Durable Medical Equipment (DME) Documentation for Medicare Payment

Recent Developments Highlight the Importance of Medical Necessity Documentation

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The U.S. Supreme Court recently denied review in a case, reaffirming the long-standing Medicare principle that suppliers must be able to demonstrate the medical necessity of durable medical equipment (DME), such as power wheelchairs and scooters, provided to beneficiaries to receive payment. The Supreme Court's action ended a decade-long Medicare payment dispute. Coincidentally, on the same day, the Centers for Medicare & Medicaid Services (CMS) announced that it was "enhanc[ing] program integrity efforts to fight fraud, waste and abuse in Medicare."[1]

CMS Acting Administrator Kerry Weems told attendees at an American Health Lawyers Association (AHLA) conference that the agency was going to "zero in" on Medicare fraud involving the highest paid DME suppliers and the highest billed equipment and supplies, including power wheelchairs.[2] The combination of these two events underscores the importance of securing and retaining documentation of medical necessity for those involved in furnishing DME and submiting claims for Medicare payment. This article discusses these issues further.

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Case History

The legal principles involved in this case were reviewed at numerous levels prior to the Supreme Court's denial of the appeal. On October 6, 2008, the Court denied a petition for a writ of certiorari filed in the case of *Maximum Comfort, Inc. v. Leavitt* seeking review and reversal of a decision by the U.S. Court of Appeals for the Ninth Circuit.[3] Rejection of the appeal means that documentation of medical necessity, in addition to a certificate of

medical necessity (CMN), may be required to substantiate a supplier's claim for Medicare coverage and payment.

Medicare Carrier Review

The *Maximum Comfort* case originated with a Medicare carrier's post-payment audits of claims submitted by a supplier of power wheelchairs in 1998 and 1999. Based on its review of a sample of claims, the carrier determined the supplier had failed to furnish documentation demonstrating that the claimed power wheelchairs were medically reasonable and necessary. The carrier then extrapolated its sample findings to the universe of the supplier's claims, assessing an overpayment of $548,555 in the first audit and an overpayment of $237,229 in the second audit.

Administrative Law Judge Review

The supplier was unsuccessful in appealing the overpayment determinations at the Medicare carrier level, so it requested review by an administrative law judge (ALJ). Two separate ALJ decisions were subsequently issued reversing both carrier overpayment assessments. The claimed DME was determined to be covered by Medicare because the supplier reasonably relied on CMNs signed by the physicians who ordered the equipment.

Medicare Appeals Council Review

Dissatisfied with the ALJ decisions, CMS asked the U.S. Department of Health and Human Services' (HHS) Medicare Appeals Council to undertake an "own motion" review. In a decision issued June 11, 2003, the Council reversed the two ALJ decisions.[4]

The Council found that the claimed equipment was not covered by Medicare. It noted that a CMN is designed to record certain information to help determine whether DME is medically reasonable and necessary. The Council rejected the supplier's arguments that the Social Security Act establishes the CMN "as the sole mechanism for establishing coverage of DME" and that the Medicare program cannot impose additional documentation requirements for evaluating whether any claimed DME is covered.[5] According to the Council, no legal support exists for the supplier's proposition "that the primary purpose of the CMN is to eliminate the need for any supporting medical documentation to establish medical necessity."[6]

The Medicare Appeals Council concluded that the supplier had claimed Medicare payment with only a CMN as support, so the equipment was not covered by Medicare. The Council also determined that the supplier had sufficient notice that the items would not be covered without additional medical documentation and, therefore, was liable for the overpayment assessments.[7]

Federal District Court Review

The supplier then requested federal court review. On June 30, 2004, a U.S. district court reversed the Medicare Appeals Council and held that a completed CMN is the only documentation needed to establish the medical reasonableness and necessity of claimed DME.[8] The judge concluded the Medicare program "cannot require that DME suppliers…obtain Medicare beneficiaries' medical records and make a judgment as to whether the equipment is medically necessary and reasonable."[9] The Court found that "Congress…established that any and all information required from suppliers to make a medical necessity determination must be contained in a CMN."[10]

Based on its legal conclusion, the Court enjoined Medicare's recovery of the two overpayments. The U.S. Department of Justice, on behalf of CMS, then filed an appeal and asked the Court of Appeals for the Fourth Circuit to reverse the district court's decision.

Court of Appeals Review

On December 21, 2007, following a review of Medicare statutory authorities,

an appeals court determined the law "does not state that the certificate of medical necessity is the sole vehicle for claims reimbursement, nor does it state that a completed certificate establishes, by itself, a right to reimbursement."[11] The Court found that section 1834(j)(2) of the Social Security Act, pertaining to CMNs, cannot be read as limiting the statutory requirement that no Medicare payment may be made for items and services not medically reasonable and necessary.[12] It held that the Medicare program "may require, as a condition of reimbursement to an equipment supplier, information in addition to that provided by the certificate of medical necessity."[13]

The Court also found, with respect to the supplier's liability for the overpayments, that various Medicare carrier issuances "provided Maximum Comfort with sufficient notice that the [Medicare program] might require documentation of medical necessity in addition to the certificate of medical necessity and would deny the claim if the additional information were not forthcoming."[14] Therefore, Maximum Comfort remained liable for the assessed overpayments.

