



Department of Health and Human Services OFFICE OF MEDICARE HEARINGS AND APPEALS Western Field Office Irvine, CA

Appeal of:	Arroyo Grande Community Hospital	ALJ Appeal No.: 1-848782038
Beneficiary:		Medicare Part: A
HICN:		Before: Eric K. H. Chinn U.S. Administrative Law Judge

DECISION

After careful consideration of all the evidence and arguments presented in the administrative record and at the hearing, an UNFAVORABLE decision is entered against Arroyo Grande Community Hospital (the "Appellant").

Procedural History

This appeal arises from an overpayment determination made by Healt	hDatalnsights, Inc., a
Recovery Audit Contractor ("RAC"), finding that Medicare had made an	improper payment to
the Appellant for inpatient hospital services provided to	(the "Beneficiary") on
through , 2009. (Exh. 12).	

The Appellant requested a redetermination from the Medicare Administrative Contractor with jurisdiction, Palmetto GBA (the "Contractor"). (*Id*). On June 9, 2011, the Contractor upheld the overpayment determination on the basis that there was an incomplete admission order and insufficient documentation to support medical necessity of this room and board inpatient admission. (*Id*. at 2).

The Appellant appealed to MAXIMUS Federal Services, a Qualified Independent Contractor ("QIC"), for a new and impartial review. (Exh. 13). On September 9, 2011, the QIC upheld the Contractor's denial, finding that there was insufficient clinical evidence to suggest that an inpatient level of service was required to accomplish the appropriate treatment of the Beneficiary safely and within the boundaries of the standard of care. (Exh. 14). The QIC held the Appellant liable for the non-covered charges. (*Id*).

The Appellant subsequently filed a request for a hearing before an Administrative Law Judge ("ALJ"), which was received by the Office of Medicare Hearings and Appeals ("OMHA") on November 1, 2011. (Exh. 15). The amount in controversy is based on the cost of the services and meets the jurisdictional threshold requirement for an ALJ hearing. (See 42 C.F.R. § 405.1006; see also 75 Federal Register 58407 (Sept. 24, 2010)). The Appellant's request for an appeal was timely filed. (See 42 C.F.R. § 405.1014). On January 31, 2012, a Notice of Hearing was sent to the Appellant, the RAC, the Contractor, and the QIC. (Exh. 16).

On February 21, 2012, an administrative hearing on this matter was held by telephone before the undersigned ALJ at the OMHA Western Field Office in Irvine, California. (Hearing CD). The Appellant appeared and was represented by Jessica Gustafson, Esq. Larry Foreman, D.O., (Physician Advisor) testified on the Appellant's behalf. Ellen Evans, M.D., (Medical Director) testified for the RAC as a non-party participant. Exhibits 11 through 17¹ were admitted into evidence without objection, which included for good cause the additional documents submitted with the Appellant's hearing request.

<u>Issues</u>

The issue on appeal before the undersigned ALJ is whether the inpatient hospital services the Appellant provided to the Beneficiary on through 2009, were medically reasonable and necessary according to Medicare coverage criteria; and, if not covered as reasonable and necessary, whether and to what extent the Appellant (or any other party) may be liable.

Findings of Fact

The administrative record establishes the following facts by a preponderance of the evidence:

- 1. The Beneficiary is a 79 year old female with diagnoses of sinoatrial and atrioventricular node disease with profound sinus bradycardia, paroxysmal atrial fibrillation with slow ventricular response rate, essential hypertension, hiatus hernia with gastroesophageal reflux disease, stable abdominal aortic aneurysm, hyperlipidemia, and retinitis pigmentosa. (Exh. 11, p. 8).
- 2. On _______, 2009, the Beneficiary's treating physician documented a plan to implant a permanent dual-chamber pacemaker to address her sinoatrial and atrioventricular node disease. (*Id*). The physician noted the Beneficiary had been hospitalized in _______ 2009 with presyncope. (*Id*. at 7). A cardiac event monitor _______, 2009, demonstrated persistent atrial fibrillation with very slow ventricular response rate. (*Id*). Echocardiography _______, 2009, demonstrated left ventricular hypertrophy with preserved left ventricular function, mild mitral regurgitation and mild tricuspid regurgitation. (*Id*).
- 3. On ______, 2009, the Beneficiary presented to the Appellant hospital for an initial dual chamber permanent pacemaker implantation. (*Id.* at 87). The procedure was performed

¹ Exhibit numbers 1-10 were intentionally omitted and the record begins at Exhibit 11.

under local anesthesia without complication. (*Id*). The pacemaker was tested functional and the Beneficiary was returned to the recovery area. (*Id*. at 88). The Beneficiary was in stable condition post-procedure. (*Id*. at 99).

