DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-2009-1209

In the case of	**Claim for**
Landmark Home Health (Appellant)	Hospital Insurance Benefits (Part A)
**** (Beneficiaries)	**** (HIC Numbers)
Cahaba Government Benefit Administrators (Contractor)	**** and **** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued two unfavorable decisions dated June 16, 2009 (beneficiary K.G.), and June 24, 2009 (beneficiary K.S.), respectively.[1] The decisions concerned home health services provided to beneficiary K.G. from October 5, 2007, through October 29, 2007, and to beneficiary K.S. from October 26, 2007, through November 16, 2007. In both cases, the ALJ determined that the home health services were not covered by Medicare because the beneficiary did not have a valid plan of care dated by their physician. The ALJ concluded that the provider remained liable for the noncovered services under section 1879 of the Social Security Act (Act). The appellant has asked the Medicare Appeals Council (Council) to review the two decisions.

The Council reviews the ALJ's decisions *de novo*. 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's actions to the exceptions raised by the party in the requests for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c).

[1] To protect the beneficiaries' privacy, this decision refers to the beneficiaries by their initials. The attachments to the decision reference the beneficiaries' names, HICNs, associated ALJ appeal numbers, and the dates of service at issue.

The Council admits the following documents to the record:

Exh. MAC-1:	Appellant's requests for review regarding beneficiaries K.G. and K.S., both dated July 31, 2009;
Exh. MAC-2:	Council's interim letters regarding the appellant's requirement to copy all parties on its request for review and submission of new evidence, each dated October 26, 2009;
Exh. MAC-3:	Beneficiary K.S.'s response to the Council's interim letters, received November 9, 2009; and
Exh. MAC-4:	Appellant's interim letter response providing evidence of notice to the parties and argument for good cause related to the new evidence submitted in both appeals, dated November 10, 2009.

As explained more fully below, the Council agrees with the ALJ's ultimate conclusion that the home health services provided to the beneficiaries did not meet Medicare requirements. However, we are modifying both of the ALJ's decisions to find that although the plans of care were valid, the services at issue were not covered because they were not medically reasonable and necessary.

PROCEDURAL HISTORY

The intermediary denied the claims initially and on redetermination, finding that neither of the two beneficiaries had required skilled services. Beneficiary K.G. Claim File Exh. 2 at 15; Beneficiary K.S. Claim File Exh. 2 at 15. On reconsideration, the Qualified Independent Contractor (QIC) also concluded that the home health services were not covered. Beneficiary K.G. Claim File Exh. 3 at 14; Beneficiary K.S. Claim File Exh. 3 at 23. In the case regarding K.G., the QIC found that the home health certification and plan of care was invalid because it was not dated by the physician. Beneficiary K.G. Claim File Exh. 3 at 14. In the case regarding beneficiary K.S., the QIC concluded that the beneficiary did not require skilled services. Beneficiary K.S. Claim File Exh. 3 at 23. In

both cases, the QIC found that the provider was responsible for the cost of the noncovered services. *Id*.

The appellant subsequently requested an ALJ hearing on both cases. The ALJ held a telephone hearing regarding both beneficiaries on June 11, 2009. K.G. Dec. at 1, K.S. Dec. at 2, ALJ Hearing CD. The ALJ issued two unfavorable decisions: on July 16, 2009, regarding beneficiary K.G., and on July 24, 2009, regarding beneficiary K.S. In each case, the ALJ concluded that the periods of service were not covered because the physician had signed, but not dated, the plan of care, citing 42 C.F.R. § 409.43(c)(3). K.G. Dec. at 6, K.S. Dec. at 8.

The appellant submitted additional documentation with its requests for review. Exh. MAC-1. Specifically, in each appeal, the appellant submitted (1) a copy of a provision in the Medicare Program Integrity Manual, (2) copies of the physician certifications/plans of care pertaining to each beneficiary, (3) a copy of the agency's physician certification log, and (4) a copy of June 19, 2009 email correspondence between the Medicare contractor and the home health agency. *Id*. The appellant submitted the above described evidence to support its assertion that the plans of care met the requirements of 42 C.F.R. § 409.43(c).

