This standardization factor includes adjustments only for the wage index. The ''savings'' from the reduced episode payments would be redistributed to all episodes.

Below is Table 6 which presents the home health low-utilization provider adjustment payment calculation.

TABLE 6.—HOME HEALTH LOW-UTILIZATION PROVIDER ADJUSTMENT PAYMENT CALCULATION

Home health discipline type	Average cost per visit from the PPS audit sample	Average cost per visit for non routine medical supplies reported as costs on the cost report	Average cost per visit for non routine medical supplies possibly unbundled and billed separately to part B and reimbursed on the fee schedule	Average cost per visit for on-going OASIS adjustment costs [3]	Ave cost per visit for one-time OASIS scheduling implementation change	Standardization factor for wage index [1]	Outlier adjustment factor [2]	Final wage standardized per visit payment amounts per 60-day episode for FY 2001
Home Health Aide Services	$41.75	$1.71	$0.23	$0.12	$.21	.96674	1.05	$43.37
Medical Social Services	153.59	1.71	0.23	0.12	.21	.96674	1.05	153.55
Occupational Therapy. Services	104.76	1.71	0.23	0.12	.21	.96674	1.05	105.44

TABLE 6.—HOME HEALTH LOW-UTILIZATION PROVIDER ADJUSTMENT PAYMENT CALCULATION—Continued

Home health discipline type	Average cost per visit from the PPS audit sample	Average cost per visit for non routine medical supplies reported as costs on the cost report	Average cost per visit for non routine medical supplies possibly unbundled and billed separately to part B and reimbursed on the fee schedule	Average cost per visit for on-going OASIS adjustment costs [3]	Ave cost per visit for one-time OASIS scheduling implementation change	Standardization factor for wage index [1]	Outlier adjustment factor [2]	Final wage standardized per visit payment amounts per 60-day episode for FY 2001
Physical Therapy Services	104.05	1.71	0.23	0.12	.21	.96674	1.05	104.74
Skilled Nursing Services	94.96	1.71	0.23	0.12	.21	.96674	1.05	95.79
Speech Pathology Services	113.26	1.71	0.23	0.12	.21	.96674	1.05	113.81

[1] (Based on 100% episode for episodes with 4 or fewer visits and wage index only standardization factor)
[2] (Adjustment to PPS rate to account for 5% of total payments to outlier episodes)
[3] (See Section II.A.3 for description of calculation of OASIS Adjustment cost)

CALCULATION FOR NON ROUTINE MEDICAL SUPPLIES PER-VISIT AMOUNT INCLUDED IN THE HOME HEALTH BENEFIT

Non routine medical supplies included in the home health benefit and reported as costs on the cost report [1]	Total number of visits for those providers in the audited cost report sample [2]	Average cost per visit for non routine medical supplies included in the home health benefit and reported as costs on the cost report	Market basket update factor to FY 2001 [3]	Updated average cost per visit for non routine medical supplies included in the home health benefit and reported as costs on the cost report
$234,547,615	145,658,396	$1.61	1.0643	$1.71

[1] Source: Audited Cost Report Data from the audit sample updated to FY 2001 and weighted to National Totals.
[2] Source: Calendar Year 1998 Episode file.
[3] Cumulative Market Basked Update Factor for years 1999–2001.

CALCULATION FOR NON ROUTINE MEDICAL SUPPLIES PER-VISIT AMOUNT POSSIBLY UNBUNDLED AND BILLED UNDER PART B

Non routine medical supplies possibly unbundled and billed separately to part B and reimbursed on the fee schedule [1]	Total number of visits for all providers in the calendar year 1998 file [2]	Average payment per visits for non routine medical supplies possibly unbundled and billed separately to part B	DME fee schedule update to FY 2001 [3]	Updated average payment per visits for non routine medical supplies possibly unbundled and billed separately to part B
$37,526,132.26	163,208,000	$0.23	1.0	$0.23

[1] Source: 1998 National Claims History Part B file extract for 178 codes matched to the 60-day episode file by beneficiary and dates of service.
[2] Source: Calendar Year 1998 Episode file.
[3] There exists no update to the DME Fee Schedule affecting Non Routine Medical Supplies for years 1999–2001.

CALCULATION FOR ONE-TIME OASIS SCHEDULING IMPLEMENTATION FOR FORM CHANGES

Total cost for OASIS scheduling implementation change [1]	Total number of visits for all providers in the calendar year 1998 file [2]	Average payment per visits for part B therapies possibly unbundled and billed separately to part B physician/supplier
$33,939,878 .50	163,208,000	$0.21

[1] Episode Rate for OASIS Scheduling Implementation Change ($5.50) / the total number of episodes in 1998 (6,170,887).
[2] Calendar year 1998 Episode File.

E. Methodology Used for Outlier Payments

As discussed above, while we are not statutorily required to make provisions for outlier payments, we are establishing outlier payments. Outlier payments are payments made in addition to regular 60-day case-mix-adjusted episode payments for episodes that incur unusually large costs due to patient home health care needs. Outlier payments are made for episodes whose estimated cost exceeds a threshold amount for each HHRG. The outlier threshold for each HHRG is defined as the 60-day episode payment for the HHRG plus a fixed dollar loss amount that is the same for all case-mix groups. Outlier payments are made for 60-day episode payments that reflect a PEP adjustment or SCIC adjustment. The PEP adjustment results in a truncated episode period and a SCIC adjustment results in a total of the proportional payments over a 60-day episode, but these periods could still incur unusually large costs. The outlier threshold for the PEP adjustment is the PEP adjustment plus the fixed dollar loss. The outlier threshold for the SCIC adjustment

equals the total SCIC payment plus a fixed dollar loss. The wage adjusted component discussed below will be applied consistently for the 60-day episode payment, the PEP adjustment, and the total SCIC adjustment. The outlier payment is defined to be a proportion of the wage adjusted estimated costs beyond the wage adjusted threshold. The threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and the wage-adjusted fixed dollar loss amount. The proportion of additional costs paid as outlier payments is referred to as the loss-sharing ratio.

The fixed dollar loss amount and the loss-sharing ratio are chosen so that estimated total outlier payments are 5 percent of total episode payments. The 5 percent constraint on total outlier payments creates a tradeoff between the values selected for the fixed dollar loss amount and the loss-sharing ratio. For a given level of outlier payments, a higher fixed dollar loss amount reduces the number of cases that receive outlier payments, but makes it possible to select a higher loss-sharing ratio and, therefore, increase outlier payments per episode. Alternatively, a lower fixed dollar loss amount means that more episodes qualify for outlier payments, but outlier payments per episode must be lower. Therefore, setting these two parameters involves policy choices about the number of outlier cases and their rate of payment.

We initially proposed a loss sharing ratio of .60 and a fixed dollar loss of 1.07 times the national standard episode payment amount. For the proposed rule, we estimated that with these variables, 7.5 percent of total episodes would have qualified for an outlier payment while holding total outlier outlays at 5 percent of outlays in a given fiscal year. In response to comments, we are increasing the loss sharing ratio from 0.60 to 0.80 to provide greater compensation for the episodes that qualify for outlier payments. We believe that this change is appropriate and will continue to monitor the impacts of the outlier policy under PPS implementation.

The simulations conducted for the proposed rule found that a loss sharing ratio of 0.80 would require a fixed dollar loss ratio of 1.35. We have rerun these simulations using the expanded and updated Abt data and are making some refinements in our simulation methods.

The new simulations also reflect the refinements for wound cases that have been incorporated into the case-mix system. The results of the new simulations indicate that a fixed dollar loss ratio of 1.13 is consistent with a loss sharing ratio of 0.80. With these parameters, we estimate that about 6.8 percent of episodes would qualify for outlier payments with total outlier outlays equal to the required 5 percent.

In estimating the final outlier policy parameters, we examined OASIS data from the national repository, an episode data set created from 1998 Medicare home health claims, and an updated and expanded data set from the Abt case-mix study. As noted in our discussion of standardization, we compared the OASIS and the Abt data in terms of the responses to the 18 OASIS items used for case-mix classification and in terms of the distribution of episodes across the HHRGs. We also compared the Abt and the 1998 episode data and found that the estimated cost distribution based on the pattern of visits within episodes was very similar in both sets of data. These comparisons increased our confidence in using the Abt data to simulate the outlier policy parameters. In addition, the Abt data is the most complete data currently available for estimating outlier policy variables. It contains information on all 80 HHRGs and a measure of resource cost for each episode. The Abt data set used for the final outlier policy is about 15 percent larger than the data set that was used for the estimates in the proposed rule.

The fixed dollar loss estimate was based on simulations that calculated PPS payments and costs for each episode in the data set. Payments were calculated twice, once for a PPS without outlier payments and again for a PPS with outlier payments. For the payment system with outlier payments, the LUPA and episode payment amounts were deflated by 1.05. Using a loss sharing ratio of 0.80, the simulation was repeated until a fixed dollar loss ratio was found that resulted in (1) equal total payments for the PPS with and without outlier payments, and (2) total outlier payments equal to 5 percent of total payments, including outlier payments. In addition, payment amounts were set to equate total payments and total costs. Because the Abt data does not represent all wage areas of the country, the simulations did not apply the wage index adjustments that will be applied to actual outlier payments. It was not possible to account for PEP or SCIC adjustments in the simulations.

Simulations were performed to obtain the most reasonable estimates possible of the fixed dollar loss ratio consistent with the 5 percent outlier payment target. Based on the experience of the Phase II per-episode prospective payment demonstration and the interim payment system, we were concerned that agencies may reduce utilization for high-cost episodes in response to the budget neutral episode payment rate. If our simulations failed to account for such reductions, the simulations might overestimate agencies' losses and lead us to set the fixed dollar loss amount higher than necessary to meet the 5 percent target. We incorporated estimates of cost reduction into our simulations that resulted in a lower fixed dollar loss ratio lower than would have been chosen otherwise. In general, we assumed that any reduction in payment rates below the level of the mean cost would be matched by a cost reduction of equal percentage.

Simulations were also performed to test the sensitivity of the fixed dollar loss to alternative proportions of LUPA episodes. LUPAs can affect the fixed dollar loss ratio consistent with a 0.8 loss sharing ratio. Because they are paid much less than regular episodes, substantial differences in their frequency can affect estimated total payments. Due to the asymmetric impacts on outlier and total payments, variations in the frequency of LUPAs could potentially lead to either overestimation or underestimation of the 5 percent outlier target.

LUPAs comprise 11.6 percent of the episodes in the Abt data used for the outlier simulations. Given the incentives under the PPS to obtain the 60-day episode payment rather than the LUPA payment, we believe that 11.6 percent overestimates the frequency of LUPAs that are likely to occur under PPS. As a result, we simulated the outlier policy under alternative percentage of LUPA episodes.

It is also worth noting that the case-mix refinements for wound cases improved regular episode payments and reduced the need for outlier payments for these cases.

The following is a case for illustrative purposes only. An HHA serves a Medicare beneficiary in State College PA. The HHA determines the patient is in HHRG C2F2S2. The patient had physician orders for and received 55 skilled nursing visits and 40 home health aide visits during the 60-day episode.

1. Calculation of the Wage-Adjusted Outlier Threshold

The Wage-Adjusted Outlier Threshold Amount is the sum of the Wage and Case-Mix Adjusted 60-Day Episode Amount and the Wage-Adjusted Fixed Dollar Loss Amount.

a. Calculate Case-Mix and Wage-

Adjusted Episode = $3,855.31
Case-Mix Weight = 1.9532

Standard 60-Day Prospective Episode Payment Amount = $2,115.30
Calculate the Case-Mix Adjusted Episode Payment
Multiply the Standard 60-Day Prospective Episode Payment Amount by the Applicable Case-Mix Weight = (1.9532 * $2,115.30) = $4,131.60
Divide the Case-Mix Adjusted Episode Payment into the Labor and Non-Labor Portions
Labor Portion = (.77668 * $4131.60) = $3,208.93
Wage-Adjust the Labor Portion by Multiplying the Labor Portion by the Wage Index Factor (.9139 * $3,208.93) = $2,932.64
Calculate Non-Labor Portion = (.22332 * $4,131.60) = $922.67
Add Wage-Adjusted Labor Portion to Non-Labor Portion to Calculate the Total Case-Mix and Wage-Adjusted Episode Payment = (2,932.64 + $922.67) = $3,855.31
b. Calculate Wage-Adjusted Fixed Dollar Loss Amount = $2,230.45
Fixed Dollar Loss Amount = Standard 60-Day Episode Payment Multiplied by 1.13 ($2115.30 * 1.13) = $2,390.29
Divide Fixed Dollar Loss Amount into Labor and Non Labor Portions:
Calculate Labor Portion of Fixed Dollar Loss Amount = (.77668 * $2,390.29) = $1,856.49
Wage Adjust the Labor Portion by Multiplying the Labor Portion of the Fixed Dollar Loss by Multiplying the Labor Portion of the Fixed Dollar Loss Amount by the Wage Index (.9139 * $1,856.49) = $1,696.65
Calculate Non-Labor Portion of Fixed Dollar Loss Amount = (.22332 * $2,390.29) = $533.80
Calculate Total Wage Adjusted Fixed Dollar Loss Amount by adding the wage adjusted portion of the fixed dollar loss amount to the non labor portion of the fixed dollar loss amount ($1,696.65 + $533.80) = $2,230.45
Wage-Adjusted Outlier Threshold = Case-Mix and Wage-Adjusted Episode Amount + Wage Adjusted Fixed Dollar Loss Amount = ($3,855.31 + $2,230.45) = $6,085.76
2. Calculate the Wage-Adjusted Imputed Cost of the Episode
Multiply the total number of visits by the national average per-visit amounts listed in Table 6.
55 skilled nursing visits * $95.79 (national average per skilled nursing visit cost) = $5,268.45
40 home health aide visits * $43.37 (national average per home health aide visit cost) = $1,734.80
Calculate the wage-adjusted labor and non-labor portions for the imputed skilled nursing visit costs
Labor Portion = ($5,268.45* .77668) = $4,091.90
Adjust the labor portion by the wage index
Wage Adjusted Skilled Nursing Labor Portion = ($4,091.90 * .9139) = $3,739.59
Wage Adjusted Skilled Nursing Labor Portion = $3,739.59
Calculate the Skilled Nursing Non-Labor Portion
Non-Labor Portion = ($5,268.45 * .22332) = $1,176.55
Non-Labor Skilled Nursing Portion = $1,176.55
Total Wage Adjusted Imputed Costs for Skilled Nursing Visits = $4,916.14
(Wage Adjusted Skilled Nursing Labor Portion of $3,739.59 + Non-Labor Skilled Nursing Portion of $1,176.55) = $ 4,916.14
Calculate the wage adjusted labor and non-labor portions for the imputed home health aide visit costs
Labor Portion = ($1,734.80 * .77668) = $1,347.38
Adjust the labor portion by the wage index
Wage Adjusted Home Health Aide Labor Portion = ($1,347.38 * .9139) = $1,231.37
Wage Adjusted Home Health Aide Labor Portion = $1,231.37
Calculate the Home Health Aide Non-Labor Portion
Non-Labor Portion = ($1,734.80 * .22332) = $387.42
Non-Labor Home Health Aide Portion = $387.42
Total Wage Adjusted Imputed Costs for Home Health Aide Visits = $1,618.79
(Wage Adjusted Home Health Aide Labor Portion of $1,231.37 + Non-Labor Home Health Aide Portion of $387.42) = $ 1,618.79
Total Wage Adjusted Imputed Costs for Skilled Nursing and Home Health Visits During the 60 Day Episode = ($4,916.14 + $1,618.79) = $ 6,534.93
3. Calculate the Amount Absorbed by the HHA in Excess of the Outlier Threshold Subtract the Outlier Threshold from the Total Wage Adjusted Imputed Per-Visit Costs for the Episode
$6534.93 (Total Imputed Wage Adjusted Per-Visit Costs)—$6,085.76 (Outlier Threshold) = $449.17
Imputed Amount in Excess of the Outlier Threshold = $449.17
4. Calculate Outlier Payment by Multiplying the Imputed Amount in Excess of the Outlier Threshold Absorbed by the HHA By the Loss Sharing Ratio (80%)
($449.17 (Imputed Amount in Excess of the Outlier Threshold Absorbed by the HHA * .80 (Risk Sharing Ratio) = $359.34
Outlier Payment = $359.34
The HHA in this illustrative example would receive the total case-mix and wage adjusted 60-day episode payment of *$3,855.31* plus the additional outlier payment of *$359.34*
Total Payment (Episode & Outlier Payment) = ($3,855.31 + 359.34) = $4,214.65

F. Examples of National Standardized 60-Day Episode Payment Amounts and Low-Utilization Payment Adjustments

For any HHRG group, to compute a case-mix and wage-adjusted 60-day episode prospective payment amount, the standardized prospective payment rate for FY 2001 (see Table 5 of this regulation) is multiplied by the case-mix index from Table 9 for that HHRG group. To compute a wage-adjusted national 60-day episode payment, the labor-related portion of the 60-day national prospective payment rate for FY 2001 is multiplied by the HHA's appropriate wage index factor listed in Table 4A or 4B. The product of that calculation is added to the corresponding nonlabor-related component. The resulting amount is the national case-mix and wage-adjusted 60-day episode prospective payment rate for FY 2001.