- 4. After the pacemaker implantation procedure on ______, 2009, the Beneficiary was admitted to a telemetry bed as an inpatient for post-operative monitoring. (*Id.* at 23). The admitting physician ordered frequent vital sign checks, bed rest, and intravenous antibiotics, with an electrocardiogram and complete blood count to be performed the following morning. (*Id*).
- 5. A chest x-ray performed at a.m. on 2009, revealed placement of a bipolar pacemaker with no evidence of infiltrate, pneumothorax, or pulmonary edema. (*Id.* at 75).
- 6. At a.m. on 2009, the Beneficiary was discharged home with orders to resume home medications. (*Id.* at 39).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services ("HHS"), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. (Section 1869(b)(1)(A) of the Social Security Act (the "Act")).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals systems for the Medicare program to OMHA. (See 70 Fed. Reg. 36386, 36387 (June 23, 2005)). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. (Id).

A hearing before an ALJ is available only if the remaining amount in controversy is \$130 or more. (75 Fed. Reg. 58407 (Sept. 24, 2010)). The request for hearing is timely filed if filed within 60 days after receipt of a reconsideration decision. (42 C.F.R. § 405.1014).

B. Scope of Review

Under the Centers for Medicare and Medicaid Services' ("CMS") implementation policy for the Medicare, Medicaid, SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"), Pub. Law 106-554, app. F, 114 Stat. 2763, 2763A-463, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. Law 108-173, 117 Stat. 2066, when considering Medicare appeals, all initial determinations by CMS contractors, subsequent to January 1, 2006 and all appeals that were subject to a QIC reconsideration, are governed by the

ALJ hearing procedures set forth at 42 C.F.R. §§ 405.1000 through 405.1064. (See 70 Fed. Reg. 11420, 11424-26 (Mar. 8, 2005)).

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. (42 C.F.R. § 405.1032(a)). However, if evidence presented before or during the hearing causes the ALJ to question a favorable portion of the determination, he or she may notify the parties before the hearing and may consider it an issue at the hearing. (*Id*).

C. Standard of Review

The OMHA is staffed with ALJs who conduct *de novo* hearings. (70 Fed. Reg. 36386 (June 23, 2005); *see also In re Atlantic Anesthesia Associates, P.C.*, MAC (June 2004) (stating that "An ALJ qualified and appointed pursuant to the Administrative Procedure Act acts as an independent finder of fact in conducting a hearing pursuant to Section 1869 of the Act. This requires *de novo* consideration of the facts and law.")).

A *de novo* review means the ALJ reviews the evidence without regard to the findings in the prior determinations on the claim and makes an independent assessment based on the evidence and the controlling laws. However, the burden of proving each element of a Medicare claim lies with the Appellant and is satisfied by submitting sufficient evidence in accordance with Medicare rules. (*See* e.g., Act §§ 1814(a)(1), 1815(b), and 1833(e); *see also* 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, 405.1030).

An appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. (See 42 C.F.R. § 405.1018; see also 42 C.F.R. §§ 405.1028 and 405.1030). The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. This late evidence restriction does not apply to unrepresented beneficiaries.

II. Principles of Law

A. Statutes and Regulations

Eligibility for Medicare benefits is determined under Title XVIII of the Social Security Act, 42 U.S.C. § 1801 et seq., and federal regulations set forth in Title 42 of the Code of Federal Regulations.

Sections 1812 and 1813 of the Act establish the scope of benefits of the hospital insurance program under Medicare Part A. Section 1814 establishes conditions for and limitations on payment for services furnished by providers. Medicare Part A entitles a beneficiary to reimbursement for a variety of costs associated with hospital, related post-hospital, home health services, and hospice care for individuals eligible for Medicare. (42 U.S.C. § 1395d(a)(1)).

