List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 413

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

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

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

PART 409--HOSPITAL INSURANCE BENEFITS

A. Amend part 409 as set forth below:

1. Revise the authority citation for part 409 to read as follows:

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

§409.43 [Amended]

2. Amend **§**409.43 as follows:

A. Revise paragraphs (c) and (e).

B. Amend paragraph (f) by removing the phrase “62-day” and adding in its place the phrase “60-day.”

§409.43 Plan of care requirements.

* * * * *

(c) Physician signature.

(1) Request for Anticipated payment signature requirements. If the physician signed plan of care is not available at the time the HHA requests an anticipated payment of the initial percentage prospective payment in accordance with §484.205, the request for the anticipated payment must be based on--

(i) A physician's verbal order that--

(A) Is recorded in the plan of care;

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

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

(D) Is copied into the plan of care and the plan of care is immediately submitted to the physician; or

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

(2) Reduction or disapproval of anticipated payment requests. HCFA has the authority to reduce or disapprove requests for anticipated payments in situations when protecting Medicare program integrity warrants this action. Since the request for anticipated payment is based on verbal orders as specified in paragraph (c)(1)(i) and/or a prescribing referral as specified in (c)(1)(ii) of this section and is not a Medicare claim for purposes of the Act (although it is a "claim" for purposes of Federal, civil, criminal, and administrative law enforcement authorities,

including but not limited to the Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a-7a (i) (2)), the Civil False Claims Act (as defined in 31 U.S.C. 3729(c)), and the Criminal False Claims Act (18 U.S.C. 287)), the request for anticipated payment will be canceled and recovered unless the claim is submitted within the greater of 60 days from the end of the episode or 60 days from the issuance of the request for anticipated payment.

(3) Final percentage payment signature requirements. The plan of care must be signed and dated--

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

(ii) Before the claim for each episode for services is submitted for the final percentage prospective payment.

(4) Changes to the plan of care signature requirements. Any changes in the plan must be signed and dated by a physician.

* * * * *

(e) Frequency of review. (1) The plan of care must be reviewed by the physician (as specified in §409.42(b)) in consultation with agency professional personnel at least every 60 days or more frequently when there is a--

(i) Beneficiary elected transfer;

(ii) Significant change in condition resulting in a change in the case-mix assignment; or

(iii) Discharge and return to the same HHA during the 60-day episode.

(2) Each review of a beneficiary's plan of care must contain the signature of the physician who reviewed it and the date of review.

* * * * *

3. In §409.100, revise paragraph (a) to read as follows:

§409.100 To whom payment is made.

(a) Basic rule. Except as provided in paragraph (b) of this section--

(1) Medicare pays hospital insurance benefits only to a participating provider.

(2) For home health services (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who at the time the item or service is furnished is under a plan of care of an HHA, payment is made to the HHA (without regard to whether the item

or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

* * * * *

PART 410--SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

B. Amend part 410 as set forth below:

1. The authority citation for part 410 continues to read as follows:

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

2. In §410.150, republish the introductory text to paragraph (b) and add new paragraph (b)(19) to read as follows:

§410.150 To whom payment is made.

* * * * *

(b) Specific rules. Subject to the conditions set forth in paragraph (a) of this section, Medicare Part B pays as follows:

* * * * *

(19) To a participating HHA, for home health services (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who

at the time the item or service is furnished is under a plan of care of an HHA (without regard to whether the item or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

PART 411--EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

C. Amend part 411 as set forth below:

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

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

2. In §411.15, republish the introductory text to the section, and add a new paragraph (q) to read as follows:

§411.15 Particular services excluded from coverage.

The following services are excluded from coverage:

* * * * *

(q) A home health service (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) as defined in section 1861(m) of the Act furnished to an individual who is under a plan of care of an HHA, unless that HHA has submitted a claim for payment for such services.

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

D. Amend part 413 as set forth below:

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a),(i) and (n), 1861(v), 1871, 1881, 1883, and 1866 of the Social Security Act (42 U.S.C. 1302, 1395f(b), 1395g, 1395l(a),(i) and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww).

2. In §413.1, add a new paragraph (h) to read as follows:

§413.1 Introduction.

* * * * *

(h) Payment for services furnished by HHAs. The amount paid for home health services as defined in section 1861(m) of the Act (except durable medical equipment and the covered osteoporosis drug as provided for in that section) that are furnished beginning on or after October 1, 2000 to an eligible beneficiary under a home health plan of care is determined according to the prospectively determined payment rates for

HHAs set forth in part 484, subpart E of this chapter.

§413.64 [Amended]

3. Amend §413.64 by:

A. Amending paragraph (h)(1) to remove the phrase "and for both Part A and Part B HHA services" at the end of the paragraph.