Example 1. An HHA is providing services to a Medicare beneficiary in State College, PA. The HHA determines the beneficiary is in HHRG C2F2S2.

COMPUTATION OF CASE-MIX AND WAGE ADJUSTED PROSPECTIVE PAYMENT AMOUNT

Case-mix index from Table 9 for case-mix group	1.9532
Standardized Prospective Payment Rate for FY 2001	$2,115.30

COMPUTATION OF CASE-MIX AND WAGE ADJUSTED PROSPECTIVE PAYMENT AMOUNT—Continued

Calculate the Case-Mix adjusted Prospective Payment Rate for FY 2001	(1.9532 * $2,115.30)	$4,131.60
Calculate the Labor portion of the Prospective Payment Rate for FY 2001	(.77668 * $4,131.60)	$3,208.93
Apply wage index factor from Table 4B for patient in State College, PA	(0.9139 * $3,208.93)	$2,932.64
Calculate the Non-Labor portion of the Prospective Payment Rate for FY 2001	(.22332 * $4,131.60)	$922.67
Calculate Total Prospective Payment Rate for FY 2001 by adding the labor and non labor portion of the case-mix and wage index amounts	($2,932.64 + $922.67)	$3,855.31

Example 2. An HHA serves a beneficiary who resides in Lake Placid, NY. The HHA determines the patient is in HHRG C1F4S3.

COMPUTATION OF CASE-MIX AND WAGE ADJUSTED PROSPECTIVE PAYMENT AMOUNT

Case-mix index from Table 9 for case-mix group		2.2360
Standardized Prospective Payment Rate for FY 2001		$2,115.30
Calculate the Case-Mix adjusted Prospective Payment Rate for FY 2001	(2.2360 * $2,115.30)	$4,729.81
Calculate the Labor portion of the Prospective Payment Rate for FY 2001	(.77668 * $4,729.81)	$3,673.55
Apply wage index factor from Table 4A for patient in Lake Placid, NY	(0.8637 * $3,673.55)	$3,172.85
Calculate the Nonlabor portion of the Prospective Payment Rate for FY 2001	(.22332 * $4,729.81)	$1,056.26
Calculate Total Prospective Payment Rate for FY 2001 by adding the labor and nonlabor portion of the case-mix and wage index amounts	($3,172.85 + $1,056.26)	$4,229.11

Example 3. HHA serves a beneficiary who resides in Fort Collins, CO. The HHA determines the beneficiary is in HHRG C3F0S0.

COMPUTATION OF CASE-MIX AND WAGE ADJUSTED PROSPECTIVE PAYMENT AMOUNT

Case-mix index from Table 9 for case-mix group		1.1973
Standardized Prospective Payment Rate for FY 2001		$2,115.30
Calculate the Case-Mix adjusted Prospective Payment Rate for FY 2001	(1.1973 * $2,115.30)	$2,532.65
Calculate the Labor portion of the Prospective Payment Rate for FY 2001	(.77668 * $2,532.65)	$1,967.06
Apply wage index factor from Table 4B for patient in Fort Collins, CO	(1.0303 * $1,967.06)	$2,026.66
Calculate the Non-Labor portion of the Prospective Payment Rate for FY 2001	(.22332 * $2,532.65)	$565.59
Calculate Total Prospective Payment Rate for FY 2001 by adding the labor and non labor portion of the case-mix and wage index amounts	($2,026.66 + $565.59)	$2,592.25

Example 4. HHA serves a beneficiary who resides in Grand Forks, ND. The HHA determines the beneficiary is in HHRG C0F3S1.

COMPUTATION OF CASE-MIX AND WAGE ADJUSTED PROSPECTIVE PAYMENT AMOUNT

Case-mix index from Table 9 for case-mix group		.8438
Standardized Prospective Payment Rate for FY 2001		$2,115.30
Calculate the Case-Mix adjusted Prospective Payment Rate for FY 2001	(.8438 * $2,115.30)	$1,784.89
Calculate the Labor portion of the Prospective Payment Rate for FY 2001	(.77668 * $1,784.89)	$1,386.29
Apply wage index factor from Table 4B for patient in Grand Forks, ND	(0.9098 * $1,386.29)	$1,261.25
Calculate the Non-Labor portion of the Prospective Payment Rate for FY 2001	(.22332 * $1,784.89)	$398.60
Calculate Total Prospective Payment Rate for FY 2001 by adding the labor and non labor portion of the case-mix and wage index amounts	($1,261.25 + $398.60)	$1,659.85

Example 5. An HHA in Baltimore, MD assigns a patient to an HHRG at the start of a 60-day episode. The claim for the patient indicates that only two visits (one skilled nursing and one home health aide) were furnished during the 60-day episode. The HHA would be paid the low-utilization payment adjustment. Any necessary adjustment to the request for advance payment for the episode would be made on subsequent claims for the HHA.

COMPUTATION OF WAGE INDEX ADJUSTED LOW UTILIZATION PAYMENT

Number and visit discipline type	Final wage standardized and budget neutral per-visit payment amounts per 60-day episode for FY 2001 [1]
1 Skilled Nursing Visit	$95.791
2 Home Health Aide Visit	43.371

[1] See Table 6 for the Calculation of Final Wage Standardized and Budget Neutral Per-Visit Payment Amounts Per 60-Day Episode for FY 2001.

Calculate the labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 Skilled Nursing Visit	(.77668 * $95.79)	$74.40
Apply wage index factor from Table 4B for Baltimore, MD	(.9892 * $74.40)	73.60
Calculate the non-labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 Skilled Nursing Visit	(.22332 * $95.79)	21.39
SUBTOTAL—Low Utilization Payment for 1 Wage Adjusted Skilled Nursing Visit rendered in a 60-day episode	($73.60 + $21.39)	94.99
Calculate the labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 home health aide visit	(.77668 * $43.37)	33.69
Apply wage index factor from Table 4B for Baltimore, MD	(.9892*$33.69)	33.33
Calculate the non-labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 home health aide visit	(.22332 * $43.37)	9.69
SUBTOTAL—Low Utilization Payment for 1 wage adjusted home health aide visit rendered in a 60-day episode	($33.33 + $9.69)	43.02
Calculate Total Low Utilization Payment Adjustment for 2 visits provided during the 60-day episode by adding the wage adjusted skilled nursing visit and the wage adjusted home health aide visit	($94.99 + $43.02)	138.01

G. Design and Methodology for Case-Mix Adjustment of 60-Day Episode Payments

1. Revisions to the Case-Mix Classification System

In the proposed rule, we described a home health case-mix system developed under a research contract with Abt Associates, Inc., of Cambridge, Massachusetts. The case-mix system uses selected data elements from the OASIS assessment instrument and an additional data element measuring receipt of at least 10 visits for therapy services. The data elements are organized into three dimensions to capture clinical severity factors, functional severity factors, and services utilization factors influencing case-mix. In the clinical and functional dimensions, each data element is assigned a score value derived from multiple regression analysis of the Abt research data. The score value measures the impact of the data element on total resource use. Scores are also assigned to data elements in the services utilization dimension. To find a patient's case-mix group, the case-mix grouper sums the patient's scores within each of the three dimensions. The resulting sum is used to assign the patient to a severity level on each dimension. There are four clinical severity levels, five functional severity levels, and four services utilization severity levels. Thus, there are 80 possible combinations of severity levels across the three dimensions. Each combination defines one of the 80 groups in the case-mix system. For example, a patient with high clinical severity, moderate functional severity, and low services utilization severity is placed in the same group with all other patients whose summed scores place them in the same set of severity levels for the three dimensions.

The initial Abt Associates sample used to develop the system described in the proposed rule was subsequently augmented for a first round of refinements, as described in the proposed rule. Following publication of the proposed rule, we augmented the Abt Associates sample with the remaining outstanding data from the 90 participating agencies, with the intention of re-estimating the case-mix relative weights based on the latest, most complete data available. We also pursued another round of refinements to the system using the augmented data, in response to public comments we received. The sample for this phase of refinements consisted of 19,204 initial episodes from the 90 agency participants.

The public comments on case-mix are summarized with our responses elsewhere in the rule. Below we describe the process we used to revise the case-mix system and the results. The revised case-mix model and scoring system are summarized in Table 7, ''Home Health Resource Group Case-mix Classification Decision Tree Logic.''

Test of newly added data. Before pursuing statistical modeling in response to comments, we checked the data newly added from the participating agencies for consistency with the previous data base. This involved re-estimating the regression equations that determined the scores, adding observations from the augmented, final sample. The results were consistent with the scores in the proposed rule. Additionally, we retested a short list of variables that were eliminated from the case-mix model at the end of the first round of refinements because of statistical insignificance. Upon retesting, they were still found to be statistically insignificant.

Investigation of wound-related variables. In response to comments from the public, indicating that certain wound care patients had costs higher than predicted by the case-mix model, we returned to the wound-related variables available on the OASIS for re-investigation. We used the learning subsample from the final, augmented sample. We tested three types of changes: Re-defining wound variables, adding more wound-related variables, and adding variables to represent interactions of wound variables with other variables. Interactions capture additional potential sources of severity or cost impact associated with certain types of wound patients. For example, patients who have certain diagnoses may be more susceptible to slow-healing wounds.

The statistical results suggested we could make meaningful score distinctions and create additional levels for the variables measuring the status of stasis ulcers and surgical wounds. In the proposed rule, the clinical dimension distinguished two statuses for the most problematic observable stasis ulcer—not healing (score=24) and all other statuses including no ulcer (score=0). The refined definition defines three statuses—early/partial granulation (score=14), not healing (score=22), and all other statuses including no observable ulcer (score=0). The proposed rule defined two statuses for the most problematic observable surgical wound—early/partial granulation or not healing (score=10) and all other statuses including no observable surgical wound (score=0). The refined definition defines three statuses—early/partial granulation (score=7), not healing (score=15), and all other statuses including no observable surgical wound (score=0).

We also retested the variables measuring pressure ulcers. We found no contribution to the model from adding variables measuring the status of pressure ulcers when the stage of the most problematic observable pressure ulcer was already in the model. We also determined that defining status levels beyond the three included in the proposed rule did not produce meaningful differences in the scores.

Therefore, the final rule model continues to define three levels: stage 1 or 2 (score=15), stage 3 or 4 (score=36), and all other (including no pressure ulcer and no observable pressure ulcer) (score=0). In addition, we tested whether the number of pressure ulcers made an independent contribution to explaining resource use. We found that having more than one pressure ulcer was a significant predictor of resource use when the multiple ulcers were stage 3 or 4. Therefore, the model in the final rule includes a variable adding 17 points if the patient has two or more stage 3 or 4 pressure ulcers.

We tested a general variable that measured the presence of any kind of open wound, decubitus ulcer, stasis ulcer, or surgical wound, based on an affirmative answer to M0445 (does patient have a pressure ulcer?), M0468 (does patient have a stasis ulcer?), M0482 (does patient have a surgical wound), or reporting of wound diagnosis codes in M0230 (primary home care diagnosis). This variable did not contribute statistically significant explanatory power when added to the model containing the other wound variables. However, we also tested separately a variable identifying burn or trauma patients with skin lesions or open wounds, identified from M0230 (primary diagnosis) and M0440 (does this patient have a skin lesion or an open wound?). This variable did contribute significantly and has been added to the model. The score for this variable is 21. The burn and trauma diagnosis code categories are shown in Table 8B.

In addition, we examined the impact of selected diagnoses that may be associated with difficult-to-heal wounds, including diabetes, atherosclerosis, peripheral vascular disease, and heart failure. We tested whether patients with these diagnoses should be assigned a higher score for their wound severity. Most results were not statistically significant. A few results were inconsistent across measures of wound severity. We also tested a variable measuring whether limited mobility results in higher cost impact for severe pressure ulcers, but this variable did not contribute significantly to the model after all other variables were included. The reasons for the weak results and inconsistency are unclear, and we did not make any of these changes to the clinical dimension. We will continue to study these types of issues during further refinement work on larger samples with more detailed diagnostic data.

Differences between the clinical dimension scores in the proposed rule and the final rule are generally small. Differences that do exist are attributable to our use of an augmented sample and the use of new variables related to wounds. In our model-building methodology, the scores in the functional dimension depend on results of the regression for deriving the clinical dimension scores. New scores for the functional dimension are very similar to the proposed-rule functional scores. Differences that do exist are attributable to the above-mentioned changes to the clinical dimension. The changes in functional scoring lead to a slightly different set of severity-score level intervals compared to the functional scoring in the proposed rule. The functional severity-score intervals are now minimal severity: 0–2; low severity: 3–15; moderate severity: 16–23; high severity: 24–29; maximum severity: 30+. The frequency distribution of the sample observations across the functional severity levels is essentially unchanged.

We validated the revised scoring for the clinical and functional dimensions using the validation subsample of the final, augmented sample. The results supported the scoring system developed with the learning subsample.

Re-examination of severity levels in clinical dimension. In response to several comments on wound-care patients, we refined the severity-score intervals in the clinical dimension to better differentiate patients who are clinically most severe from remaining patients. The revised score intervals are as follows: minimal severity: 0–7; low severity: 8–19; moderate severity: 20–40; high severity: 41+. To determine the refined severity-score intervals, we used the same process we followed in developing the case-mix system initially. We examined the array of scores for natural clustering and the impact of alternative sets of intervals on the proportion of variation explained by the model (R-squared). We also considered increases in the imbalance of the population across severity levels. The refined severity score intervals do result in more imbalance. The relative frequencies in the Abt sample for the revised clinical severity levels are 30 percent, 36 percent, 28 percent, 6 percent, for minimal, low, moderate, and high clinical severity, respectively. In contrast, the previous model's corresponding percentages were 30 percent, 30 percent, 23 percent, 17 percent. However, this change has also generally resulted in higher case-mix relative weights for the case-mix groups involving moderate and high clinical severity, where the most severe wound patients are likely to be found. It has also resulted in a wider range of weights for therapy-threshold case-mix groups and non-therapy-threshold case-mix groups.

Comparison with the earlier model. All combined, the refinements made to the case-mix model cause a modest improvement in explanatory power. The proportion of variation explained (R-squared) is now .34, compared to .32 for the model in the proposed rule. The model now provides for more adequate payment for wound care patients. Some of these high-cost patients would have been assigned to a different group under the model we presented in the proposed rule. Their removal from those earlier groups potentially results in a lower average cost, and lower case-mix weight, for those groups. We examined the impact on the array of relative case-mix weights across the case-mix groups. For the most part, we find generally small changes in the individual weights other than the weights for groups involving the moderate and high clinical severity levels.

The case-mix system will continue to be studied and refined in future years. Larger and better data resources, and information accumulated from users like those who commented, will both contribute to the evolution of the system.

2. Diagnosis Coding Changes in the Revised Case-Mix Model

When we published the proposed rule, we listed ICD–9–CM three-digit diagnosis category codes to identify orthopedic, neurologic, and diabetes diagnoses recognized in the clinical dimension. The scores associated with these diagnoses were based on analysis of the OASIS primary diagnosis item (M0230). A commenter pointed out that certain diagnoses within the category codes we listed should never be reported as primary diagnoses, according to ICD–9–CM coding rules and official coding guidelines. These diagnoses must be used with a higher-coded diagnosis that indicates the underlying disease. The affected category codes are 711, 712, 713, 720, 730, 731, 320, 321, 323, 330, 331, 334, 336, 337, 357, 358.