Medicare Part A covers "inpatient" hospital services provided to beneficiaries who are patients

in qualified hospitals participating in the Medicare program for up to 90 days in any one "spell of illness." (Act $\S 1812(a)(1)$). In addition, each beneficiary has a lifetime reserve of 60 days that can be used after the 90 days have been exhausted. (*Id*).

Specifically, the following services or supplies provided while the beneficiary is an inpatient in the hospital are covered: 1) bed and board; 2) nursing services (other than the services of a private-duty nurse of attendant) and other related services that are ordinarily are furnished by the hospital for the care and treatment of inpatients; 3) use of hospital facilities and such medical social services as customarily are furnished by the hospital for the care and treatment of inpatients; 4) drugs, biologicals, supplies, appliances, and equipment for use in the hospital that ordinarily are furnished by the hospital for the care and treatment of inpatients; and 5) diagnostic and therapeutic items and services that are ordinarily furnished to inpatients. (Act § 1861(b)).

According to Section 1862(a)(1)(A) of the Act, no payment may be made under Medicare for any expenses incurred for items or services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." (See 42 U.S.C. § 1395y(a)(1)(A); see also 42 C.F.R. § 411.15(k)(1)).

Section 1833(e) of the Act provides that claims for payment must be supported by sufficient information and documentation. The provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment. (42 C.F.R. § 424.5(a)(6)).

Section 1879 of the Act provides that when Medicare excludes payment and coverage pursuant to Section 1862(a)(1), or Sections 1814(a)(2)(C) and 1835(a)(2)(A), payment may nevertheless be made for the items or services if neither the beneficiary nor the provider or supplier knew, or could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare. (See also 42 C.F.R. § 411.406).

B. Policy and Guidance

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a national coverage determination ("NCD"), can establish or change a substantive legal standard governing the scope of the benefits or payment for services under the Medicare program unless promulgated as a regulation by CMS. NCDs promulgated by the Secretary of HHS under the authority of Section 1862(a)(1) of the Act dictate the criteria under which Medicare covers specified services, procedures or supplies. NCDs are binding upon ALJs. (42 C.F.R. § 405.732(a)(4)). "An ALJ may not disregard, set aside or otherwise review an NCD." (*Id.* § 405.732(b)(1)).

Although not subject to the force and effect of law, CMS and its contractors issue policies, manuals and guidelines that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies ("LMRPs") or local coverage determinations ("LCDs").

42 C.F.R. § 405.1062(a) and (b) state that an ALJ is not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

An ALJ may give consideration to the manuals and rulings issued by the CMS in determining benefit coverage and eligibility. Although not binding on the ALJ, the respective manuals provide guidance in the administration of the Medicare program. (*Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995)).

The Medicare Benefit Policy Manual ("MBPM") defines an "inpatient" as a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. (CMS, MBPM (Internet-Only Manual Publ'n 100-02) Ch. 1, § 10). A person is considered an inpatient if formally admitted as an inpatient with the expectation of remaining at least overnight and occupying a bed, even if it later develops that discharge or transfer to another hospital is possible and a hospital bed actually is not used overnight. (Id). The manual further states:

The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. Physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis. However, the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting. Factors to be considered when making the decision to admit include such things as:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of something adverse happening to the patient;
- The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and
- The availability of diagnostic procedures at the time when and at the location where the patient presents. (*Id*).

The Medicare Program Integrity Manual ("MPIM"), provides guidelines for medical review of inpatient hospital claims. (CMS, MPIM (Internet-Only Manual Publ'n 100-08) Ch. 6, § 6.5). According to the MPIM, inpatient services must be supported by documentation showing they were medically necessary, reasonable, and appropriate for the diagnosis and condition of the beneficiary at any time during the stay. (Id. § 6.5.2). The beneficiary must demonstrate signs

and/or symptoms severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis. (*Id*). Inpatient care rather than outpatient care is required only if the beneficiary's medical condition, safety, or health would be significantly and directly threatened if care was provided in a less intensive setting, such as observation care. (*Id*).

Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment, that are furnished while a decision is being made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge. Observation services are covered only when provided by the order of a physician or another individual authorized by State licensure law and hospital staff bylaws to admit patients to the hospital or to order outpatient services.

Observation services must also be reasonable and necessary to be covered by Medicare. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. (CMS, *Medicare Claims Processing Manual* ("MCPM") (*Internet-Only Manual Publ'n 100-04*) Ch. 4, § 290).

Analysis

The issue on appeal is whether the inpatient hospital services the Appellant provided to the Beneficiary on through 2009, were medically reasonable and necessary pursuant to Medicare coverage criteria. After reviewing the record, the testimony, and the arguments presented, the undersigned ALJ concludes that the documentation does not support an inpatient level of care was medically necessary for purposes of Medicare Part A coverage.

An inpatient level of care was not medically necessary, reasonable, and appropriate for the Beneficiary's treatment.

Under Section 1862(a)(1)(A) of the Social Security Act, payment under Medicare may only be made for services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Medicare Part A covers "inpatient" hospital services when supported by documentation showing that they were medically necessary, reasonable, and appropriate for the diagnosis and condition of the beneficiary. The beneficiary must demonstrate signs and symptoms severe enough to warrant medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis. An inpatient level of care is required only if the

beneficiary's medical condition, safety, or health would be significantly and directly threatened if care was provided in a less-intensive setting, such as observation care.

Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment, that are furnished while a decision is being made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge. In the majority of cases, the decision whether to discharge a patient from observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours

According to the *Medicare Benefit Policy Manual*, physicians should only order admission for patients who are expected to need hospital care for 24 hours or more. However, the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors. These factors include such things as: (i) the severity of the signs and symptoms exhibited by the patient; (ii) the medical predictability of something adverse happening to the patient; (iii) the need for diagnostic studies that appropriately are outpatient services to assist in assessing whether the patient should be admitted; and (iv) the availability of diagnostic procedures at the time when and at the location where the patient presents.

In this case, the Beneficiary is a 79 year old female with a primary diagnosis of sinoatrial and atrioventricular node disease. On 2009, the Beneficiary presented to the Appellant hospital for an elective initial dual chamber permanent pacemaker implantation. The procedure was performed on an outpatient basis under local anesthesia with no complications. After the procedure, the Beneficiary was admitted to a telemetry bed as an inpatient for post-operative monitoring. The admitting physician ordered frequent vital sign checks, bed rest, and intravenous antibiotics, with an electrocardiogram and complete blood count to be performed the following morning. At a.m. on 2009, the Beneficiary was discharged home with orders to resume home medications.

The RAC determined Medicare payment for the provided inpatient hospital services was improper on the basis that there was an incomplete admission order and insufficient documentation to support medical necessity of this room and board inpatient admission. The QIC upheld the overpayment determination, finding that there was insufficient clinical evidence to suggest that an inpatient level of service was required to accomplish the appropriate treatment of the Beneficiary safely and within the boundaries of the standard of care. The Appellant, on the other hand, argued that the inpatient hospital admission in this case was medically necessary, appropriate, and consistent with the best local and national standards of medical practice.

Upon review of the administrative record, the undersigned ALJ finds the submitted documentation does not support an inpatient admission was reasonable and necessary pursuant to Medicare coverage criteria. The severity of signs and symptoms exhibited by the Beneficiary at the time of admission did not support an inpatient level of care. Medicare limits hospital inpatient reimbursement to services deemed to require complex and extended hospital level care. The Beneficiary's inpatient management was limited to routine testing and observation, without

complex interventions. According to the procedure record, the Beneficiary's pacemaker implantation was performed under conscious sedation without complications. The Beneficiary was stable post-procedure with no indication the device was not functioning properly. A chest x-ray shortly after the procedure revealed no evidence of infiltrate, pneumothorax, or pulmonary edema. Moreover, according to the preponderance of the reviewing medical opinions, the care contemplated for the Beneficiary at the time of admission consisted largely of monitoring and lab work that was typically available on an outpatient basis. The admitting physician ordered frequent vital sign checks, bed rest, and intravenous antibiotics, with an electrocardiogram and complete blood count to be performed the following morning. Ultimately, the undersigned ALJ finds that the weight of the evidence available at the time of admission did not support that the Beneficiary's medical condition, safety, or health would have been significantly and directly threatened if her care was provided in a less-intensive setting, such as outpatient observation.

