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 filmpercent48 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 an 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.

Ž 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.

Ž 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.

Ž 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.

Ž 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 is 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 statue 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

PROVIDER TYPE	CONTINUUM CODE 1/	Average Cost Per Beneficiary 1997 2/	Average Cost Per Beneficiary 2001 3/
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 competed 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 <u>with</u> 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 <u>with</u> 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 recertification (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 <u>without</u> 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.