Accordingly, we have revised the diagnosis coding list. The revised list shows the complete code for the affected category codes, and is divided into two sections, one for primary diagnoses and one for secondary diagnoses (see Table 8A). The case-mix system will recognize the appropriate score for a diagnosis that should never be reported as a primary diagnosis, provided that the diagnosis appears as the first OASIS secondary diagnosis

(line b, under OASIS M0240) and that the code shows all digits required by ICD–9–CM coding guidelines. Remaining diagnoses from the affected categories must appear as the primary diagnosis (line a, under OASIS M0230) and the code must show all digits required by ICD–9–CM coding rules. The case-mix system will not recognize remaining diagnoses from the affected categories if they appear as a secondary diagnosis on the OASIS record. Nor will it recognize diagnoses that must never be reported as primary if they are placed on the primary diagnosis line (line a, M0230).

The refined case-mix system recognizes burns and trauma primary diagnoses, if the OASIS item M0440 shows the patient has a skin lesion or open wound. The diagnosis code categories for burns and trauma diagnoses included in the case-mix system are shown in Table 8B.

A lack of specificity in diagnosis code assignment may be a hindrance to case-mix refinement. Agencies that voluntarily code all diagnoses to the complete four- or five-digit level in accordance with ICD–9–CM coding rules would help us in subsequent review and examination of the case-mix methodology.

TABLE 7.—HOME HEALTH RESOURCE GROUP CASE-MIX CLASSIFICATION DECISION TREE LOGIC

Clinical severity domain

OASIS+ Item	Description	Value	Scoring
M0230/M0240	Primary home care diagnosis (or initial secondary diagnosis ONLY for selected ICD-9 manifestation codes).	—credit *only* the single highest value: If Orthopedic diagnostic group (DG)*, add 11 to score If Diabetes DG*, add 17 to score If Neurological DG*, add 20 to score	Min = 0–7 Low = 8–19 Mod = 20–40 High = 41+
M0250	IV/Infusion/Parenteral/Enteral Therapies.	—credit *only* the single highest value: If box 1, add 14 to score If box 2, add 20 to score If box 3, add 24 to score	
M0390	Vision	If box 1 or 2, add 6 to score	
M0420	Pain	If box 2 or 3, add 5 to score	
M0440	Wound/Lesion	If box 1 and M0230 is Burn/Trauma DG*, add 21 to score	
M0450	Multiple pressure ulcers	If 2 or more stage 3 or 4 pressure ulcers, add 17 to score	
M0460	Most problematic pressure ulcer stage.	If box 1 or 2, add 15 to score If box 3 or 4, add 36 to score	
M0476	Stasis ulcer status	If box 2, add 14 to score If box 3, add 22 to score	
M0488	Surgical wound status	If box 2, add 7 to score If box 3, add 15 to score	
M0490	Dyspnea	If box 2, 3 or 4, add 5 to score	
M0530	Urinary incontinence	If box 1 or 2, add 6 to score	
M0540	Bowel incontinence	If box 2–5, add 9 to score	
M0550	Bowel ostomy	If box 1 or 2, add 10 to score	
M0610	Behavioral Problems	If box 1–6, add 3 to score	

*See table for ICD9–CM codes included in each diagnosis group (DG)

Functional status domain

OASIS+ Item	Description	Value	Scoring
M0650 (current) M0660 (current)	Dressing	If M0650 = box 1, 2 or 3 Or M0660 = box 1, 2 or 3 } add 4 to score	Min = 0–2 Low = 3–15 Mod = 16–23
M0670 (current)	Bathing	If box 2, 3, 4 or 5 add 8 to score	High = 24–29
M0680 (current)	Toileting	If box 2–4, add 3 to score	Max = 30+
M0690 (current)	Transferring	If box 1, add 3 to score If box 2–5, add 6 to score	
M0700 (current)	Locomotion	If box 1 or 2, add 6 to score	
		If box 3–5, add 9 to score	

Service utilization domain

Variable	Description	Value	Scoring
M0170—line 1	No Hospital discharge past 14 days.	If box 1 IS BLANK, add 1 to score	Min = 0–2
M0170—line 2 or 3	Inpatient rehab/SNF discharge past 14 days.	If box 2 or 3, add 2 to score	Low = 3
Receipt of Therapy	10 or more therapy visits	If yes, add 4 to score	Mod = 4–6 High = 7

TABLE 8A.—DIAGNOSIS GROUPS IN THE CLINICAL DIMENSION

[**Note:** Codes shown at the 3-digit level include all the related 4- and 5-digit codes. Diagnoses coded with 4 or 5 digits must be coded as shown to receive a score in the clinical dimension.]

Diagnosis group	ICD–9–CM Code	Description
Primary Diagnoses		
DM	250	DIABETES MELLITUS
NEURO	013	CNS TUBERCULOSIS
NEURO	045	ACUTE POLIOMYELITIS
NEURO	046	CNS SLOW VIRUS INFECTION
NEURO	047	ENTEROVIRAL MENINGITIS
NEURO	048	OTH ENTEROVIRAL CNS DIS
NEURO	049	OTH NONARTHROPOD CNS VIR
NEURO	191	MALIGNANT NEOPLASM BRAIN
NEURO	192	MAL NEO NERVE NEC/NOS
NEURO	225	BENIGN NEO NERVOUS SYST
NEURO	320.0	HEMOPHILUS MENINGITIS
NEURO	320.1	PNEUMOCOCCAL MENINGITIS
NEURO	320.2	STREPTOCOCCAL MENINGITI
NEURO	320.3	STAPHYLOCOCC MENINGITIS
NEURO	320.81	ANAEROBIC MENINGITIS
NEURO	320.82	MNINGTS GRAM-NEG BCT NEC
NEURO	320.89	MENINGITIS OTH SPCF BAC
NEURO	320.9	BACTERIAL MENINGITIS NOS
NEURO	322	MENINGITIS, UNSPECIFIED
NEURO	323.5	POSTIMMUNIZAT ENCEPHALI
NEURO	323.8	ENCEPHALITIS NEC
NEURO	323.9	ENCEPHALITIS NOS
NEURO	324	CNS ABSCESS
NEURO	325	PHLEBITIS INTRCRAN SINU
NEURO	326	LATE EFF CNS ABSCESS
NEURO	330.0	LEUKODYSTROPHY
NEURO	330.1	CEREBRAL LIPIDOSES
NEURO	330.8	CEREB DEGEN IN CHILD NEC
NEURO	330.9	CEREB DEGEN IN CHILD NOS
NEURO	331.0	ALZHEIMER'S DISEASE
NEURO	331.1	PICK'S DISEASE
NEURO	331.2	SENILE DEGENERAT BRAIN
NEURO	331.3	COMMUNICAT HYDROCEPHALU
NEURO	331.4	OBSTRUCTIV HYDROCEPHALU
NEURO	331.81	REYE'S SYNDROME
NEURO	331.89	CEREB DEGENERATION NEC
NEURO	331.9	CEREB DEGENERATION NOS
NEURO	332	PARKINSON'S DISEASE
NEURO	333	EXTRAPYRAMIDAL DIS NEC
NEURO	334.0	FRIEDREICH'S ATAXIA
NEURO	334.1	HERED SPASTIC PARAPLEGI
NEURO	334.2	PRIMARY CEREBELLAR DEGE
NEURO	334.3	CEREBELLAR ATAXIA NEC
NEURO	334.8	SPINOCEREBELLAR DIS NEC
NEURO	334.9	SPINOCEREBELLAR DIS NOS
NEURO	335	ANT HORN CELL DISEASE
NEURO	336.0	SYRINGOMYELIA
NEURO	336.1	VASCULAR MYELOPATHIES
NEURO	336.8	MYELOPATHY NEC
NEURO	336.9	SPINAL CORD DISEASE NOS
NEURO	337.0	IDIOPATH AUTO NEUROPATH
NEURO	337.20	UNSP RFLX SYMPTH DYSTRP
NEURO	337.21	RFLX SYM DYSTRPH UP LIM
NEURO	337.22	RFLX SYM DYSTRPH LWR LM
NEURO	337.29	RFLX SYM DYSTRPH OTH ST
NEURO	337.3	AUTONOMIC DYSREFLEXIA
NEURO	337.9	AUTONOMIC NERVE DIS NEC
NEURO	340	MULTIPLE SCLEROSIS
NEURO	341	OTHER CNS DEMYELINATION
NEURO	342	HEMIPLEGIA
NEURO	343	INFANTILE CEREBRAL PALSY
NEURO	344	OTH PARALYTIC SYNDROMES
NEURO	347	CATAPLEXY AND NARCOLEPS
NEURO	348	OTHER BRAIN CONDITIONS
NEURO	349	CNS DISORDER NEC/NOS
NEURO	352	DISORDER CRAN NERVE NEC
NEURO	356	HERED PERIPH NEUROPATHY
NEURO	357.0	AC INFECT POLYNEURITIS

TABLE 8A.—DIAGNOSIS GROUPS IN THE CLINICAL DIMENSION—Continued

[**Note:** Codes shown at the 3-digit level include all the related 4- and 5-digit codes. Diagnoses coded with 4 or 5 digits must be coded as shown to receive a score in the clinical dimension.]

Diagnosis group	ICD–9–CM Code	Description
NEURO	357.5	ALCOHOLIC POLYNEUROPATH
NEURO	357.6	NEUROPATHY DUE TO DRUGS
NEURO	357.7	NEURPTHY TOXIC AGENT NEC
NEURO	357.8	INFLAM/TOX NEUROPTHY NEC
NEURO	357.9	INFLAM/TOX NEUROPTHY NOS
NEURO	358.0	MYASTHENIA GRAVIS
NEURO	358.2	TOXIC MYONEURAL DISORDE
NEURO	358.8	MYONEURAL DISORDERS NEC
NEURO	358.9	MYONEURAL DISORDERS NOS
NEURO	392	RHEUMATIC CHOREA
NEURO	430	SUBARACHNOID HEMORRHAGE
NEURO	431	INTRACEREBRAL HEMORRHAG
NEURO	432	INTRACRANIAL HEM NEC/NOS
NEURO	433	PRECEREBRAL OCCLUSION
NEURO	434	CEREBRAL ARTERY OCCLUS
NEURO	435	TRANSIENT CEREB ISCHEMIA
NEURO	436	CVA
NEURO	437	OTH CEREBROVASC DISEASE
NEURO	741	SPINA BIFIDA
NEURO	742	OTH NERVOUS SYSTEM ANOM
NEURO	851	CEREBRAL LACER/CONTUSION
NEURO	852	MENINGEAL HEM FOLLOW INJ
NEURO	853	OTH TRAUMATIC BRAIN HEM
NEURO	854	OTHER BRAIN INJURY
NEURO	907	LATE EFF NERV SYSTEM INJ
NEURO	950	INJ OPTIC NERV/PATHWAYS
NEURO	951	CRANIAL NERVE INJURY NEC
NEURO	952	SPINAL CORD INJ W/O FX
NEURO	953	INJ NERVE ROOT/SPIN PLEX
NEURO	954	INJURY OTH TRUNK NERVE
NEURO	955	INJ PERIPH NERV SHLD/ARM
NEURO	956	INJ PERIPH NERV PELV/LEG
ORTHO	170	MAL NEO BONE/ARTIC CART
ORTHO	171	MAL NEO SOFT TISSUE
ORTHO	213	BEN NEO BONE/ARTIC CART
ORTHO	274	GOUT
ORTHO	710	DIFF CONNECTIVE TISS DIS
ORTHO	711.00	PYOGEN ARTHRITIS—UNSPEC
ORTHO	711.01	PYOGEN ARTHRITIS—SHLDER
ORTHO	711.02	PYOGEN ARTHRITIS—UP/ARM
ORTHO	711.03	PYOGEN ARTHRITIS—FOREAR
ORTHO	711.04	PYOGEN ARTHRITIS—HAND
ORTHO	711.05	PYOGEN ARTHRITIS—PELVIS
ORTHO	711.06	PYOGEN ARTHRITIS—L/LEG
ORTHO	711.07	PYOGEN ARTHRITIS—ANKLE
ORTHO	711.08	PYOGEN ARTHRITIS NEC
ORTHO	711.09	PYOGEN ARTHRITIS—MULT
ORTHO	711.90	INF ARTHRITIS NOS—UNSPE
ORTHO	711.91	INF ARTHRITIS NOS—SHLDE
ORTHO	711.92	INF ARTHRITIS NOS—UP/AR
ORTHO	711.93	INF ARTHRIT NOS—FOREARM
ORTHO	711.94	INF ARTHRIT NOS—HAND
ORTHO	711.95	INF ARTHRIT NOS—PELVIS
ORTHO	711.96	INF ARTHRIT NOS—L/LEG
ORTHO	711.97	INF ARTHRIT NOS—ANKLE
ORTHO	711.98	INF ARTHRIT NOS—OTH SIT
ORTHO	711.99	INF ARTHRITIS NOS—MULT
ORTHO	712.80	CRYST ARTHROP NEC—UNSPE
ORTHO	712.81	CRYST ARTHROP NEC—SHLDE
ORTHO	712.82	CRYST ARTHROP NEC—UP/AR
ORTHO	712.83	CRYS ARTHROP NEC—FOREAR
ORTHO	712.84	CRYST ARTHROP NEC—HAND
ORTHO	712.85	CRYST ARTHROP NEC—PELVI
ORTHO	712.86	CRYST ARTHROP NEC—L/LEG
ORTHO	712.87	CRYST ARTHROP NEC—ANKLE
ORTHO	712.88	CRY ARTHROP NEC—OTH SIT
ORTHO	712.89	CRYST ARTHROP NEC—MULT
ORTHO	712.90	CRYST ARTHROP NOS—UNSPE
ORTHO	712.91	CRYST ARTHROP NOS—SHLDR
ORTHO	712.92	CRYST ARTHROP NOS—UP/AR

TABLE 8A.—DIAGNOSIS GROUPS IN THE CLINICAL DIMENSION—Continued

[**Note:** Codes shown at the 3-digit level include all the related 4- and 5-digit codes. Diagnoses coded with 4 or 5 digits must be coded as shown to receive a score in the clinical dimension.]

Diagnosis group	ICD–9–CM Code	Description
ORTHO	712.93	CRYS ARTHROP NOS—FOREAR
ORTHO	712.94	CRYST ARTHROP NOS—HAND
ORTHO	712.95	CRYST ARTHROP NOS—PELVI
ORTHO	712.96	CRYST ARTHROP NOS—L/LEG
ORTHO	712.97	CRYST ARTHROP NOS—ANKLE
ORTHO	712.98	CRY ARTHROP NOS—OTH SIT
ORTHO	712.99	CRYST ARTHROP NOS—MULT
ORTHO	714	OTH INFLAMM POLYARTHROP
ORTHO	716	ARTHROPATHIES NEC/NOS
ORTHO	717	INTERNAL DERANGEMNT KNEE
ORTHO	718	OTHER JOINT DERANGEMENT
ORTHO	720.0	ANKYLOSING SPONDYLITIS
ORTHO	720.1	SPINAL ENTHESOPATHY
ORTHO	720.2	SACROILIITIS NEC
ORTHO	720.89	INFLAM SPONDYLOPATHY NEC
ORTHO	720.9	INFLAM SPONDYLOPATHY NOS
ORTHO	721	SPONDYLOSIS ET AL
ORTHO	722	INTERVERTEBRAL DISC DIS
ORTHO	723	OTHER CERVICAL SPINE DIS
ORTHO	724	BACK DISORDER NEC & NOS
ORTHO	725	POLYMYALGIA RHEUMATICA
ORTHO	728	DIS OF MUSCLE/LIG/FASCIA
ORTHO	730.00	AC OSTEOMYELITIS—UNSP
ORTHO	730.01	AC OSTEOMYELITIS—SHLDER
ORTHO	730.02	AC OSTEOMYELITIS—UP/ARM
ORTHO	730.03	AC OSTEOMYELITIS—FOREAR
ORTHO	730.04	AC OSTEOMYELITIS—HAND
ORTHO	730.05	AC OSTEOMYELITIS—PELVIS
ORTHO	730.06	AC OSTEOMYELITIS—L/LEG
ORTHO	730.07	AC OSTEOMYELITIS—ANKLE
ORTHO	730.08	AC OSTEOMYELITIS NEC
ORTHO	730.09	AC OSTEOMYELITIS—MULT
ORTHO	730.10	CHR OSTEOMYELITIS—UNSP
ORTHO	730.11	CHR OSTEOMYELIT—SHLDER
ORTHO	730.12	CHR OSTEOMYELIT—UP/ARM
ORTHO	730.13	CHR OSTEOMYELIT—FOREARM
ORTHO	730.14	CHR OSTEOMYELIT—HAND
ORTHO	730.15	CHR OSTEOMYELIT—PELVIS
ORTHO	730.16	CHR OSTEOMYELIT—L/LEG
ORTHO	730.17	CHR OSTEOMYELIT—ANKLE
ORTHO	730.18	CHR OSTEOMYELIT NEC
ORTHO	730.19	CHR OSTEOMYELIT—MULT
ORTHO	730.20	OSTEOMYELITIS NOS—UNSPE
ORTHO	730.21	OSTEOMYELITIS NOS—SHLDE
ORTHO	730.22	OSTEOMYELITIS NOS—UP/AR
ORTHO	730.23	OSTEOMYELIT NOS—FOREARM
ORTHO	730.24	OSTEOMYELITIS NOS—HAND
ORTHO	730.25	OSTEOMYELITIS NOS—PELVI
ORTHO	730.26	OSTEOMYELITIS NOS—L/LEG
ORTHO	730.27	OSTEOMYELITIS NOS—ANKLE
ORTHO	730.28	OSTEOMYELIT NOS—OTH SIT
ORTHO	730.29	OSTEOMYELITIS NOS—MULT
ORTHO	730.30	PERIOSTITIS—UNSPEC
ORTHO	730.31	PERIOSTITIS—SHLDER
ORTHO	730.32	PERIOSTITIS—UP/ARM
ORTHO	730.33	PERIOSTITIS—FOREARM
ORTHO	730.34	PERIOSTITIS—HAND
ORTHO	730.35	PERIOSTITIS—PELVIS
ORTHO	730.36	PERIOSTITIS—L/LEG
ORTHO	730.37	PERIOSTITIS—ANKLE
ORTHO	730.38	PERIOSTITIS NEC
ORTHO	730.39	PERIOSTITIS—MULT
ORTHO	730.90	BONE INFEC NOS—UNSP SIT
ORTHO	730.91	BONE INFECT NOS—SHLDER
ORTHO	730.92	BONE INFECT NOS—UP/ARM
ORTHO	730.93	BONE INFECT NOS—FOREARM
ORTHO	730.94	BONE INFECT NOS—HAND
ORTHO	730.95	BONE INFECT NOS—PELVIS
ORTHO	730.96	BONE INFECT NOS—L/LEG
ORTHO	730.97	BONE INFECT NOS—ANKLE