B. Removing paragraph (h)(2)(iv) and redesignating paragraphs (h)(2)(v) and (h)(2)(vi) as paragraphs (h)(2)(iv) and (h)(2)(v) respectively.

PART 424--CONDITIONS FOR MEDICARE PAYMENT

E. Amend part 424 as set forth below:

1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1895hh).

2. In §424.22, revise paragraph (b)(1) to read as follows:

§424.22 Requirements for home health services.

* * * * *

(b) Recertification. (1) Timing and signature of recertification. Recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed by the physician who reviews the plan of care. The

recertification is required at least every 60 days when there is a--

(i) Beneficiary elected transfer; or

(ii) Discharge and return to the same HHA during the 60-day episode.

* * * * *

PART 484--HOME HEALTH SERVICES

F. Amend part 484 as set forth below:

1. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh), unless otherwise indicated.

2. Revise the heading for part 484 to read as set forth above.

3. Add a new paragraph (a)(3) to §484.1 to read as follows:

§484.1 Basis and scope.

(a) Basis and scope.* * *

(3) Section 1895 provides for the establishment of a prospective payment system for home health services covered under Medicare.

* * * * *

§484.18 [Amended]

4. In §484.18, in paragraph (b), remove the phrase "62 days" and in its place add the phrase "60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode."

5. In §484.55, revise paragraph (d)(1) to read as follows:

§484.55 Condition of participation: Comprehensive assessment of patients.

* * * * *

(d) Standard: Update of the comprehensive assessment.

* * *

(1) The last five days of every 60 days beginning with the start-of-care date, unless there is a--

(i) Beneficiary elected transfer;

(ii) Significant change in condition resulting in a new case-mix assignment; or

(iii) Discharge and return to the same HHA during the 60-day episode.

* * * * *

6. Add and reserve a new subpart D.

7. Add a new subpart E to read as follows:

Subpart E--Prospective Payment System for Home Health Agencies

Sec.

payment.

Subpart E--Prospective Payment System for Home Health Agencies

§484.200 Basis and scope.

(a) Basis. This subpart implements section 1895 of the Act, which provides for the implementation of a prospective payment system (PPS) for HHAs for portions of cost reporting periods occurring on or after October 1, 2000.

(b) Scope. This subpart sets forth the framework for the HHA PPS, including the methodology used for the development of the payment rates, associated adjustments, and related rules.

§484.202 Definitions.

As used in this subpart--

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

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

pathology services, and medical social services).

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

§484.205 Basis of payment.

(a) Method of payment. An HHA receives a national prospective 60-day episode payment of a predetermined rate for a home health service previously paid on a reasonable cost basis (except the osteoporosis drug defined in section 1861(kk) of the Act) as of August 5, 1997. The national 60-day episode payment is determined in accordance with §484.215. The national prospective 60-day episode payment is subject to the following adjustments and additional payments:

(1) A low-utilization payment adjustment (LUPA) of a predetermined per-visit rate as specified in §484.230.

(2) A partial episode payment (PEP) adjustment due to an intervening event defined as a beneficiary elected transfer or a discharge and return to the same HHA during the 60-day episode, that warrants a new 60-day episode payment during an existing 60-day episode, that initiates the start of a new 60-day episode payment and a new physician certification of the new plan of care. The PEP adjustment is determined in accordance with §484.235.

(3) A significant change in condition (SCIC) payment adjustment due to the intervening event defined as a significant change in the patient's condition during an existing 60-day episode. The SCIC adjustment occurs when a beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. The SCIC adjustment is determined in accordance with §484.237.

(4) An outlier payment is determined in accordance with §484.240.

(b) Episode payment. The national prospective 60-day episode payment represents payment in full for all costs associated with furnishing home health services previously paid on a reasonable cost basis (except the osteoporosis drug listed in section 1861(m) of the Act as defined in section 1861(kk) of the Act) as of August 5, 1997 unless the national 60-day episode payment is subject to a low-utilization payment adjustment set forth in §484.230, a partial episode payment adjustment set forth at §484.235, a significant change in condition payment set forth at §484.237, or an additional outlier payment set forth in §484.240. All payments under this system may be subject to a medical review adjustment reflecting beneficiary eligibility, medical necessity

determinations, and HHRG assignment. DME provided as a home health service as defined in section 1861(m) of the Act continues to be paid the fee schedule amount.

(1) Split percentage payment for initial episodes. The initial percentage payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage adjusted 60-day episode rate. The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage adjusted 60-day episode rate. Split percentage payments are made in accordance with requirements at §409.43(c) of this chapter.