By letter dated October 26, 2009, the Council informed the appellant that it had not indicated whether any of the additional documentation submitted with its request for review was new evidence. Exh. MAC-2. The Council advised the appellant that if any of the evidence had not been previously submitted during the appeal, it must show good cause for submitting the documentation at this stage of the appeal. *Id*; *see* 42 C.F.R. §§ 405.966(a)(2), 405.1018, 405.1122(c).

The appellant argues that it submitted the new evidence in both cases because it "did not anticipate that this information would be required prior to the ALJ level, since the issue was not identified as a problem prior to the hearing, through all levels of review." Exh. MAC-4. As explained below, the Council has decided that there is good cause for admitting the new evidence in the case of K.S., but not in the case of K.G.

DISCUSSION

Introduction

For the reasons explained below, the Council has determined that the two cases before us may not be resolved based on the issue of whether the beneficiaries had valid plans of care. Rather, in order to determine whether the services were covered, we focus first on whether the two beneficiaries were homebound and/or received skilled home health services. Therefore, we have considered each of the two cases in its entirety in order to determine whether the home health services provided to each beneficiary met Medicare coverage requirements. Specifically, in addition to analyzing the new evidence, we consider whether the two beneficiaries were confined to the home, under the care of a physician, and whether they both needed and received skilled services, during the periods at issue. 42 C.F.R. § 409.42.

Homebound Requirement

The Medicare Benefit Policy Manual (MBPM), CMS Pub. 100-02, chapter 7, section 30.1.1, provides guidance on interpreting the requirement that a beneficiary be "confined to the home":

> An individual does not have to be bedridden to be considered confined to the home. However, the condition of these patients should be such that there exists a normal inability to leave home and, consequently, leaving home would require a considerable and taxing effort.
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> * * *
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> Generally speaking, a patient will be considered to be homebound if they have a condition due to an illness or injury that restricts their ability to leave their place of residence except with the aid of: supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person; or if leaving home is medically contraindicated.

The ALJ did not address whether the beneficiaries were homebound. The record indicates, however, that the beneficiaries were homebound. The record reflects that

beneficiary K.G. was homebound due to severely impaired vision, required assistance for most activities of daily living, and ambulated with assistance. These restrictions were due to her insulin dependent diabetes mellitus, hypertension (HTN), macular degeneration, congestive heart failure (CHF), legal blindness, and recent kidney transplant. Beneficiary K.G. Claim File Exh. 5. The record for beneficiary K.S. indicates that the beneficiary was homebound due to physical impairments, that although the beneficiary was independent with most activities, the beneficiary utilized a walker to ambulate, and experienced dyspnea with moderate exertion related to her atrial fibrillation, coronary artery disease, and recent pacemaker insertion. Beneficiary K.S. Claim File Exh. 5.

Plan of Care

The appellant argues that the ALJ erred in finding that the plans of care for both beneficiaries were invalid because the physician did not date the plans of care when signed. Exhs. MAC-1, MAC-4. In particular, the appellant contends that the home health agency's handwritten dates of receipt on the plans of care satisfy the date requirements. *Id*.

The regulatory requirements for a plan of care are set forth in 42 C.F.R. § 409.43. As pertinent herein, the physician orders for services in the plan of care must specify the medical treatments to be furnished, as well as the type of home health discipline that will furnish the services and at what frequency the services will be furnished. 42 C.F.R. § 409.43(b).

Verbal orders for the plan of care may be used under the following circumstances:

> (d) Oral (verbal) orders. If any services are provided based on a physician's oral orders, the orders must be put in writing and be signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in Sec. 484.4 of this chapter) responsible for furnishing or supervising the ordered services. Oral orders may only be accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies. The oral orders must also be countersigned and dated by the physician before the HHA bills for the care.