TABLE 8A.—DIAGNOSIS GROUPS IN THE CLINICAL DIMENSION—Continued

[**Note:** Codes shown at the 3-digit level include all the related 4- and 5-digit codes. Diagnoses coded with 4 or 5 digits must be coded as shown to receive a score in the clinical dimension.]

Diagnosis group	ICD–9–CM Code	Description
ORTHO	730.98	BONE INFECT NOS—OTH SIT
ORTHO	730.99	BONE INFECT NOS—MULT
ORTHO	731.0	OSTEITIS DEFORMANS NOS
ORTHO	731.2	HYPERTROPH OSTEOARTHROP
ORTHO	732	OSTEOCHONDROPATHIES
ORTHO	781	NERV/MUSCULSKEL SYS SYMP
ORTHO	800	SKULL VAULT FRACTURE
ORTHO	801	SKULL BASE FRACTURE
ORTHO	802	FRACTURE OF FACE BONES
ORTHO	803	OTHER SKULL FRACTURE
ORTHO	804	MULT FX SKULL W OTH BONE
ORTHO	805	VERTEBRL FX W/O CORD INJ
ORTHO	806	VERTEBRAL FX W CORD INJ
ORTHO	807	FX RIB/STERN/LARYN/TRACH
ORTHO	808	PELVIC FRACTURE
ORTHO	809	FRACTURE OF TRUNK BONES
ORTHO	810	CLAVICLE FRACTURE
ORTHO	811	SCAPULA FRACTURE
ORTHO	812	HUMERUS FRACTURE
ORTHO	813	RADIUS & ULNA FRACTURE
ORTHO	814	CARPAL FRACTURE
ORTHO	815	METACARPAL FRACTURE
ORTHO	816	FRACTURE PHALANGES, HAND
ORTHO	817	MULTIPLE HAND FRACTURES
ORTHO	818	FRACTURE ARM MULT/NOS
ORTHO	819	FX ARMS W RIB/STERNUM
ORTHO	820	FRACTURE NECK OF FEMUR
ORTHO	821	OTHER FEMORAL FRACTURE
ORTHO	822	PATELLA FRACTURE
ORTHO	823	TIBIA & FIBULA FRACTURE
ORTHO	824	ANKLE FRACTURE
ORTHO	825	FX OF TARSAL/METATARSAL
ORTHO	827	LOWER LIMB FRACTURE NEC
ORTHO	828	FX LEGS W ARM/RIB
ORTHO	831	SHOULDER DISLOCATION
ORTHO	832	ELBOW DISLOCATION
ORTHO	833	WRIST DISLOCATION
ORTHO	835	DISLOCATION OF HIP
ORTHO	836	DISLOCATION OF KNEE
ORTHO	837	DISLOCATION OF ANKLE
ORTHO	838	DISLOCATION OF FOOT
ORTHO	846	SPRAIN SACROILIAC REGION
ORTHO	847	SPRAIN OF BACK NEC/NOS
ORTHO	887	TRAUMATIC AMPUT ARM/HAND
ORTHO	896	TRAUMATIC AMPUTAT FOOT
ORTHO	897	TRAUMATIC AMPUTATION LEG
ORTHO	927	CRUSHING INJ UPPER LIMB
ORTHO	928	CRUSHING INJURY OF LEG

Secondary Diagnoses

The following diagnoses should never be used as primary diagnoses, according to ICD–9–CM coding guidelines. The case-mix system will recognize them in the clinical dimension if they appear as the first secondary diagnosis (line b, M0240 on the OASIS record). Diagnoses coded with 4 or 5 digits must be coded as shown to be recognized in the clinical dimension.

NEURO	320.7	MENINGITIS IN OTH BAC
NEURO	321.0	CRYPTOCOCCAL MENINGITIS
NEURO	321.1	MENING IN OTH FUNGAL DI
NEURO	321.2	MENING IN OTH VIRAL DIS
NEURO	321.3	TRYPANOSOMIASIS MENINGI
NEURO	321.4	MENINGIT D/T SARCOIDOSI
NEURO	321.8	MENING IN OTH NONBAC DI
NEURO	323.0	ENCEPHALIT IN VIRAL DIS
NEURO	323.1	RICKETTSIAL ENCEPHALITI
NEURO	323.2	PROTOZOAL ENCEPHALITIS
NEURO	323.4	OTH ENCEPHALIT D/T INFE
NEURO	323.6	POSTINFECT ENCEPHALITIS
NEURO	323.7	TOXIC ENCEPHALITIS
NEURO	330.2	CEREB DEGEN IN LIPIDOSI
NEURO	330.3	CERB DEG CHLD IN OTH DI

TABLE 8A.—DIAGNOSIS GROUPS IN THE CLINICAL DIMENSION—Continued

[**Note:** Codes shown at the 3-digit level include all the related 4- and 5-digit codes. Diagnoses coded with 4 or 5 digits must be coded as shown to receive a score in the clinical dimension.]

Diagnosis group	ICD–9–CM Code	Description
NEURO	331.7	CEREB DEGEN IN OTH DIS
NEURO	334.4	CEREBEL ATAX IN OTH DIS
NEURO	336.2	COMB DEG CORD IN OTH DI
NEURO	336.3	MYELOPATHY IN OTH DIS
NEURO	337.1	AUT NEUROPTHY IN OTH DI
NEURO	357.1	NEURPTHY IN COL VASC DI
NEURO	357.2	NEUROPATHY IN DIABETES
NEURO	357.3	NEUROPATHY IN MALIG DIS
NEURO	357.4	NEUROPATHY IN OTHER DIS
NEURO	358.1	MYASTHENIA IN OTH DIS
ORTHO	711.10	REITER ARTHRITIS—UNSPEC
ORTHO	711.11	REITER ARTHRITIS—SHLDER
ORTHO	711.12	REITER ARTHRITIS—UP/ARM
ORTHO	711.13	REITER ARTHRITIS—FOREAR
ORTHO	711.14	REITER ARTHRITIS—HAND
ORTHO	711.15	REITER ARTHRITIS—PELVIS
ORTHO	711.16	REITER ARTHRITIS—L/LEG
ORTHO	711.17	REITER ARTHRITIS—ANKLE
ORTHO	711.18	REITER ARTHRITIS NEC
ORTHO	711.19	REITER ARTHRITIS—MULT
ORTHO	711.20	BEHCET ARTHRITIS—UNSPEC
ORTHO	711.21	BEHCET ARTHRITIS—SHLDER
ORTHO	711.22	BEHCET ARTHRITIS—UP/ARM
ORTHO	711.23	BEHCET ARTHRITIS—FOREAR
ORTHO	711.24	BEHCET ARTHRITIS—HAND
ORTHO	711.25	BEHCET ARTHRITIS—PELVIS
ORTHO	711.26	BEHCET ARTHRITIS—L/LEG
ORTHO	711.27	BEHCET ARTHRITIS—ANKLE
ORTHO	711.28	BEHCET ARTHRITIS NEC
ORTHO	711.29	BEHCET ARTHRITIS—MULT
ORTHO	711.30	DYSENTER ARTHRIT—UNSPEC
ORTHO	711.31	DYSENTER ARTHRIT—SHLDER
ORTHO	711.32	DYSENTER ARTHRIT—UP/ARM
ORTHO	711.33	DYSENTER ARTHRIT—FOREAR
ORTHO	711.34	DYSENTER ARTHRIT—HAND
ORTHO	711.35	DYSENTER ARTHRIT—PELVIS
ORTHO	711.36	DYSENTER ARTHRIT—L/LEG
ORTHO	711.37	DYSENTER ARTHRIT—ANKLE
ORTHO	711.38	DYSENTER ARTHRIT NEC
ORTHO	711.39	DYSENTER ARTHRIT—MULT
ORTHO	711.40	BACT ARTHRITIS—UNSPEC
ORTHO	711.41	BACT ARTHRITIS—SHLDER
ORTHO	711.42	BACT ARTHRITIS—UP/ARM
ORTHO	711.43	BACT ARTHRITIS—FOREARM
ORTHO	711.44	BACT ARTHRITIS—HAND
ORTHO	711.45	BACT ARTHRITIS—PELVIS
ORTHO	711.46	BACT ARTHRITIS—L/LEG
ORTHO	711.47	BACT ARTHRITIS—ANKLE
ORTHO	711.48	BACT ARTHRITIS NEC
ORTHO	711.49	BACT ARTHRITIS—MULT
ORTHO	711.50	VIRAL ARTHRITIS—UNSPEC
ORTHO	711.51	VIRAL ARTHRITIS—SHLDER
ORTHO	711.52	VIRAL ARTHRITIS—UP/ARM
ORTHO	711.53	VIRAL ARTHRITIS—FOREARM
ORTHO	711.54	VIRAL ARTHRITIS—HAND
ORTHO	711.55	VIRAL ARTHRITIS—PELVIS
ORTHO	711.56	VIRAL ARTHRITIS—L/LEG
ORTHO	711.57	VIRAL ARTHRITIS—ANKLE
ORTHO	711.58	VIRAL ARTHRITIS NEC
ORTHO	711.59	VIRAL ARTHRITIS—MULT
ORTHO	711.60	MYCOTIC ARTHRITIS—UNSPE
ORTHO	711.61	MYCOTIC ARTHRITIS—SHLDE
ORTHO	711.62	MYCOTIC ARTHRITIS—UP/AR
ORTHO	711.63	MYCOTIC ARTHRIT—FOREARM
ORTHO	711.64	MYCOTIC ARTHRITIS—HAND
ORTHO	711.65	MYCOTIC ARTHRITIS—PELVI
ORTHO	711.66	MYCOTIC ARTHRITIS—L/LEG
ORTHO	711.67	MYCOTIC ARTHRITIS—ANKLE
ORTHO	711.68	MYCOTIC ARTHRITIS NEC
ORTHO	711.69	MYCOTIC ARTHRITIS—MULT

TABLE 8A.—DIAGNOSIS GROUPS IN THE CLINICAL DIMENSION—Continued

[**Note:** Codes shown at the 3-digit level include all the related 4- and 5-digit codes. Diagnoses coded with 4 or 5 digits must be coded as shown to receive a score in the clinical dimension.]

Diagnosis group	ICD–9–CM Code	Description
ORTHO	711.70	HELMINTH ARTHRIT—UNSPEC
ORTHO	711.71	HELMINTH ARTHRIT—SHLDER
ORTHO	711.72	HELMINTH ARTHRIT—UP/ARM
ORTHO	711.73	HELMINTH ARTHRIT—FOREAR
ORTHO	711.74	HELMINTH ARTHRIT—HAND
ORTHO	711.75	HELMINTH ARTHRIT—PELVIS
ORTHO	711.76	HELMINTH ARTHRIT—L/LEG
ORTHO	711.77	HELMINTH ARTHRIT—ANKLE
ORTHO	711.78	HELMINTH ARTHRIT NEC
ORTHO	711.79	HELMINTH ARTHRIT—MULT
ORTHO	711.80	INF ARTHRITIS NEC—UNSPE
ORTHO	711.81	INF ARTHRITIS NEC—SHLDE
ORTHO	711.82	INF ARTHRITIS NEC—UP/AR
ORTHO	711.83	INF ARTHRIT NEC—FOREARM
ORTHO	711.84	INF ARTHRITIS NEC—HAND
ORTHO	711.85	INF ARTHRITIS NEC—PELVI
ORTHO	711.86	INF ARTHRITIS NEC—L/LEG
ORTHO	711.87	INF ARTHRITIS NEC—ANKLE
ORTHO	711.88	INF ARTHRIT NEC—OTH SIT
ORTHO	711.89	INF ARTHRITIS NEC—MULT
ORTHO	712.10	DICALC PHOS CRYST—UNSPE
ORTHO	712.11	DICALC PHOS CRYST—SHLDE
ORTHO	712.12	DICALC PHOS CRYST—UP/AR
ORTHO	712.13	DICALC PHOS CRYS—FOREAR
ORTHO	712.14	DICALC PHOS CRYST—HAND
ORTHO	712.15	DICALC PHOS CRYST—PELVI
ORTHO	712.16	DICALC PHOS CRYST—L/LEG
ORTHO	712.17	DICALC PHOS CRYST—ANKLE
ORTHO	712.18	DICALC PHOS CRY—SITE NE
ORTHO	712.19	DICALC PHOS CRYST—MULT
ORTHO	712.20	PYROPHOSPH CRYST—UNSPEC
ORTHO	712.21	PYROPHOSPH CRYST—SHLDER
ORTHO	712.22	PYROPHOSPH CRYST—UP/ARM
ORTHO	712.23	PYROPHOSPH CRYST—FOREAR
ORTHO	712.24	PYROPHOSPH CRYST—HAND
ORTHO	712.25	PYROPHOSPH CRYST—PELVIS
ORTHO	712.26	PYROPHOSPH CRYST—L/LEG
ORTHO	712.27	PYROPHOSPH CRYST—ANKLE
ORTHO	712.28	PYROPHOS CRYST—SITE NEC
ORTHO	712.29	PYROPHOS CRYST—MULT
ORTHO	712.30	CHONDROCALCIN NOS—UNSPE
ORTHO	712.31	CHONDROCALCIN NOS—SHLDE
ORTHO	712.32	CHONDROCALCIN NOS—UP/AR
ORTHO	712.33	CHONDROCALC NOS—FOREARM
ORTHO	712.34	CHONDROCALCIN NOS—HAND
ORTHO	712.35	CHONDROCALCIN NOS—PELVI
ORTHO	712.36	CHONDROCALCIN NOS—L/LEG
ORTHO	712.37	CHONDROCALCIN NOS—ANKLE
ORTHO	712.38	CHONDROCALC NOS—OTH SIT
ORTHO	712.39	CHONDROCALCIN NOS—MULT
ORTHO	713.0	ARTHROP W ENDOCR/MET DI
ORTHO	713.1	ARTHROP W NONINF GI DIS
ORTHO	713.2	ARTHROPATH W HEMATOL DI
ORTHO	713.3	ARTHROPATHY W SKIN DIS
ORTHO	713.4	ARTHROPATHY W RESP DIS
ORTHO	713.5	ARTHROPATHY W NERVE DIS
ORTHO	713.6	ARTHROP W HYPERSEN REAC
ORTHO	713.7	ARTHROP W SYSTEM DIS NE
ORTHO	713.8	ARTHROP W OTH DIS NEC
ORTHO	720.81	SPONDYLOPATHY IN OTH DI
ORTHO	730.70	POLIO OSTEOPATHY—UNSPEC
ORTHO	730.71	POLIO OSTEOPATHY—SHLDER
ORTHO	730.72	POLIO OSTEOPATHY—UP/ARM
ORTHO	730.73	POLIO OSTEOPATHY—FOREAR
ORTHO	730.74	POLIO OSTEOPATHY—HAND
ORTHO	730.75	POLIO OSTEOPATHY—PELVIS
ORTHO	730.76	POLIO OSTEOPATHY—L/LEG
ORTHO	730.77	POLIO OSTEOPATHY—ANKLE
ORTHO	730.78	POLIO OSTEOPATHY NEC
ORTHO	730.79	POLIO OSTEOPATHY—MULT

TABLE 8A.—DIAGNOSIS GROUPS IN THE CLINICAL DIMENSION—Continued

[**Note:** Codes shown at the 3-digit level include all the related 4- and 5-digit codes. Diagnoses coded with 4 or 5 digits must be coded as shown to receive a score in the clinical dimension.]