(2) Split percentage payment for subsequent episodes. The initial percentage payment for subsequent episodes is paid to an HHA at 50 percent of the case-mix and wage adjusted 60-day episode rate. The residual final payment for subsequent episodes is paid at 50 percent of the case- mix and wage adjusted 60-day episode rate. Split percentage payments are made in accordance with requirements at §409.43(c) of this chapter.

(c) Low-utilization payment. An HHA receives a national 60-day episode payment of a predetermined rate for home health services previously paid on a reasonable cost basis as of August 5, 1997, unless HCFA determines at the end of the 60-day episode that the HHA furnished minimal services to a

patient during the 60-day episode. A low-utilization payment adjustment is determined in accordance with §484.230.

(d) Partial episode payment adjustment. An HHA receives a national 60-day episode payment of a predetermined rate for home health services previously paid on a reasonable cost basis as of August 5, 1997, unless HCFA determines an intervening event, defined as a beneficiary elected transfer, or discharge and return to the same HHA during a 60-day episode, warrants a new 60-day episode payment. The PEP adjustment would not apply in situations of transfers among HHAs of common ownership as defined in §424.22 of this chapter. Those situations would be considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 60-day episode. The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 60-day episode before the transfer to the receiving HHA. The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid. The discharge and return to the same HHA during the 60-day episode

is only recognized in those circumstances when a beneficiary reached the goals in the original plan of care. The original plan of care must have been terminated with no anticipated need for additional home health services for the balance of the 60-day episode. If the intervening event warrants a new 60-day episode payment and the new physician certification of a new plan of care, the initial HHA receives a partial episode payment adjustment reflecting the length of time the patient remained under its care. A partial episode payment adjustment is determined in accordance with §484.235.

(e) Significant change in condition adjustment

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

proportional payment adjustment reflecting the time both prior and after the patient experienced a significant change in condition during the 60-day episode. A SCIC adjustment is determined in accordance with §484.237.

(f) Outlier payment. An HHA receives a national 60-day episode payment of a predetermined rate for a home health service paid on a reasonable cost basis as of August 5, 1997, unless the imputed cost of the 60-day episode exceeds a threshold amount. The outlier payment is defined to be a proportion of the imputed costs beyond the threshold. An outlier payment is a payment in addition to the national 60-day episode payment. The total of all outlier payments is limited to 5 percent of total outlays under the HHA PPS. An outlier payment is determined in accordance with §484.240.

§484.210 Data used for the calculation of the national prospective 60-day episode payment.

To calculate the national prospective 60-day episode payment, HCFA uses the following:

(a) Medicare cost data on the most recent audited cost report data available.

(b) Utilization data based on Medicare claims.

(c) An appropriate wage index to adjust for area wage differences.

(d) The most recent projections of increases in costs from the HHA market basket index.

(e) OASIS assessment data and other data that account for the relative resource utilization for different HHA Medicare patient case-mix.

§484.215 Initial establishment of the calculation of the national 60-day episode payment.

(a) Determining an HHA's costs. In calculating the initial unadjusted national 60-day episode payment applicable for a service furnished by an HHA using data on the most recent available audited cost reports, HCFA determines each HHA's costs by summing its allowable costs for the period. HCFA determines the national mean cost per visit.

(b) Determining HHA utilization. In calculating the initial unadjusted national 60-day episode payment, HCFA determines the national mean utilization for each of the six disciplines using home health claims data.

(c) Use of the market basket index. HCFA uses the HHA market basket index to adjust the HHA cost data to reflect cost increases occurring between October 1, 1996 through September 30, 2001.

(d) Calculation of the unadjusted national average prospective payment amount for the 60-day episode. HCFA calculates the unadjusted national 60-day episode payment in the following manner:

(1) By computing the mean national cost per visit.

(2) By computing the national mean utilization for each discipline.

(3) By multiplying the mean national cost per visit by the national mean utilization summed in the aggregate for the six disciplines.

(4) By adding to the amount derived in paragraph (d)(3) of this section, amounts for nonroutine medical supplies, an OASIS adjustment for estimated ongoing reporting costs, an OASIS adjustment for the one time implementation costs associated with assessment scheduling form changes and amounts for Part B therapies that could have been unbundled to Part B prior to October 1, 2000. The resulting amount is the unadjusted national 60-day episode rate.

(e) Standardization of the data for variation in area wage levels and case-mix. HCFA standardizes--

(1) The cost data described in paragraph (a) of this section to remove the effects of geographic variation in wage

levels and variation in case-mix;

(2) The cost data for geographic variation in wage levels using the hospital wage index; and

(3) The cost data for HHA variation in case-mix using the case-mix indices and other data that indicate HHA case-mix.

§484.220 Calculation of the adjusted national prospective 60-day episode payment rate for case-mix and area wage levels.