> e) Frequency of review. (1) The plan of care must be reviewed by the physician (as specified in Sec. 409.42(b)) in consultation with agency professional personnel at least every 60 days . . . .
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> (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.

42 C.F.R. §§ 409.43(d) and (e).

The MBPM, chapter 7, section 30.2, provides guidance on the use of verbal orders and the physician signature requirement.

> **30.2.5 - Use of Oral (Verbal) Orders**
> **(Rev. 1, 10-01-03)**
> **A3-3117.2.E, HHA-204-2.E**
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> When services are furnished based on a physician's oral order, the orders may be accepted and put in writing by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies. The orders must be signed and dated with the date of receipt by the registered nurse or qualified therapist (i.e., physical therapist, speech-language pathologist, occupational therapist, or medical social worker) responsible for furnishing or supervising the ordered services. The orders may be signed by the supervising registered nurse or qualified therapist after the services have been rendered, as long as HHA personnel who receive the oral orders notify that nurse or therapist before the service is rendered. Thus, the rendering of a service that is based on an oral order would not be delayed pending signature of the supervising nurse or therapist. Oral orders must be countersigned and dated by the physician before the HHA bills for the care in the same way as the plan of care.
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> Services which are provided from the beginning of the 60-day episode certification period based on a request for anticipated payment and before the physician signs the plan of care are considered to be provided under a plan of care established and approved by the physician where there is an oral order for the care prior to rendering the services which is documented in the medical record and where the services are included in a signed plan of care.

* * *

30.2.6 - Frequency of Review of the Plan of Care (Rev. 1, 10-01-03)
A3-3117.2.F, HHA-204.2.F
The plan of care must be reviewed and signed by the physician who established the plan of care, in consultation with HHA professional personnel, at least every 60 days. Each review of a patient's plan of care must contain the signature of the physician and the date of review.

In the present appeals, each plan of care contains a nurse's signature and date for verbal orders for the start of a plan of care (SOC) in block 23. *See, e.g.*, Beneficiary K.G. Claim File Exh. 5 at 50. Each plan of care also bears a handwritten date in block 24, "Date HHA Received Signed POT [plan of treatment]." *Id*. However, for each certification period on appeal, the beneficiary's plan of care contains a physician signature but lacks a date the physician signed it.

The regulations indicate that the plan of care must be dated for two reasons. One, the plan of care must be dated before the HHA bills for the care if the services are provided based on verbal orders. 42 C.F.R. § 409.43(d). Two, the plan of care must be dated to indicate that the plan of care was reviewed at least every 60 days. *Id.* at (e).

In this case, the handwritten date in block 24 of the Home Health Certification and Plan of Care forms provides proof that both of these regulatory requirements were met. The HHA cannot force an independent physician to date his or her signature. We conclude that a technical defect due to a physician not dating the form does not serve to invalidate an otherwise acceptable plan of care.

Skilled Services

The appellant does not make any specific contentions that the beneficiaries required and received medically reasonable and necessary skilled services. Exhs. MAC-1, MAC-4. Having reviewed the record as a whole, the Council concludes that intermittent skilled nursing services were not reasonable and necessary for the beneficiaries.

A beneficiary must need "skilled services" in the form of intermittent skilled nursing services, physical therapy

services, speech-language pathology services, or occupational therapy services. 42 C.F.R. § 409.42(c). To qualify for Medicare coverage, the intermittent skilled nursing services provided must meet the criteria for skilled services and the need for skilled services found in section 409.32.

The skilled services at issue in this case are seven hours of skilled nursing services provided to each beneficiary. Beneficiary K.G. Claim File, Exh. 2 at 15; Beneficiary K.S. Claim File, Exh. 2 at 16. The regulation at 42 C.F.R. § 409.33(a)(2)(i) explains when observation and assessment of the patient's changing condition constitute skilled services: "Observation and assessment constitute skilled services when the skills of a technical or professional person are required to identify and evaluate the patient's need for modification of treatment or for additional medical procedures until his or her condition is stabilized."