Diagnosis group	ICD–9–CM Code	Description
ORTHO	730.80	BONE INFECT NEC—UNSPEC
ORTHO	730.81	BONE INFECT NEC—SHLDER
ORTHO	730.82	BONE INFECT NEC—UP/ARM
ORTHO	730.83	BONE INFECT NEC—FOREARM
ORTHO	730.84	BONE INFECT NEC—HAND
ORTHO	730.85	BONE INFECT NEC—PELVIS
ORTHO	730.86	BONE INFECT NEC—L/LEG
ORTHO	730.87	BONE INFECT NEC—ANKLE
ORTHO	730.88	BONE INFECT NEC—OTH SIT
ORTHO	730.89	BONE INFECT NEC—MULT
ORTHO	731.1	OSTEITIS DEF IN OTH DIS
ORTHO	731.8	BONE INVOLV IN OTH DIS

TABLE 8B.—BURNS AND TRAUMA DIAGNOSES

[**Note:** Codes shown at the 3-digit level include all of the related 4- and 5-digit codes. Burns and trauma diagnoses are included in the clinical dimension if the diagnosis is the primary diagnosis and if box 1 of the OASIS item M0440 is checked.]

ICD–9–CM code	Description
870	OCULAR ADNEXA OPEN WOUND
872	OPEN WOUND OF EAR
873	OTHER OPEN WOUND OF HEAD
874	OPEN WOUND OF NECK
875	OPEN WOUND OF CHEST
876	OPEN WOUND OF BACK
877	OPEN WOUND OF BUTTOCK
878	OPEN WOUND GENITAL ORGAN
879	OPEN WOUND SITE NEC
880	OPN WND SHOULDR/UPPR ARM
881	OPEN WOUND OF LOWER ARM
882	OPEN WOUND OF HAND
883	OPEN WOUND OF FINGER
884	OPEN WOUND ARM MULT/NOS
885	TRAUM AMPUTATION THUMB
886	TRAUM AMPUTATION FINGER
890	OPEN WOUND OF HIP/THIGH
891	OPEN WND KNEE/LEG/ANKLE
892	OPEN WOUND OF FOOT
893	OPEN WOUND OF TOE
894	OPEN WOUND OF LEG NEC
895	TRAUMATIC AMPUTATION TOE
941	BURN OF HEAD/FACE/NECK
942	BURN OF TRUNK
943	BURN OF ARM
944	BURN OF HAND & WRIST
945	BURN OF LEG
946	BURN OF MULTIPLE SITE
948	BURN BY % BODY SURFACE
949	BURN UNSPECIFIED

3. Determining the Case-Mix Indices

Calculation of the case-mix relative weights. We derived the relative weights for the case-mix groups from a straightforward multiple regression analysis. The data for the regression came from the Abt sample episodes with more than four visits (the same sample used to develop and validate the case-mix model).

The coefficients that resulted from the regression equation are shown below. The multiple regression coefficients are estimates of the average addition to resource cost due to each severity level above the lowest-severity case-mix group (C0F0S0). For each case-mix group, the average resource cost is calculated from the sum of the appropriate regression coefficients. In the example below, the average resource cost for case-mix group C3F0S3 is the sum of the average resource cost for the base group (C0F0S0) plus the average additional cost due to C3 plus the average additional cost due to S3. We then used the computed case-mix-group average resource costs to find the relative case-mix weights. Specifically, the case-mix group averages (that is, sum of appropriate regression coefficients) are divided by the overall average resource cost. The case-mix weights are shown in Table 9.

The methodology for calculating the case-mix weights is the same one we used to find the case-mix weights in the proposed rule, except that we did not use weighted regression for the final rule. We determined that the distribution of the unweighted Abt Associates data better resembled the 1998 episode file distribution than did the weighted Abt Associates data. Thus, unweighted regression was the appropriate methodology. As stated in the proposed rule, we plan to refine the case-mix weights to adjust for changes in patient population, actual changes in home health care practice patterns, and changes in the coding or classification of patients that do not reflect real changes in case-mix.

Regression Coefficients for Calculating Case-Mix Relative Weights

Intercept*—$1,271.95
C1—$230.98
C2—$652.42
C3—$1,620.75
F1—$229.14
F2—$479.30
F3—$571.20
F4—$976.08
S1—$195.53
S2—$2,315.15
S3—$2,923.22

Example:

Calculate case-mix relative weight for group C3F0S3

Overall average resource cost (scaled to national average episode cost): $2,416.00

Relative weight = average resource cost for group C3F0S3 divided by overall average resource cost = (base group cost +C3 increment +S3 increment)/overall average resource cost = (1271.95 + 1620.75 + 2923.22)/2416.00 = 2.4073

Below we show the average resource cost calculated from the regression coefficients for each case-mix group.

Regression coefficient	Average resource cost
C0F0S0	$1,271.95
C0F0S1	1,467.48
C0F0S2	3,587.10
C0F0S3	4,195.17
C0F1S0	1,501.09
C0F1S1	1,696.62
C0F1S2	3,816.24
C0F1S3	4,424.31
C0F2S0	1,751.25
C0F2S1	1,946.77
C0F2S2	4,066.40
C0F2S3	4,674.46
C0F3S0	1,843.15
C0F3S1	2,038.68
C0F3S2	4,158.30

* Intercept value is the average resource cost for the base group, C0F0S0.

Regression coefficient	Average resource cost
C0F3S3	4,766.37
C0F4S0	2,248.03
C0F4S1	2,443.56
C0F4S2	4,563.18
C0F4S3	5,171.25
C1F0S0	1,502.93
C1F0S1	1,698.46
C1F0S2	3,818.08
C1F0S3	4,426.15
C1F1S0	1,732.07
C1F1S1	1,927.60
C1F1S2	4,047.22
C1F1S3	4,655.29
C1F2S0	1,982.23
C1F2S1	2,177.75
C1F2S2	4,297.38
C1F2S3	4,905.45
C1F3S0	2,074.13
C1F3S1	2,269.66
C1F3S2	4,389.28
C1F3S3	4,997.35
C1F4S0	2,479.01
C1F4S1	2,674.54
C1F4S2	4,794.16
C1F4S3	5,402.23
C2F0S0	1,924.37
C2F0S1	2,119.90
C2F0S2	4,239.52
C2F0S3	4,847.59
C2F1S0	2,153.51
C2F1S1	2,349.04
C2F1S2	4,468.66
C2F1S3	5,076.73
C2F2S0	2,403.67
C2F2S1	2,599.19
C2F2S2	4,718.82
C2F2S3	5,326.89
C2F3S0	2,495.57
C2F3S1	2,691.10
C2F3S2	4,810.72
C2F3S3	5,418.79
C2F4S0	2,900.45
C2F4S1	3,095.98
C2F4S2	5,215.61
C2F4S3	5,823.67
C3F0S0	2,892.70
C3F0S1	3,088.23
C3F0S2	5,207.85
C3F0S3	5,815.92
C3F1S0	3,121.84
C3F1S1	3,317.37
C3F1S2	5,436.99
C3F1S3	6,045.06
C3F2S0	3,372.00
C3F2S1	3,567.52
C3F2S2	5,687.15
C3F2S3	6,295.22
C3F3S0	3,463.91
C3F3S1	3,659.43
C3F3S2	5,779.06
C3F3S3	6,387.12
C3F4S0	3,868.79
C3F4S1	4,064.31
C3F4S2	6,183.94
C3F4S3	6,792.00

Construction of the Relative Weights for the HHRGs

TABLE 9.—RELATIVE CASE-MIX WEIGHTS CORRESPONDING TO HOME HEALTH RESOURCE GROUPS

HHRG group	HHRG description	Case-mix weight
C0F0S0	''Clinical=Min, Functional=Min, Service=Min''	0.5265
C0F0S1	''Clinical=Min, Functional=Min, Service=Low''	0.6074
C0F0S2	''Clinical=Min, Functional=Min, Service=Mod''	1.4847
C0F0S3	''Clinical=Min, Functional=Min, Service=High''	1.7364
C0F1S0	''Clinical=Min, Functional=Low, Service=Min''	0.6213
C0F1S1	''Clinical=Min, Functional=Low, Service=Low''	0.7022
C0F1S2	''Clinical=Min, Functional=Low, Service=Mod''	1.5796
C0F1S3	''Clinical=Min, Functional=Low, Service=High''	1.8313
C0F2S0	''Clinical=Min, Functional=Mod, Service=Min''	0.7249
C0F2S1	''Clinical=Min, Functional=Mod, Service=Low''	0.8058
C0F2S2	''Clinical=Min, Functional=Mod, Service=Mod''	1.6831
C0F2S3	''Clinical=Min, Functional=Mod, Service=High''	1.9348
C0F3S0	''Clinical=Min, Functional=High, Service=Min''	0.7629
C0F3S1	''Clinical=Min, Functional=High, Service=Low''	0.8438
C0F3S2	''Clinical=Min, Functional=High, Service=Mod''	1.7212
C0F3S3	''Clinical=Min, Functional=High, Service=High''	1.9728
C0F4S0	''Clinical=Min, Functional=Max, Service=Min''	0.9305
C0F4S1	''Clinical=Min, Functional=Max, Service=Low''	1.0114
C0F4S2	''Clinical=Min, Functional=Max, Service=Mod''	1.8887
C0F4S3	''Clinical=Min, Functional=Max, Service=High''	2.1404
C1F0S0	''Clinical=Low, Functional=Min, Service=Min''	0.6221
C1F0S1	''Clinical=Low, Functional=Min, Service=Low''	0.7030
C1F0S2	''Clinical=Low, Functional=Min, Service=Mod''	1.5803
C1F0S3	''Clinical=Low, Functional=Min, Service=High''	1.8320
C1F1S0	''Clinical=Low, Functional=Low, Service=Min''	0.7169
C1F1S1	''Clinical=Low, Functional=Low, Service=Low''	0.7978
C1F1S2	''Clinical=Low, Functional=Low, Service=Mod''	1.6752
C1F1S3	''Clinical=Low, Functional=Low, Service=High''	1.9269
C1F2S0	''Clinical=Low, Functional=Mod, Service=Min''	0.8205
C1F2S1	''Clinical=Low, Functional=Mod, Service=Low''	0.9014
C1F2S2	''Clinical=Low, Functional=Mod, Service=Mod''	1.7787
C1F2S3	''Clinical=Low, Functional=Mod, Service=High''	2.0304
C1F3S0	''Clinical=Low, Functional=High, Service=Min''	0.8585
C1F3S1	''Clinical=Low, Functional=High, Service=Low''	0.9394
C1F3S2	''Clinical=Low, Functional=High, Service=Mod''	1.8168
C1F3S3	''Clinical=Low, Functional=High, Service=High''	2.0684
C1F4S0	''Clinical=Low, Functional=Max, Service=Min''	1.0261
C1F4S1	''Clinical=Low, Functional=Max, Service=Low''	1.1070
C1F4S2	''Clinical=Low, Functional=Max, Service=Mod''	1.9843
C1F4S3	''Clinical=Low, Functional=Max, Service=High''	2.2360
C2F0S0	''Clinical=Mod, Functional=Min, Service=Min''	0.7965
C2F0S1	''Clinical=Mod, Functional=Min, Service=Low''	0.8774
C2F0S2	''Clinical=Mod, Functional=Min, Service=Mod''	1.7548
C2F0S3	''Clinical=Mod, Functional=Min, Service=High''	2.0065
C2F1S0	''Clinical=Mod, Functional=Low, Service=Min''	0.8914

TABLE 9.—RELATIVE CASE-MIX WEIGHTS CORRESPONDING TO HOME HEALTH RESOURCE GROUPS—Continued

HHRG group	HHRG description	Case-mix weight
C2F1S1	''Clinical=Mod, Functional=Low, Service=Low''	0.9723
C2F1S2	''Clinical=Mod, Functional=Low, Service=Mod''	1.8496
C2F1S3	''Clinical=Mod, Functional=Low, Service=High''	2.1013
C2F2S0	''Clinical=Mod, Functional=Mod, Service=Min''	0.9949
C2F2S1	''Clinical=Mod, Functional=Mod, Service=Low''	1.0758
C2F2S2	''Clinical=Mod, Functional=Mod, Service=Mod''	1.9532
C2F2S3	''Clinical=Mod, Functional=Mod, Service=High''	2.2048
C2F3S0	''Clinical=Mod, Functional=High, Service=Min''	1.0329
C2F3S1	''Clinical=Mod, Functional=High, Service=Low''	1.1139
C2F3S2	''Clinical=Mod, Functional=High, Service=Mod''	1.9912
C2F3S3	''Clinical=Mod, Functional=High, Service=High''	2.2429
C2F4S0	''Clinical=Mod, Functional=Max, Service=Min''	1.2005
C2F4S1	''Clinical=Mod, Functional=Max, Service=Low''	1.2814
C2F4S2	''Clinical=Mod, Functional=Max, Service=Mod''	2.1588
C2F4S3	''Clinical=Mod, Functional=Max, Service=High''	2.4105
C3F0S0	''Clinical=High, Functional=Min, Service=Min''	1.1973
C3F0S1	''Clinical=High, Functional=Min, Service=Low''	1.2782
C3F0S2	''Clinical=High, Functional=Min, Service=Mod''	2.1556
C3F0S3	''Clinical=High, Functional=Min, Service=High''	2.4073
C3F1S0	''Clinical=High, Functional=Low, Service=Min''	1.2922
C3F1S1	''Clinical=High, Functional=Low, Service=Low''	1.3731
C3F1S2	''Clinical=High, Functional=Low, Service=Mod''	2.2504
C3F1S3	''Clinical=High, Functional=Low, Service=High''	2.5021
C3F2S0	''Clinical=High, Functional=Mod, Service=Min''	1.3957
C3F2S1	''Clinical=High, Functional=Mod, Service=Low''	1.4766
C3F2S2	''Clinical=High, Functional=Mod, Service=Mod''	2.3540
C3F2S3	''Clinical=High, Functional=Mod, Service=High''	2.6056
C3F3S0	''Clinical=High, Functional=High, Service=Min''	1.4337
C3F3S1	''Clinical=High, Functional=High, Service=Low''	1.5147
C3F3S2	''Clinical=High, Functional=High, Service=Mod''	2.3920
C3F3S3	''Clinical=High, Functional=High, Service=High''	2.6437
C3F4S0	''Clinical=High, Functional=Max, Service=Min''	1.6013
C3F4S1	''Clinical=High, Functional=Max, Service=Low''	1.6822
C3F4S2	''Clinical=High, Functional=Max, Service=Mod''	2.5596
C3F4S3	''Clinical=High, Functional=Max, Service=High''	2.8113

H. Consolidated Billing

1. Background

Under the HHA consolidated billing requirement established by sections 4603(c)(2)(B) and (c)(2)(C) of the BBA, the HHA that establishes the home health plan of care has the Medicare billing responsibility for all of the Medicare-covered home health services listed in section 1861(m) of the Act that the patient receives and are ordered by the physician in the plan of care. Section 305 of BBRA of 1999 amended the consolidated billing language governing home health PPS by eliminating DME covered as a home health service from the consolidated billing requirements.