HCFA adjusts the national prospective 60-day episode payment rate to account for--

(a) HHA case-mix using a case-mix index to explain the relative resource utilization of different patients; and

(b) Geographic differences in wage levels using an appropriate wage index based on the site of service of the beneficiary.

§484.225 Annual update of the unadjusted national prospective 60-day episode payment rate.

(a) HCFA updates the unadjusted national 60-day episode payment rate on a fiscal year basis.

(b) For fiscal year 2001, the unadjusted national 60-day episode payment rate is adjusted using the latest available home health market basket index factors.

(c) For fiscal years 2002 and 2003, the unadjusted national prospective 60-day episode payment rate is updated by a factor equal to the applicable home health market basket minus 1.1 percentage points.

(d) For subsequent fiscal years, the unadjusted national rate is equal to the rate for the previous fiscal year increased by the applicable home health market basket index amount.

§484.230 Methodology used for the calculation of the low-utilization payment adjustment.

An episode with four or fewer visits is paid the national per-visit amount by discipline updated annually by the applicable market basket for each visit type. The national per-visit amount is determined by using cost data set forth in §484.210(a) and adjusting by the appropriate wage index based on the site of service for the beneficiary.

§484.235 Methodology used for the calculation of the partial episode payment adjustment.

(a) HCFA makes a PEP adjustment to the original 60-day episode payment that is interrupted by an intervening event described in §484.205(d).

(b) The original 60-day episode payment is adjusted to reflect the length of time the beneficiary remained under the care of the original HHA based on the first billable visit date through and including the last billable visit date.

(c) The partial episode payment is calculated by determining the actual days served by the original HHA as a proportion of 60 multiplied by the initial 60-day episode payment.

§**484.237 Methodology used for the calculation of the significant change in condition payment adjustment**.

(a) HCFA makes a SCIC payment adjustment to the original 60-day episode payment that is interrupted by the intervening event defined in **§**484.205(e).

(b) The SCIC payment adjustment is calculated in two parts.

(1) The first part of the SCIC payment adjustment reflects the adjustment to the level of payment prior to the significant change in the patient's condition during the 60-day episode. The first part of the SCIC adjustment is determined by taking the span of days (the first billable visit date through and including the last billable visit date) prior to the patient's significant change in condition as a proportion of 60 multiplied by the original episode amount.

(2) The second part of the SCIC payment adjustment reflects the adjustment to the level of payment after the significant change in the patient's condition occurs during the 60-day episode. The second part of the SCIC adjustment is calculated by using the span of days (the first billable visit date through and including the last billable visit date) through the balance of the 60-day episode.

(c) The initial percentage payment provided at the start of the 60-day episode will be adjusted at the end of the episode to reflect the first and second parts of the total SCIC adjustment determined at the end of the 60-day episode.

§484.240 Methodology used for the calculation of the outlier payment.

(a) HCFA makes an outlier payment for an episode whose estimated cost exceeds a threshold amount for each case-mix group.

(b) The outlier threshold for each case-mix group is the episode payment amount for that group, the PEP adjustment amount for the episode or the total significant change in condition adjustment amount for the episode plus a fixed dollar loss amount that is the same for all case-mix groups.

(c) The outlier payment is a proportion of the amount of estimated cost beyond the threshold.

(d) HCFA imputes the cost for each episode by multiplying the national per-visit amount of each discipline by the number of visits in the discipline and computing the total imputed cost for all disciplines.

(e) The fixed dollar loss amount and the loss sharing proportion are chosen so that the estimated total outlier payment is no more than 5 percent of total payment under home health PPS.

§484.245 Accelerated payments for home health agencies.

(a) General rule. Upon request, an accelerated payment may be made to an HHA that is receiving payment under the home health prospective payment system if the HHA is experiencing financial difficulties because there is a delay by the intermediary in making payment to the HHA.

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

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

(d) Recovery of payment. Recovery of the accelerated payment is made by recoupment as HHA bills are processed or by direct payment by the HHA.

§484.250 Patient assessment data.

An HHA must submit to HCFA the OASIS data described at §484.55(b)(1) and (d)(1) in order for HCFA to administer the payment rate methodologies described in §§484.215, 484.230, 484.235, and 484.237.

§484.260 Limitation on review.

An HHA is not entitled to judicial or administrative review under sections 1869 or 1878 of the Act, or otherwise, with regard to the establishment of the payment unit, including the national 60-day prospective episode payment rate, adjustments and outlier payments. An HHA is not entitled to the review regarding the establishment of the transition period, definition and application of the unit of payments, the computation of initial standard prospective payment amounts, the establishment of the adjustment for outliers, and the establishment of case-mix and area wage adjustment factors.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: _____

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Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: _____

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Donna E. Shalala,

Secretary.

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