The MBPM, section 40.1.2.1, provides further guidance on when skilled observation and assessment are reasonable and necessary for a beneficiary's condition:

> Observation and assessment of the patient's condition by a nurse are reasonable and necessary skilled services when the likelihood of change in a patient's condition requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment or initiation of additional medical procedures until the patient's treatment regimen is essentially stabilized. When a patient was admitted to home health care for skilled observation because there was a reasonable potential of a complication or further acute episode, but did not develop a further acute episode or complication, the skilled observation services are still covered for three weeks or so long as there remains a reasonable potential for such a complication or further acute episode.
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> However, observation and assessment by a nurse is not reasonable and necessary to the treatment of the illness or injury where these indications are part of a longstanding pattern of the patient's condition, and there is no attempt to change the treatment to resolve them.

Section 40.1.2.2 - Management and Evaluation of a Patient Care Plan, provides:

> Skilled nursing visits for management and evaluation of the patient's care plan are also reasonable and necessary where underlying conditions or complications require that only a registered nurse can ensure that essential nonskilled care is achieving its purpose. For skilled nursing care to be reasonable and necessary for management and evaluation of the patient's plan of care, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of skilled nursing personnel to promote the patient's recovery and medical safety in view of the patient's overall condition.

As the MBPM makes clear, observation and assessment are reasonable and necessary skilled services when required to "evaluate the patient's need for possible modification of treatment or initiation of additional medical procedures until the patient's treatment regimen is essentially stabilized." MBPM, ch. 7, § 40.1.2.1.

Beneficiary K.G.

The record in the present case does not demonstrate that the beneficiary required intermittent skilled nursing services during the period at issue. The physician ordered home health services for the beneficiary beginning on October 5, 2007, for observation and assessment of the beneficiary's vital signs and signs and symptoms or exacerbation or complications of diabetes, hypertension, macular degeneration, congestive heart failure, and status/post an April 4, 2007, kidney transplant. Beneficiary K.G. Claim File Exh. 5 at 50.

The MBPM provides that "the services of a nurse that are required to administer . . . medications safely and effectively may be covered if they are reasonable and necessary to the treatment of the illness or injury." MBPM, § 40.1.2.4. Thus, while "[i]nsulin is customarily self-injected by patients or is injected by their families, . . . where a patient is either physically or mentally unable to self-inject insulin and there is no other person who is able and willing to inject the patient, the injections would be considered a reasonable and necessary skilled nursing service." *Id.*

The record reflects that the beneficiary was not newly diagnosed with diabetes. Instead, the beneficiary had been managing her diabetes with insulin injections. Although the beneficiary may have been unable to pre-fill the insulin syringes due to visual deficits, she was able to self-inject once the syringe was prepared. The beneficiary's husband had prepared the syringes, however, he may have been unavailable on the first date of home care services. Beneficiary K.G. Claim File Exh. 5 at 47. Although the beneficiary's husband may have been unavailable during part of one day of service, there is no evidence that another caregiver was not willing and able to pre-fill the beneficiary's syringes, nor has the appellant made any arguments in support of this element. Exh. MAC-1, MAC-4.

Additionally, the medical records submitted do not demonstrate significant changes in the beneficiary's condition. The record shows that the nurse assessed the beneficiary as having elevated blood sugar on two occasions; however, this assessment did not lead to any significant changes in the beneficiary's plan of care or treatment regimen. Also during the period at issue, the record shows that the beneficiary was medically stable without medication modifications or treatment plan that would require the skills of a nurse. Beneficiary K.G. Claim File Exh. 5. As such, observation and assessment by a skilled nurse was not reasonable and necessary to treat the beneficiary's medical problems when they are part of a longstanding pattern in the patient's condition, and there has been no attempt to change the treatment to resolve them. *See* MBPM, ch. 7, § 40.1.2.1.