2. HHA Consolidated Billing Legislation

Specific Provisions of the Legislation. Sections 4603(c)(2)(B) and (c)(2)(C) of the BBA amend sections 1842(b)(6) and 1862(a) of the Act, respectively, to require a new consolidated billing and bundling of all home health services while a beneficiary is under the plan of care. The statute now requires payment for all items and services to be made to an agency. As stated above, section 305 of BBRA of 1999 excludes DME covered as a home health service from the consolidated billing requirements.

Specifically, the law requires, ''in the case of home health services (including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who (at the time the item or service is furnished) is under the plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or when any other contracting or consulting arrangement, or otherwise).''

Moreover, there will be separate payment for DME items and services provided under the home health benefit, which are under the DME fee schedule. As discussed previously, under the HHA PPS, DME covered as a home health service as part of the Medicare home health benefit will continue to be paid under the DME fee schedule and will also be excluded from the consolidated billing requirements. In addition to the prospective payment amount for home health services a separate payment amount will be made for DME currently covered as a home health service under the PPS.

3. Types of Services That Are Subject to the Provision

Under the consolidated billing requirement, we require that the HHA must submit all Medicare claims for all home health services included in section 1861(m) of the Act (including medical supplies described in section 1861(m)(5)) of the Act, but excluding DME to the extent provided for in such section), while the beneficiary is under the home health plan of care established by a physician and eligible for the home health benefit. The home health services included in consolidated billing are:

- Part-time or intermittent skilled nursing care.
- Part-time or intermittent home health aide services.
- Physical therapy.
- Speech-language pathology.
- Occupational therapy, medical social services.

• Routine and nonroutine medical supplies.
• A covered osteoporosis drug (as defined in section 1861(kk) of the Act-(not paid under PPS rate, see 1833(a)(2)(A)), but excluding other drugs and biologicals).
• Medical services provided by an intern or resident- in-training of the hospital, under an approved teaching program of the hospital in the case of an HHA that is affiliated or under common control with a hospital.
• Services at hospitals, SNFs, or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

4. Effects of This Provision

HHAs will no longer be able to ''unbundle'' services to an outside supplier that can then submit a separate bill directly to the Part B carrier. Instead, the HHA itself will have to furnish the home health services (except DME) either directly or under an arrangement with an outside supplier in which the HHA itself, rather than the supplier, bills Medicare. With the exception of DME, the outside supplier must look to the HHA rather than to Medicare Part B for payment. Beneficiaries receiving DME prior to establishment of a home health plan of care, can continue the relationship with that same DME supplier. The consolidated billing requirement eliminates the potential for duplicative billings for the same services to the RHHI by the HHA and to the Part B carrier by an outside supplier. All covered home health services listed in section 1861(m) of the Act, (including medical supplies described in section 1861(m)(5) of the Act, but excluding DME to the extent provided in such section) ordered in the patient's plan of care must be billed by the HHA.

As discussed in the proposed rule published on October 28, 1999, the responsibility for consolidated billing moves to the transfer HHA. The consolidated billing requirement enhances the HHA's capacity to meet its existing responsibility to oversee and coordinate the Medicare- covered home health services that each of its patients receives.

Consistent with SNF PPS consolidated billing, the beneficiary exercises his or her freedom of choice for the entire home health benefit of services listed in section 1861(m) of the Act, including medical supplies described in section 1861(m)(5) of the Act, but excluding DME as a home health service by choosing the HHA. Once a home health patient chooses a particular HHA, he or she has clearly exercised freedom of choice with respect to all items and services included within the scope of the Medicare home health benefit (except DME). The HHA's consolidated billing role supersedes all other billing situations the beneficiary may wish to establish for home health services covered under the scope of the home health benefit during the certified episode.

Current law is silent regarding the specific terms of an HHA's payment to an outside supplier, and does not authorize the Medicare program to impose any requirements in this regard. We remain concerned, however, over the potential for the provision of unnecessary services, and will continue to evaluate approaches addressing this concern. One appropriate way to address any abusive practices would be through more vigorous enforcement of existing statutes and regulations (such as medical review procedures). Furthermore, since under current law, an HHA's relationship with its supplier is essentially a private contractual matter, the terms of the supplier's payment by the HHA must be arrived 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 HHA's payment would be for the supplier to ensure that any terms to which it agrees in such negotiations satisfactorily address those concerns. Finally, we note that matters relating to the enforcement of the statutory anti-kickback provisions lie exclusively within the purview of the Office of the Inspector General, and any questions or concerns in this area should be directed to the attention of that agency.

5. Effective Date for Consolidated Billing

The effective date for consolidated billing is October 1, 2000.

V. Provisions of the Final Rule

We are adopting the provisions of the proposed rule with the following revisions:

Section 409.43

We revised paragraph (c) to clarify that the request for anticipated payment for the initial percentage payment is not a Medicare claim under the Act and subject to the requirement that the physician sign the plan of care before the HHA bills for the initial percentage payment. The request for anticipated payment for the initial percentage episode payment may be based on verbal orders that are copied into the plan of care with the plan of care being immediately submitted to the physician. However, the requests for anticipated payments may be modified or withheld in order to protect Medicare program integrity. However, the final percentage payment is a claim subject to the current physician signature requirements. We revised current paragraph (c) governing physician signature of the plan of care. Specifically, paragraph (c)(1) of this section specifies, ''If the physician signed plan of care is not available, the request for anticipated payment of the initial percentage payment must be based on—

• A physician's verbal order that—
++ Is recorded in the plan of care;
++ Includes a description of the patient's condition and the services to be provided by the home health agency;
++ Includes an attestation (relating to the physician's orders and the date received) signed and dated by the registered nurse or qualified therapist (as defined in 42 CFR 484.4) responsible for furnishing or supervising the ordered service in the plan of care; and
++ Is copied into the plan of care and the plan of care is immediately submitted to the physician; or
• A referral prescribing detailed orders for the services to be provided that is signed and dated by a physician.''

In paragraph (c)(2) of this section, we specify that ''HCFA has the authority to reduce or disapprove requests for anticipated payments in situations when protecting Medicare program integrity warrants this action. Since the request for anticipated payment is based on verbal orders as specified in paragraphs (c)(1)(i) and/or a prescribing referral as specified in (c)(1)(ii) of this section and is not a Medicare claim for purposes of the Act (although it is a ''claim'' for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a–7a (i) (2)), the Civil False Claims Act (as defined in 31 U.S.C. 3729(c)), and the Criminal False Claims Act (18 U.S.C. 287)), the request for anticipated payment will be canceled and recovered unless the claim is submitted within the greater of 60 days from the end of the episode or 60 days from the issuance of the request for anticipated payment.''

Paragraph (c)(3) of this section specifies that ''The plan of care must be signed and dated—

• By a physician as described who meets the certification and recertification requirements of § 424.22 of this chapter and;

• Before the claim for each episode for services is submitted for the final percentage payment.''

Paragraph (c)(4) of this section specifies that ''Any changes in the plan must be signed and dated by a physician.''

Section 409.43

We revised the paragraph (e) of this section to clarify that the plan of care must be reviewed by the physician at least every 60 days or more frequently when there is a beneficiary elected transfer, significant change in condition, or discharge and return to the same HHA during the same 60-day episode.

We also made a conforming change in paragraph (f) of this section regarding the termination of the plan of care by replacing ''62-day'' with ''60-day.'' We amended this paragraph to specify that if specific services are not provided to the beneficiary at least once every 60-days, the plan of care is terminated unless the physician documents that the interval without this care is appropriate to the treatment of the beneficiary's condition.

Sections 409.100(a)(2), 410.150(b)(19), and 411.15(q)

We revised the regulations at §§ 409.100(a)(2), 410.150(b)(19), and 411.15(q) to conform to the BBRA revisions that eliminate DME from the consolidated billing requirements.

Section 413.64

We revised § 413.1(h) to clarify that durable medical equipment and the covered osteoporosis drug as defined in section 1861(m) of the Act are not included in the HHA PPS rate.

We deleted § 413.64(h)(2)(iv). This corresponds to our revision in the proposed rule to remove Part A and Part B home health services from § 413.64(h)(1). PIP is eliminated for home health services upon implementation of PPS.

Section 424.22

We are not adopting proposed paragraph (a)(1)(v) that would have required the physician to certify the correct HHRG.

Section 484.1(a)

We amended this section by adding a new paragraph (3) to include the provision under the Act that provides the basis for establishing the new prospective payment system for home health services covered under Medicare.

Section 484.18

We revised the paragraph (b) to clarify that the plan of care must be reviewed by the physician at least every 60 days or more frequently when there is a beneficiary elected transfer, significant change in condition, or discharge and return to the same HHA during the same 60-day episode.

Section 484.55

We revised paragraph (d)(1) to specify that the update to the comprehensive assessment is required the last five days of every 60 days beginning with the start of care date unless there is an applicable payment adjustment. This clarification parallels the current OASIS requirements governing the timeframe of the update.

Section 484.202

We amended this section by removing the term ''clinical model'' from the list of definitions because we did not use the term in this subpart.

Section 484.205

We revised paragraph (a)(1) and (b) to clarify that the PPS payments are based on a predetermined rate for a home health service previously paid on a reasonable cost basis and that the osteoporosis drug covered under the home health benefit is the only home health service listed in section 1861(m) of the Act that continues to be paid on a reasonable cost basis under PPS. The revised language will read, ''The national 60-day episode payment represents payment in full for all costs associated with furnishing a home health service paid on a reasonable cost basis (except the osteoporosis drug listed in section 1861(m) of the Act as defined in section 1861(kk) of the Act) as of August 5, 1997 * * *''

We also clarify in paragraph (b) that all payments under this system must be subject to a medical review adjustment reflecting beneficiary eligibility, medical necessity determinations, and the HHRG assignment.

We added paragraphs (b)(1) and (b)(2) that provides for the requirements governing the final split percentage payment approach. New paragraph (b)(1) governs the split percentage payment approach for initial episodes. The initial percentage payment for initial episodes is paid at 60 percent of the case-mix and wage adjusted 60 day episode rate. The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage adjusted 60 day episode rate. New paragraph (b)(2) governs the split percentage payment approach for subsequent episodes. The initial percentage payment for subsequent episodes is paid at 50 percent of the case-mix and wage adjusted 60 day episode rate. The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage adjusted 60 day episode rate.

We revised paragraph (d) of this section to clarify that PEP adjustments do not apply in situations of transfer among HHAs of common ownership as defined in § 424.22. Those situations would be considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 60-day episode. The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 60-day episode before the transfer to the receiving HHA. The transferring HHA in situations of transfers among HHAs of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided for under arrangements to be paid.

Section 484.215

We renamed the heading of section 484.215 to clarify that the calculation reflects the initial establishment of the PPS rates. Section 484.215 has been revised to read ''Initial establishment of the calculation of the national 60-day episode payment.'' We revised paragraph (d)(4) to reflect the amounts that are added to the nonstandardized episode amount for the OASIS adjustment for the one time implementation costs associated with assessment scheduling form changes and amounts for Part B therapies that could have been unbundled to Part B prior to PPS implementation.

Section 424.220

We revised § 484.220 to specify that HCFA adjusts the national 60-day episode payment rate to account for geographic differences in wage levels using an appropriate wage index based on the site of the service for the beneficiary.

Section 484.225(c)

We revised paragraph (c) to reflect that for each of FYs 2002 *and* 2003 the rates are updated by the applicable home health market basket minus 1.1 percentage points.

Section 484.230

We revised the language in this section to reflect the higher per-visit amounts that will be used to calculate the LUPA payments. The amounts will be referred to as national per-visit amounts. We also clarified that the wage

index are based on the site of service for the beneficiary.

Section 484.235

We revised paragraph (b) to reflect the use of billable visit dates as the defining points for the PEP adjustment. The following phrase will be added to the end of the sentence, ''* * * based on the first billable visit date through and including the last billable visit date.''

Section 484.237

We revised paragraphs (b)(1) and (b)(2) governing the SCIC adjustment to reflect the use of billable visit dates to define the span of days used to calculate the proportional payments both before and after a patient experiences a significant change in condition. In §§ 484.237(b)(1) and (b)(2) we inserted the phrase ''(the first billable visit date through and including the last billable visit date)'' after the phrase ''span of days.''

Section 484.240

We revised paragraph (d) to reflect the higher per- visit amounts that will be used to calculate the imputed costs for each episode for outlier payment determination. The amounts are referred to as national per-visit amounts.

Section 484.245

We added new § 484.245 that sets forth the processes involving accelerated payment requests by an HHA under PPS if there is a delay by the intermediary in making payment.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

However, the requirements summarized below are currently approved as indicated by the appropriate OMB control number.

Section 409.43 Plan of Care Requirements

Section 409.43(c) states that a plan of care must be signed and dated by a physician and meets the certification and recertification requirements of § 424.22 of this chapter, before the episode claim for services is submitted for the final percentage payment. This provision also states that any changes in the plan must be signed and dated by the physician. The requirements and burden associated with the plan of care are currently approved under OMB control numbers 0938–0357, with a current expiration date of 11/30/2000, 0938–0760 with a current expiration date of 09/30/2000, and 0938–0761 with a current expiration date of 09/30/2000.

Section 409.43(e) states that a plan of care must be reviewed, signed, and dated by the physician who reviews the plan of care (as specified in § 409.42(b))in consultation with agency professional personnel at least every 60 days. The requirements and burden associated with the plan of care are currently approved under OMB control numbers 0938–0357, with a current expiration date of 11/30/2000, 0938–0760 with a current expiration date of 09/30/2000, and 0938–0761 with a current expiration date of 09/30/2000.

Section 424.22 Requirements for Home Health Services

Section 424.22(b) states that a recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed by the physician who reviews the plan of care. The requirements and burden associated with the plan of care are currently approved under OMB control numbers 0938–0357, with a current expiration date of 11/30/2000, 0938–0760 with a current expiration date of 09/30/2000, and 0938–0761 with a current expiration date of 09/30/2000.

Section 484.55 Comprehensive Assessment of Patients

Section 484.55 states that an HHA must update the comprehensive assessment by completing the appropriate OASIS schedule the last five days of every 60 days beginning with the start of care date unless there is a PEP adjustment or SCIC adjustment. The new requirement replaces the current language regarding ''every second calendar month'' with every 60 days.'' The requirements and burden associated with the plan of care are currently approved under OMB control numbers 0938–0357, with a current expiration date of 11/30/2000, 0938–0760 with a current expiration date of 09/30/2000, and 0938–0761 with a current expiration date of 09/30/2000.

Section 484.250 Patient Assessment Data.

Section 484.250 states that an HHA must submit OASIS data to HCFA as described at § 484.55(b)(1) and (d)(1) to administer the payment rate methodologies described in §§ 484.215, 484.230, 484.235, and 484.237. The requirements and burden associated with the plan of care are currently approved under OMB control numbers 0938–0357, with a current expiration date of 11/30/2000, 0938–0760 with a current expiration date of 09/30/2000, and 0938–0761 with a current expiration date of 09/30/2000.

VII. Regulatory Impact Analysis

Section 804(2) of title 5, United States Code (as added by section 251 of Public Law 104–121), specifies that a ''major rule'' is any rule that the Office of Management and Budget finds is likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment productivity, innovation, or on the ability of United States based enterprises to compete with foreign based enterprises in domestic and export markets.

We estimate, based on a simulation model, that the redistributional effects on HHAs participating in the Medicare program associated with this final rule would range from a positive $428 million for freestanding not-for-profit agencies to a negative $363 million for freestanding for-profit agencies in FY 2001. Therefore, this rule, is a major rule as defined in Title 5, United States Code, section 804(2).

We have examined the impacts of this final rule as required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995, (Public Law 104–4), 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). Section 1895(b)(3)(A)(i) of the Act requires that the total amounts payable under the HHA PPS be equal to the total amount that would have been paid if this system had not been in effect. Section 302 of the BBRA amends section 1895(b)(3)(A)(ii) of the Act and delays the application of a 15 percent reduction in HHA PPS payment amounts until 1 year after its implementation. Section 306 of the BBRA amends section 1895(b)(3)(B)(ii) of the Act to require the standard prospective payment amounts to be increased by a factor equal to the home health market basket minus 1.1 percentage points for each of FYs 2002 and 2003. In addition, for subsequent fiscal years, the law requires the rates to be increased by the applicable home health market basket index change. Thus, subject to these adjustments, the statutory construction of this final rule is budget neutral. However, we are aware that there would be a number of organizational accommodations that must be made by HHAs in order to make the transition from the cost-based/interim payment system environment to a prospective payment environment that would result in costs to these entities. On that basis, we are preparing this RIA.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in any given year. We believe that the costs associated with this final rule that apply to these governmental sectors would fall below this threshold. Therefore, the law does not apply and we have not prepared an assessment of anticipated costs and benefits of this final rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and governmental agencies. Most HHAs are considered small entities, either by nonprofit status or by having revenues of $5 million or less annually.