For the above reasons, the undersigned ALJ concludes that payment Medicare cannot be allowed for the inpatient hospital services the Appellant provided to the Beneficiary on through through through through , 2009. Medicare coverage criteria were not met. Admission to an inpatient level of care was not reasonable and necessary based on the totality of the circumstances.

The Appellant is not entitled to limitation of liability pursuant to Act § 1879.

According to Section 1879 of the Social Security Act, when Medicare excludes payment and coverage pursuant to Section 1862(a)(1), payment may nevertheless be made for the items or services if neither the beneficiary nor the provider or supplier knew, or could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare. The provisions of Section 1879 become pertinent when Medicare's denial is based on medical necessity.

The undersigned ALJ finds the Beneficiary did not know or could not reasonably be expected to have known the provided services would not be covered or payable by Medicare. There is no evidence the Appellant gave the Beneficiary sufficient advance notice Medicare was not likely to provide coverage.

The undersigned ALJ is not convinced, however, that the Appellant is eligible for a waiver of liability pursuant to Section 1879. Providers are presumed to have knowledge of published Medicare coverage rules and regulations, CMS Rulings, Medicare coverage policies in bulletins, manuals, written guides, directives, or websites, and acceptable standards of practice within the local medical community. As a Medicare program participant, the Appellant knew or reasonably should have known of Medicare rules, regulations, policies and procedures for obtaining payment on covered items or services, including inpatient hospital admission criteria, and shall therefore remain liable for the non-covered charges.

Recoupment of the overpayment is not waived under Act § 1870.

Section 1870 of the Act provides an opportunity for a provider of medical services to avoid liability when an overpayment is determined if the provider was "without fault" in causing the overpayment and its recovery would defeat the purpose of Title XVIII of the Act or would be

against equity and good conscience. Here, the overpayment determination was made within the three year period after notice of payment of the claim. As discussed above, the Appellant, as a professional provider, is expected to have knowledge of the billing and practice information contained in the appropriate CMS notices, including manual issuances, bulletins, or other written guidelines or directives from the carriers, and is expected to have knowledge or experience of acceptable standard of practice by the local medical community. Consequently, the undersigned ALJ finds that the Appellant accepted payments which it knew or could have been expected to know were incorrect and is therefore not without fault in causing the overpayment at issue.

Conclusions of Law

Based on the totality of the evidence of record, the undersigned ALJ concludes that payment cannot be allowed under Medicare Part A for the inpatient hospital services the Appellant provided to the Beneficiary on through 2009. The record does not support that an inpatient level of care was medically reasonable and necessary pursuant to Section 1862(a)(1)(A) of the Social Security Act and 42 C.F.R. § 411.15(k)(1). The Appellant is not without fault in causing the overpayment at issue and shall therefore remain liable for the non-covered charges.

Accordingly, the prior decision of MAXIMUS Federal Services is hereby affirmed.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated:	MAY 0 4 2012	A L
		Eric K. H. Chinn

U.S. Administrative Law Judge



Department of Health and Human Services Office of Medicare Hearings and Appeals Western Field Office 27 Technology Drive, Suite 100 Irvine, CA 92618

Appeal of:

ARROYO GRANDE

COMMUNITY HOSPITAL

ALJ Appeal #:

1-848782038

Beneficiary:

Medicare Part: A

HICN:

Before: Eric K. H. Chinn

U.S. Administrative Law Judge

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION Exhibits 1 – 10 have been intentionally omitted	NUMBER RANGE
11	Treating Notes and Medical Records	106
12	Redetermination Decision dated 6/9/11, with Initial and Redetermination Level Documents	66
13	Request for Reconsideration dated 7/11/11, with attached documents	123
14	Reconsideration Decision, dated 9/9/11, with other Reconsideration Level Documents	19
15	Request for Administrative Law Judge Hearing dated 10/31/11, received 11/10/11, with attached documents	185
16	Notice of Hearing, dated 1/31/12	8
17	Response to Notice of Hearing dated 02/09/12	4