In conclusion, we find that the record does not reflect that the beneficiary was in need of skilled services pursuant to 42 C.F.R. § 409.42(c). Therefore, the home health services provided to beneficiary K.G. from October 5, 2007, through October 29, 2007, were not medically reasonable and necessary and are not covered by Medicare in accordance with section 1862(a)(1)(A) of the Act.

Beneficiary K.S.

The record does not demonstrate that the beneficiary required intermittent skilled nursing services during the period at issue. The home health services were ordered for observation and assessment, instruction, and venipuncture. Beneficiary K.S. Claim File, Exh. 5 at 37. The beneficiary began receiving home health services after a hospitalization for an elective pacemaker insertion. Beneficiary K.S. Claim File Exh. 5. The documentation submitted does not reflect complications or signs

or symptoms of infection related to the surgery or incision site. *Id*. The beneficiary's condition remained stable and there were no significant changes in the beneficiary's condition or treatment regimen. *Id*. The only modification was in Coumadin, which the beneficiary had been taking on a long-term basis. *Id*.

The nursing notes reflect that the primary duty of the skilled nurse was to conduct venipuncture. *Id*. As CMS has explained, venipuncture for blood tests does not alone justify coverage of a SN visit unless other skilled services are needed. A pertinent manual section explains that –

> [V]enipuncture for the purposes of obtaining a blood sample can no longer be the sole reason for Medicare home health eligibility. However, if a beneficiary qualifies for home health eligibility based on a skilled need other than solely venipuncture (e.g., eligibility based on the skilled nursing service of wound care and meets all other Medicare home health eligibility criteria), medically reasonable and necessary venipuncture coverage may continue during the 60-day episode under a home health plan of care. Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act specifically exclude venipuncture, as a basis for qualifying for Medicare home health services if this is the sole skilled service the beneficiary requires. However, the Medicare home health benefit will continue to pay for a blood draw if the beneficiary has a need for another qualified skilled service and meets all home health eligibility criteria.

MBPM, Ch. 7, § 40.1.2.13.

Therefore, whether the skilled nurse visit is covered depends on whether other qualifying home health services have been provided. In this case, there were no other qualifying home health services provided; thus, the venipuncture services provided were not covered by Medicare.

For the foregoing reasons, the Council concludes that the beneficiary did not require or receive skilled nursing services during the dates of service at issue. Accordingly, the home health services provided from October 26, 2007, through November 16, 2007, are not covered by Medicare in accordance with section 1862(a)(1)(A) of the Act.

Limitation on Liability

The Council concurs with the ALJ's determination that the appellant remains liable for the costs of the noncovered services pursuant to Section 1879 of the Act. Section 1879 of the Act provides that when Medicare coverage is denied under section 1862(a)(1) or (a)(9) of the Act, payment may nevertheless be made for the item or service if neither the beneficiary nor the provider/supplier knew, or could not reasonably be expected to have known, that the items or services would not be covered by Medicare. There is no evidence in the record that either beneficiary received written notice of noncoverage from the appellant-provider in this case. 42 C.F.R. § 411.404. On the other hand, a provider or supplier is considered to have notice that an item or service is not covered based on its receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from the Medicare contractors. 42 C.F.R. § 411.406. Accordingly, the Council finds the appellant remains liable for the noncovered charges.

DECISION

It is the decision of the Medicare Appeals Council that the home health services provided to beneficiary K.G. from October 5, 2007, through October 29, 2007, and to beneficiary K.S. from October 26, 2007, through November 16, 2007, remain not covered by Medicare pursuant to section 1862(a)(1) of the Act. The provider remains liable for the cost of the above-referenced services under section 1879 of the Act. The ALJ's decisions are modified accordingly.

MEDICARE APPEALS COUNCIL

/s/ M. Susan Wiley
Administrative Appeals Judge

/s/ Susan S. Yim
Administrative Appeals Judge

Date: February 19, 2010