Table 10 illustrates the distribution of HHAs by provider type participating in Medicare as of March 16, 2000.

TABLE 10.—NUMBER OF HHAS BY PROVIDER TYPE

HHA Provider Type	Number of HHAs
Visiting Nurse Association	451
Combination of Government & Voluntary	35
Official Health Agency	910
Rehabilitation Facility Based	0
Hospital Based	2,278
Skilled Nursing Facility Based	161
Other	3,801
Total	7,636

Source: HCFA—On Line Survey Certification and Reporting System Standard Report 10—March 16, 2000.

The following RIA/RFA analysis, together with the rest of this preamble, explains the rationale for and purposes of this final rule.

A. Background

This final rule establishes requirements for the new prospective payment system for home health agencies as required by section 4603 of the Balanced Budget Act of 1997, as amended by section 5101 of OCESAA and sections 302, 305, and 306 of BBRA. The requirements include the implementation of a prospective payment system for home health agencies and a number of other related changes. The prospective payment system described in this rule would replace the retrospective reasonable cost-based system currently used by Medicare for the payment of home health services under Part A and Part B. This final rule sets forth a prospective payment system for all costs of home health services under section 1895 of the Act.

B. Revisions to the Proposed Rule

Below are listed a number of the significant changes to the proposed rule that are reflected in the final rule.

Section 409.100

Section 305 of the BBRA excludes DME covered as a home health service from the consolidated billing requirements. Specifically, the law requires, ''in the case of home health services (including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who (at the time the item or service is furnished) is under the plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or when any other contracting or consulting arrangement, or otherwise).''

However, under HHA PPS there is a separate payment for DME items and services currently provided as a home health service and paid under the DME fee schedule. As discussed earlier, under the HHA PPS, DME covered as a home health service as part of the Medicare home health benefit will continue to be paid under the DME fee schedule. Further, in accordance with the statue, as amended by section 305 of BBRA, DME is also excluded from the consolidated billing requirements. A separate payment amount in addition to the prospective payment amount for home health services will be made for DME currently covered as a home health service under the PPS.

HHAs will no longer be able to ''unbundle'' home health services (other than DME) to an outside supplier that can then submit a separate bill directly to the Part B carrier or DMERC. Instead, the HHA itself will have to furnish the home health services (except DME) either directly or under an arrangement with an outside supplier in which the HHA itself, rather than the supplier, bills Medicare. The outside supplier must look to the HHA rather than to Medicare Part B for payment, except in the case of DME. Beneficiaries receiving DME prior to establishment of a home health plan of care can continue the relationship with that same DME supplier. The consolidated billing requirement eliminates the potential for duplicative billings for the same services to the RHHI by the HHA and to the Part B carrier by an outside supplier. All covered home health services listed in section 1861(m) (including medical supplies described in section 1861(m)(5), but excluding DME to the extent provided in such section) of the Act under a plan of care must be billed by the HHA.

Section 484.205

- We revised paragraph (a)(1) and (b) to clarify that the osteoporosis drug covered under the home health benefit is the only home health service listed in section 1861(m) of the Act that continues to be paid on a reasonable cost basis under PPS.
- We added paragraphs (b)(1) and (b)(2) that provides for the requirements governing the final split percentage payment approach. New paragraph (b)(1) governs the split percentage payment approach for initial episodes. The initial percentage payment for initial episodes is paid at 60 percent of the case-mix and wage adjusted 60 day episode rate. The residual final payment for initial episodes is paid at 40 percent

of the case-mix and wage adjusted 60 day episode rate. New paragraph (b)(2) governs the split percentage payment approach for subsequent episodes. The initial percentage payment for subsequent episodes is paid at 50 percent of the case-mix and wage adjusted 60 day episode rate. The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage adjusted 60 day episode rate.

Section 484.215

We revised paragraph (d)(4) to reflect the amounts that are added to the nonstandardized episode amount for the OASIS adjustment for the one time implementation costs associated with assessment scheduling form changes and amounts for Part B therapies that could have been unbundled to Part B prior to PPS implementation.

Section 484.225

We revised paragraph (c) to reflect that for each of FYs 2002 and 2003 the rates are updated by the applicable home health market basket minus 1.1 percentage points.

Section 484.230

We revised the language in this section to reflect the higher per-visit amounts that will be used to calculate the LUPA payments.

Section 484.235

We revised paragraph (b) to reflect the use of billable visit dates as the defining points for the PEP adjustment.

Section 484.237

We revised paragraphs (b)(1) and (b)(2) governing the SCIC adjustment to reflect the use of billable visit dates to define the span of days used to calculate the proportional payments both before and after a patient experiences a significant change in condition.

Section 484.240

We revised paragraph (d) to reflect the higher per-visit amounts that will be used to calculate the imputed costs for each episode for outlier payment determination.

C. Effects of This Final Rule

Section 1895(b)(3)(A)(i) of the Act requires the computation of a standard prospective payment amount to be initially based on the most recent audited cost-report data available to the Secretary. In accordance with this section of the Act, the primary data source in developing the cost basis for the 60-day episode payments was the audited cost- report sample of HHAs whose cost reporting periods ended in fiscal year 1997 (that is, ending on or after October 1, 1996 through September 30, 1997). We also adopted the most current complete utilization data available from 1998.

Table 11 below illustrates the proportion of HHAs that are likely to be affected. This table reflects how agencies would be paid under PPS versus how they would be paid under IPS. The limits under IPS were determined by updating the per-visit limits in effect for FY 2000 by the market basket minus 1.1 percent and updating each agency's per-beneficiary cap for FY 2000 by this same percentage. For each agency in the audited cost report data set, we updated their costs from FY 1997 to FY 2001 by our best estimate of HHA cost increases during this period. We then compared each agency's FY 2001 costs to the IPS limits to determine their IPS payment in FY 2001. To determine each agency's payment under PPS, we translated the cost report data into 60-day episodes and used the average case-mix for urban/rural and provider type as a proxy. We extrapolated the audited cost report data to reflect the total Medicare HHA distribution. We obtained average case-mix values based on the type of provider and whether the HHA was urban or rural from the Abt data set. We then multiplied the agency's expected number of episodes in FY 2001 by the wage-adjusted and case-mix- adjusted episode payment to obtain the agency's expected PPS payment. The PPS payment was then compared to the IPS payment.

TABLE 11.—IMPACT OF THE HOME HEALTH PROSPECTIVE PAYMENT AMOUNTS ON HOME HEALTH AGENCIES BY TYPE AND LOCATION FOR THE 563 AUDITED COST REPORT SAMPLE AGENCIES

Type of agency	Percentage change from IPS to PPS
All Agencies	0.0
By Urban/Rural and Provider Type:	
Rural:	
Freestanding: For-Profit	−7.50
Governmental	29.98
Non-Profit	13.28
Provider Based	5.31
Urban:	
Freestanding: For-Profit	−14.25
Governmental	20.58
Non-Profit	18.89
Provider Based	−2.50
By Provider Type:	
Freestanding: For-Profit	−12.77
Governmental	26.50
Non-Profit	17.88
Provider Based	−1.03
By Urban/Rural:	
Rural Agencies	5.94
Urban Agencies	−0.08
By Region:	
Midwest States	14.77
Northeast States	15.37
Southern States	−16.75
Western States	17.84

Table 11 represents the projected effects of the HHA PPS and is based on the 563 providers in the audited cost-report sample weighted to the national total of HHAs. This sample has been adjusted by the most recent market basket factors to reflect the expected cost increases occurring between the cost-reporting periods for the data contained in the database and September 30, 2001.

This impact table compares the effect on categories of HHAs in moving from the IPS payment methodology to the PPS payment methodology. These cost limits have already had the effect of reducing many extremes in the cost of the system; therefore, as a result of IPS, a majority of HHA providers are currently held at the median national cost per-beneficiary or below. It should be noted that HHAs will have had 2 or more years experience under this system before PPS implementation. The effect of IPS payment restraint combined with the improvements in this final rule have significantly reduced the degree of variation between providers and regions as well as the overall impact of the rule. Because we believe it was important that the impact tables provide the most accurate representation possible, it was necessary for us to use the data set drawn upon from the audited cost report file. This file of course is nationally representative and these data become decreasingly valid when divided into smaller geographic areas. Thus, the lowest level of analysis we could reasonably provide using this data is the four census regions. Any finer level of analysis would introduce a level of statistical error that we believe would be unacceptable.

Column one of this table divides HHAs by a number of characteristics including provider type, region, and urban versus rural location. For purposes of this impact table four regions have been defined: Northeast, South, Midwest, and West. The Northeast Region consists of Connecticut, Massachusetts, Maine, New Hampshire, New Jersey, New York, Pennsylvania, Puerto Rico, Rhode Island, Vermont, and the Virgin Islands. The South Region consists of Alabama, Arkansas, the District of Columbia, Delaware, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia. The Midwest Region consists of Iowa, Illinois, Indiana, Kansas, Michigan, Minnesota, Missouri, North Dakota, Nebraska, Ohio, South Dakota, and Wisconsin. The West Region consists of Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, New Mexico, Nevada, Oregon, Utah, Washington, and Wyoming.

Column two shows the percentage change in Medicare payments a particular category of HHAs would experience in moving from the IPS payment methodology to the final PPS payment methodology. Because the statute requires aggregate payments under the HHA PPS and HHA IPS payment methodology to be budget neutral, the effect on agencies in the aggregate is zero.

Rural freestanding for-profit HHAs experience an 7.50 percent decrease in moving from the IPS payment methodology to the PPS payment methodology. Rural freestanding governmental HHAs experience an 29.98 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Rural freestanding nonprofit HHAs experience an 13.28 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Rural provider-based HHAs, in the aggregate, experience an 5.31 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Rural agencies, in the aggregate, experience an 5.94 percent increase in moving from the IPS payment methodology to the PPS payment methodology.

Urban freestanding for-profit HHAs experience an 14.25 percent decrease in moving from the IPS payment methodology to the PPS payment methodology. Urban freestanding governmental HHAs experience an 20.58 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Urban freestanding nonprofit HHAs experience an 18.89 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Urban provider-based HHAs, in the aggregate, experience an 2.50 percent decrease in moving from the IPS payment methodology to the PPS payment methodology. Urban agencies, in the aggregate, experience an 0.08 percent decrease in moving from the IPS payment methodology to the PPS payment methodology.

The current IPS cost limits have been criticized as providing better financial treatment of urban providers relative to rural providers. The HHA PPS system, which is based on patient characteristics, tends to level the playing field; thus, rural providers, in general, fare relatively better than urban providers. The largest impact on urban providers is in the urban freestanding for-profit category where it can be argued that historical costs have been disproportionately high compared to other providers for reasons unrelated to the relative needs of the patients they serve.

Freestanding for-profit HHAs, in the aggregate, experience an 12.77 percent decrease in moving from the IPS payment methodology to the PPS payment methodology. Freestanding governmental HHAs, in the aggregate, experience an 26.50 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Freestanding nonprofit HHAs, in the aggregate, experience an 17.88 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Provider-based HHAs, in the aggregate, experience an 1.03 percent decrease in moving from the IPS payment methodology to the PPS payment methodology.

It should be noted that governmental providers fare relatively better under the HHA PPS system than other types of providers. In part, this is because the HHA PPS system is driven primarily by the needs of patients rather than utilization incentives. Thus, governmental providers are less affected by the IPS payment methodology because their costs have been historically lower and visit utilization per episode is much lower. On average, governmental agencies have reported lower average costs per visit as well as fewer visits per episode. It should be noted that this category of HHAs accounts for only 3.8 percent of total home health expenditures and, therefore, the large increase attributed to them has little impact in the aggregate system costs.

Provider-based agencies historically tended to have, as a group, higher per-visit costs. As could be anticipated, the payment differential reflected in this impact table for provider-based agencies is in a negative direction, but relatively modest, probably due to the cost discipline already in place due to IPS.

HHAs in the Midwest region experience an 14.77 percent increase in moving from the IPS payment methodology to the PPS payment methodology. HHAs in the Northeast region experience an 15.37 percent increase in moving from the IPS payment methodology to the PPS payment methodology. HHAs in the South region experience an 16.75 percent decrease in moving from the IPS payment methodology to the PPS payment methodology. HHAs in the West region experience an 17.84 percent increase in moving from the IPS

payment methodology to the PPS payment methodology.

We would have preferred to provide an impact table with more regions; however, the limitations of our data prevented us from obtaining provider data at a lower level than the four major regions. However, this regional breakdown does reflect what one might expect in moving from our current IPS cost limitations payment methodology to a national PPS payment methodology. Medicare payments have historically varied by region without regard to the relative needs/conditions of patients; therefore, that region that had the highest unexplained costs for home health services is the most impacted area (South region). In contrast, the Midwest, Northeast, and West regions fare relatively well by comparison. It must be noted that in a payment methodology system that is legislatively required to achieve budget neutrality, any effort to increase payments to those regions more affected by a national payment system necessarily results in a reduction of payments to those regions that have historically restrained costs under home health.

It should be noted that to the degree that agencies respond to the incentives of the prospective payment system and apply resources commensurate with the measured characteristics of their patients, the impacts predicted in this model will further be reduced.

D. 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. This analysis must conform to the provisions of section 603 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 have not prepared a rural impact statement since we have determined, and the Secretary certifies, that this rule would not have a significant economic impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism. We have determined that this final rule would not have substantial direct effects on the rights, roles, and responsibilities of States.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

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 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 484

Health facilities, Health professions, 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. Amend part 409 as set forth below:

1. Revise the authority citation for part 409 to read as follows:

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

2. Amend § 409.43 as follows:

A. Revise paragraphs (c) and (e).

B. Amend paragraph (f) by removing the phrase ''62-day'' and adding in its place the phrase ''60-day.''

§ 409.43 Plan of care requirements.

* * * * *

(c) *Physician signature.* (1) *Request for Anticipated payment signature requirements.* If the physician signed plan of care is not available at the time the HHA requests an anticipated payment of the initial percentage prospective payment in accordance with § 484.205, the request for the anticipated payment must be based on—

(i) A physician's verbal order that—

(A) Is recorded in the plan of care;

(B) Includes a description of the patient's condition and the services to be provided by the home health agency;

(C) Includes an attestation (relating to the physician's orders and the date received) signed and dated by the registered nurse or qualified therapist (as defined in 42 CFR 484.4) responsible for furnishing or supervising the ordered service in the plan of care; and

(D) Is copied into the plan of care and the plan of care is immediately submitted to the physician; or

(ii) A referral prescribing detailed orders for the services to be rendered that is signed and dated by a physician.

(2) *Reduction or disapproval of anticipated payment requests.* HCFA has the authority to reduce or disapprove requests for anticipated payments in situations when protecting Medicare program integrity warrants this action. Since the request for anticipated payment is based on verbal orders as specified in paragraph (c)(1)(i) and/or a prescribing referral as specified in (c)(1)(ii) of this section and is not a Medicare claim for purposes of the Act (although it is a ''claim'' for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a–7a (i) (2)), the Civil False Claims Act (as defined in 31 U.S.C. 3729(c)), and the Criminal False Claims Act (18 U.S.C. 287)), the request for anticipated payment will be canceled and recovered unless the claim is submitted within the greater of 60 days from the end of the episode or 60 days from the issuance of the request for anticipated payment.

(3) *Final percentage payment signature requirements.* The plan of care must be signed and dated—

(i) By a physician as described who meets the certification and recertification requirements of § 424.22 of this chapter; and

(ii) Before the claim for each episode for services is submitted for the final percentage prospective payment.

(4) *Changes to the plan of care signature requirements.* Any changes in the plan must be signed and dated by a physician.

* * * * *

(e) *Frequency of review.* (1) The plan of care must be reviewed by the physician (as specified in § 409.42(b)) in consultation with agency professional personnel at least every 60 days or more frequently when there is a—

(i) Beneficiary elected transfer;

(ii) Significant change in condition resulting in a change in the case-mix assignment; or

(iii) Discharge and return to the same HHA during the 60-day episode.

(2) Each review of a beneficiary's plan of care must contain the signature of the

physician who reviewed it and the date of review.

* * * * *

3. In § 409.100, revise paragraph (a) to read as follows:

§ 409.100 To whom payment is made.

(a) *Basic rule.* Except as provided in paragraph (b) of this section—

(1) Medicare pays hospital insurance benefits only to a participating provider.

(2) For home health services (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who at the time the item or service is furnished is under a plan of care of an HHA, payment is made to the HHA (without regard to whether the item or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

B. Amend part 410 as set forth below:

1. The authority citation for part 410 continues to read as follows:

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

2. In § 410.150, republish the introductory text to paragraph (b) and add new paragraph (b)(19) to read as follows:

§ 410.150 To whom payment is made.

* * * * *

(b) *Specific rules.* Subject to the conditions set forth in paragraph (a) of this section, Medicare Part B pays as follows:

* * * * *

(19) To a participating HHA, for home health services (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who at the time the item or service is furnished is under a plan of care of an HHA (without regard to whether the item or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

C. Amend part 411 as set forth below:

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

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

2. In § 411.15, republish the introductory text to the section, and add a new paragraph (q) to read as follows:

§ 411.15 Particular services excluded from coverage.

The following services are excluded from coverage:

* * * * *

(q) A home health service (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) as defined in section 1861(m) of the Act furnished to an individual who is under a plan of care of an HHA, unless that HHA has submitted a claim for payment for such services.

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

D. Amend part 413 as set forth below:

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a),(i) and (n), 1861(v), 1871, 1881, 1883, and 1866 of the Social Security Act (42 U.S.C. 1302, 1395f(b), 1395g, 1395l(a),(i) and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww).

2. In § 413.1, add a new paragraph (h) to read as follows:

§ 413.1 Introduction.

* * * * *

(h) *Payment for services furnished by HHAs.* The amount paid for home health services as defined in section 1861(m) of the Act (except durable medical equipment and the covered osteoporosis drug as provided for in that section) that are furnished beginning on or after October 1, 2000 to an eligible beneficiary under a home health plan of care is determined according to the prospectively determined payment rates for HHAs set forth in part 484, subpart E of this chapter.

§ 413.64 [Amended]

3. Amend § 413.64 by:

A. Amending paragraph (h)(1) to remove the phrase ''and for both Part A and Part B HHA services'' at the end of the paragraph.

B. Removing paragraph (h)(2)(iv) and redesignating paragraphs (h)(2)(v) and (h)(2)(vi) as paragraphs (h)(2)(iv) and (h)(2)(v) respectively.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

E. Amend part 424 as set forth below:

1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1895hh).

2. In § 424.22, revise paragraph (b)(1) to read as follows:

§ 424.22 Requirements for home health services.

* * * * *

(b) *Recertification.* (1) *Timing and signature of recertification.* Recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed by the physician who reviews the plan of care. The recertification is required at least every 60 days when there is a—

(i) Beneficiary elected transfer; or

(ii) Discharge and return to the same HHA during the 60-day episode.

* * * * *

PART 484—HOME HEALTH SERVICES

F. Amend part 484 as set forth below:

1. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh), unless otherwise indicated.

2. Revise the heading for part 484 to read as set forth above.

3. Add a new paragraph (a)(3) to § 484.1 to read as follows:

§ 484.1 Basis and scope.

(a) *Basis and scope.* * * *

(3) Section 1895 provides for the establishment of a prospective payment system for home health services covered under Medicare.

* * * * *

§ 484.18 [Amended]

4. In § 484.18, in paragraph (b), remove the phrase ''62 days'' and in its place add the phrase ''60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode.''

5. In § 484.55, revise paragraph (d)(1) to read as follows:

§ 484.55 Condition of participation: Comprehensive assessment of patients.

* * * * *

(d) *Standard: Update of the comprehensive assessment.*

* * * * *

(1) The last five days of every 60 days beginning with the start-of-care date, unless there is a—

(i) Beneficiary elected transfer;

(ii) Significant change in condition resulting in a new case-mix assignment; or

(iii) Discharge and return to the same HHA during the 60-day episode.

* * * * *

6. Add and reserve a new subpart D.

7. Add a new subpart E to read as follows:

Subpart E—Prospective Payment System for Home Health Agencies

Sec.

Subpart E—Prospective Payment System for Home Health Agencies

§ 484.200 Basis and scope.

(a) *Basis.* This subpart implements section 1895 of the Act, which provides for the implementation of a prospective payment system (PPS) for HHAs for portions of cost reporting periods occurring on or after October 1, 2000.

(b) *Scope.* This subpart sets forth the framework for the HHA PPS, including the methodology used for the development of the payment rates, associated adjustments, and related rules.

§ 484.202 Definitions.

As used in this subpart—

Case-mix index means a scale that measures the relative difference in resource intensity among different groups in the clinical model.

Discipline means one of the six home health disciplines covered under the Medicare home health benefit (skilled nursing services, home health aide services, physical therapy services, occupational therapy services, speech-language pathology services, and medical social services).

Home health market basket index means an index that reflects changes over time in the prices of an appropriate mix of goods and services included in home health services.

§ 484.205 Basis of payment.

(a) *Method of payment.* An HHA receives a national prospective 60-day episode payment of a predetermined rate for a home health service previously paid on a reasonable cost basis (except the osteoporosis drug defined in section 1861(kk) of the Act) as of August 5, 1997. The national 60-day episode payment is determined in accordance with § 484.215. The national prospective 60-day episode payment is subject to the following adjustments and additional payments:

(1) A low-utilization payment adjustment (LUPA) of a predetermined per-visit rate as specified in § 484.230.

(2) A partial episode payment (PEP) adjustment due to an intervening event defined as a beneficiary elected transfer or a discharge and return to the same HHA during the 60-day episode, that warrants a new 60-day episode payment during an existing 60-day episode, that initiates the start of a new 60-day episode payment and a new physician certification of the new plan of care. The PEP adjustment is determined in accordance with § 484.235.

(3) A significant change in condition (SCIC) payment adjustment due to the intervening event defined as a significant change in the patient's condition during an existing 60-day episode. The SCIC adjustment occurs when a beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. The SCIC adjustment is determined in accordance with § 484.237.

(4) An outlier payment is determined in accordance with § 484.240.

(b) *Episode payment.* The national prospective 60-day episode payment represents payment in full for all costs associated with furnishing home health services previously paid on a reasonable cost basis (except the osteoporosis drug listed in section 1861(m) of the Act as defined in section 1861(kk) of the Act) as of August 5, 1997 unless the national 60-day episode payment is subject to a low-utilization payment adjustment set forth in § 484.230, a partial episode payment adjustment set forth at § 484.235, a significant change in condition payment set forth at § 484.237, or an additional outlier payment set forth in § 484.240. All payments under this system may be subject to a medical review adjustment reflecting beneficiary eligibility, medical necessity determinations, and HHRG assignment. DME provided as a home health service as defined in section 1861(m) of the Act continues to be paid the fee schedule amount.

(1) *Split percentage payment for initial episodes.* The initial percentage payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage adjusted 60-day episode rate. The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage adjusted 60-day episode rate. Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(2) *Split percentage payment for subsequent episodes.* The initial percentage payment for subsequent episodes is paid to an HHA at 50 percent of the case-mix and wage adjusted 60-day episode rate. The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage adjusted 60-day episode rate. Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(c) *Low-utilization payment.* An HHA receives a national 60-day episode payment of a predetermined rate for home health services previously paid on a reasonable cost basis as of August 5, 1997, unless HCFA determines at the end of the 60-day episode that the HHA furnished minimal services to a patient during the 60-day episode. A low-utilization payment adjustment is determined in accordance with § 484.230.

(d) *Partial episode payment adjustment.* An HHA receives a national 60-day episode payment of a predetermined rate for home health services previously paid on a reasonable cost basis as of August 5, 1997, unless HCFA determines an intervening event, defined as a beneficiary elected transfer, or discharge and return to the same HHA during a 60-day episode, warrants a new 60-day episode payment. The PEP adjustment would not apply in situations of transfers among HHAs of common ownership as defined in § 424.22 of this chapter. Those situations would be considered services provided under arrangement on behalf

of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 60-day episode. The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 60-day episode before the transfer to the receiving HHA. The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid. The discharge and return to the same HHA during the 60-day episode is only recognized in those circumstances when a beneficiary reached the goals in the original plan of care. The original plan of care must have been terminated with no anticipated need for additional home health services for the balance of the 60-day episode. If the intervening event warrants a new 60-day episode payment and the new physician certification of a new plan of care, the initial HHA receives a partial episode payment adjustment reflecting the length of time the patient remained under its care. A partial episode payment adjustment is determined in accordance with § 484.235.

(e) *Significant change in condition adjustment.* The HHA receives a national 60-day episode payment of a predetermined rate for home health services paid on a reasonable cost basis as of August 5, 1997, unless HCFA determines an intervening event defined as a beneficiary experiencing a significant change in condition during a 60-day episode that was not envisioned in the original plan of care occurred. In order to receive a new case-mix assignment for purposes of payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in the treatment approach in the patient's plan of care. The total significant change in condition payment adjustment is a proportional payment adjustment reflecting the time both prior and after the patient experienced a significant change in condition during the 60-day episode. A SCIC adjustment is determined in accordance with § 484.237.

(f) *Outlier payment.* An HHA receives a national 60-day episode payment of a predetermined rate for a home health service paid on a reasonable cost basis as of August 5, 1997, unless the imputed cost of the 60-day episode exceeds a threshold amount. The outlier payment is defined to be a proportion of the imputed costs beyond the threshold. An outlier payment is a payment in addition to the national 60-day episode payment. The total of all outlier payments is limited to 5 percent of total outlays under the HHA PPS. An outlier payment is determined in accordance with § 484.240.

§ 484.210 Data used for the calculation of the national prospective 60-day episode payment.

To calculate the national prospective 60-

day episode payment, HCFA uses the following:

(a) Medicare cost data on the most recent audited cost report data available.

(b) Utilization data based on Medicare claims.

(c) An appropriate wage index to adjust for area wage differences.

(d) The most recent projections of increases in costs from the HHA market basket index.

(e) OASIS assessment data and other data that account for the relative resource utilization for different HHA Medicare patient case-mix.

§ 484.215 Initial establishment of the calculation of the national 60-day episode payment.

(a) *Determining an HHA's costs.* In calculating the initial unadjusted national 60-day episode payment applicable for a service furnished by an HHA using data on the most recent available audited cost reports, HCFA determines each HHA's costs by summing its allowable costs for the period. HCFA determines the national mean cost per visit.

(b) *Determining HHA utilization.* In calculating the initial unadjusted national 60-day episode payment, HCFA determines the national mean utilization for each of the six disciplines using home health claims data.

(c) *Use of the market basket index.* HCFA uses the HHA market basket index to adjust the HHA cost data to reflect cost increases occurring between October 1, 1996 through September 30, 2001.

(d) *Calculation of the unadjusted national average prospective payment amount for the 60-day episode.* HCFA calculates the unadjusted national 60-day episode payment in the following manner:

(1) By computing the mean national cost per visit.

(2) By computing the national mean utilization for each discipline.

(3) By multiplying the mean national cost per visit by the national mean utilization summed in the aggregate for the six disciplines.

(4) By adding to the amount derived in paragraph (d)(3) of this section, amounts for nonroutine medical supplies, an OASIS adjustment for estimated ongoing reporting costs, an OASIS adjustment for the one time implementation costs associated with assessment scheduling form changes and amounts for Part B therapies that could have been unbundled to Part B prior to October 1, 2000. The resulting amount is the unadjusted national 60-day episode rate.

(e) *Standardization of the data for variation in area wage levels and case-mix.* HCFA standardizes—

(1) The cost data described in paragraph (a) of this section to remove the effects of geographic variation in wage levels and variation in case-mix;

(2) The cost data for geographic variation in wage levels using the hospital wage index; and

(3) The cost data for HHA variation in case-mix using the case-mix indices and other data that indicate HHA case- mix.

§ 484.220 Calculation of the adjusted national prospective 60-day episode payment rate for case-mix and area wage levels.

HCFA adjusts the national prospective 60-day episode payment rate to account for—

(a) HHA case-mix using a case-mix index to explain the relative resource utilization of different patients; and

(b) Geographic differences in wage levels using an appropriate wage index based on the site of service of the beneficiary.

§ 484.225 Annual update of the unadjusted national prospective 60-day episode payment rate.

(a) HCFA updates the unadjusted national 60-day episode payment rate on a fiscal year basis.

(b) For fiscal year 2001, the unadjusted national 60-day episode payment rate is adjusted using the latest available home health market basket index factors.

(c) For fiscal years 2002 and 2003, the unadjusted national prospective 60-day episode payment rate is updated by a factor equal to the applicable home health market basket minus 1.1 percentage points.

(d) For subsequent fiscal years, the unadjusted national rate is equal to the rate for the previous fiscal year increased by the applicable home health market basket index amount.

§ 484.230 Methodology used for the calculation of the low-utilization payment adjustment.

An episode with four or fewer visits is paid the national per-visit amount by

discipline updated annually by the applicable market basket for each visit type. The national per-visit amount is determined by using cost data set forth in § 484.210(a) and adjusting by the appropriate wage index based on the site of service for the beneficiary.

§ 484.235 Methodology used for the calculation of the partial episode payment adjustment.

(a) HCFA makes a PEP adjustment to the original 60-day episode payment that is interrupted by an intervening event described in § 484.205(d).

(b) The original 60-day episode payment is adjusted to reflect the length of time the beneficiary remained under the care of the original HHA based on the first billable visit date through and including the last billable visit date.

(c) The partial episode payment is calculated by determining the actual days served by the original HHA as a proportion of 60 multiplied by the initial 60-day episode payment.

§ 484.237 Methodology used for the calculation of the significant change in condition payment adjustment.

(a) HCFA makes a SCIC payment adjustment to the original 60-day episode payment that is interrupted by the intervening event defined in § 484.205(e).

(b) The SCIC payment adjustment is calculated in two parts.

(1) The first part of the SCIC payment adjustment reflects the adjustment to the level of payment prior to the significant change in the patient's condition during the 60-day episode. The first part of the SCIC adjustment is determined by taking the span of days (the first billable visit date through and including the last billable visit date) prior to the patient's significant change in condition as a proportion of 60 multiplied by the original episode amount.

(2) The second part of the SCIC payment adjustment reflects the adjustment to the level of payment after the significant change in the patient's condition occurs during the 60-day episode. The second part of the SCIC adjustment is calculated by using the span of days (the first billable visit date through and including the last billable visit date) through the balance of the 60-day episode.

(c) The initial percentage payment provided at the start of the 60-day episode will be adjusted at the end of the episode to reflect the first and second parts of the total SCIC adjustment determined at the end of the 60-day episode.

§ 484.240 Methodology used for the calculation of the outlier payment.

(a) HCFA makes an outlier payment for an episode whose estimated cost exceeds a threshold amount for each case-mix group.

(b) The outlier threshold for each case-mix group is the episode payment amount for that group, the PEP adjustment amount for the episode or the total significant change in condition adjustment amount for the episode plus a fixed dollar loss amount that is the same for all case-mix groups.

(c) The outlier payment is a proportion of the amount of estimated cost beyond the threshold.

(d) HCFA imputes the cost for each episode by multiplying the national per-visit amount of each discipline by the number of visits in the discipline and computing the total imputed cost for all disciplines.

(e) The fixed dollar loss amount and the loss sharing proportion are chosen so that the estimated total outlier payment is no more than 5 percent of total payment under home health PPS.

§ 484.245 Accelerated payments for home health agencies.

(a) *General rule.* Upon request, an accelerated payment may be made to an HHA that is receiving payment under the home health prospective payment system if the HHA is experiencing financial difficulties because there is a delay by the intermediary in making payment to the HHA.

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

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

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

§ 484.250 Patient assessment data.

An HHA must submit to HCFA the OASIS data described at § 484.55(b)(1) and (d)(1) in order for HCFA to administer the payment rate methodologies described in §§ 484.215, 484.230, 484.235, and 484.237.

§ 484.260 Limitation on review.

An HHA is not entitled to judicial or administrative review under sections 1869 or 1878 of the Act, or otherwise, with regard to the establishment of the payment unit, including the national 60-day prospective episode payment rate, adjustments and outlier payments. An HHA is not entitled to the review regarding the establishment of the transition period, definition and application of the unit of payments, the computation of initial standard prospective payment amounts, the establishment of the adjustment for outliers, and the establishment of case-mix and area wage adjustment factors.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 19, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: June 22, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 00–16432 Filed 6–28–00; 2:00 pm]

BILLING CODE 4120–01–P