The appeals court reaffirmed the position previously expressed by the HHS Medicare Appeals Council that power wheelchairs and other DME furnished to beneficiaries and supported solely by a CMN, without supporting medical documentation, may be determined not medically reasonable and necessary and, therefore, not covered by Medicare.[15]

Medicare Payment Requirements for DME

Regulations

In 1996, CMS revised the regulations governing Medicare coverage and payment for DME. CMS published specific "conditions for payment" for power mobility devices (PMDs), such as power wheelchairs and power-operated vehicles or scooters. Effective June 5, 2006, the following requirements were imposed:

- A physician or treating practitioner must conduct a face-to-face examination of the beneficiary for the purpose of determining the medical necessity of a PMD as part of the overall treatment plan.
- A prescription for the DME must be issued and furnished to the supplier within 45 days after the examination.
- Documentation, including pertinent portions of the beneficiary's medical records (*e.g.*, history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans), supporting the medical necessity of the prescribed PMD must be furnished to the supplier within 45 days of the examination.[16]

The regulations state that a supplier "may not dispense a PMD to a beneficiary until the PMD prescription and the supporting documentation have been received from the physician or treating practitioner who performed the face-to-face examination of the beneficiary."[17] A supplier is required to retain the prescription and other supporting medical documentation. Further, upon request, a supplier must "submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity of the power mobility device."[18]

Program Guidance

More recently, CMS issued program guidance for suppliers on documentation requirements for obtaining Medicare coverage and payment of DME. The *Medicare Program Integrity Manual* was revised, effective March 1, 2008, and now provides:

- For DME to be covered by Medicare, the medical records must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items claimed.

- The information in the medical records should include the patient's diagnosis and other pertinent information, including duration of the condition, clinical course, prognosis, nature and extent of functional limitations, other therapeutic interventions and results, and past experience with related items.
- Neither a physician's order nor a CMN or physician attestation, by itself, provides sufficient documentation of medical necessity, even though it may be signed by the treating physician or supplier.
- There must be information in the patient's medical record that supports the medical necessity for the claimed items and substantiates the answers of the CMN (if applicable).
- The patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, home health agency, or records from other health care professionals.
- If the information in the patient's medical record does not adequately support the medical necessity for the claimed item, then the supplier is liable for the DME unless a properly executed advance beneficiary notice regarding possible denial has been furnished.[19]
- A supplier should obtain as much documentation from the patient's medical record as it determines is needed to ensure that coverage criteria for an item have been met.
- Documentation must be maintained in the supplier's files for seven years.[20]

Office of Inspector General Review and Recommendations

The HHS Office of Inspector General (OIG) has identified ongoing problems with Medicare payment of DME claims. The OIG issued a report in August 2008 regarding an audit of CMS' medical review of DME claims paid by Medicare in fiscal year 2006. Based on its review of a sample of DME claims, the OIG estimated that the Medicare payment error rate was 28.9 percent. In other words, almost 30 percent of the DME claims reviewed were erroneously paid by the Medicare program.

In its report, the OIG noted that "Medicare claims from DME suppliers have historically been more vulnerable to billing fraud and abuse than claims from other providers because of weak Medicare payment controls. It recommended that, in reviewing DME claims, "CMS obtain all medical records (including, but not limited to, physician's records) for DME claims and contact the beneficiaries named on high-risk claims."[21] In its Semi-Annual Report to Congress, the OIG further highlighted the recommendation that CMS have its contractors "review all available supplier documentation and all medical records necessary to determine compliance with applicable requirements on medical necessity."[22]

Lessons for the Future

The recent action by the U.S. Supreme Court, coupled with the OIG's recent recommendations and CMS' new "high dollar" DME review program, should highlight to suppliers the importance of securing and retaining documentation of medical necessity.

The U.S. Supreme Court's denial of review in the *Maximum Comfort* case resolves the legal debate about whether a CMN may be the sole basis for determining Medicare coverage and payment of expensive DME. Three courts of appeals have now affirmed the principle that supporting medical documentation, in addition to a CMN, may be required to establish Medicare coverage.[23] This position is consistent with the Medicare statutory requirement that "[n]o payment shall be made to any provider of services or other person under [Medicare] unless there has been furnished such information as may be necessary in order to de-

termine the amounts due such provider or other person."[24]

The Medicare statute places the burden of supporting and substantiating a claim for Medicare payment on the supplier submitting the claim. This principle was reinforced by the CMS regulations issued in 2006 and the program guidance issued in 2008. Suppliers need to recognize that receiving Medicare payment depends on their obtaining and retaining sufficient documentation to establish the medical necessity of claimed items and services.

Without supporting medical records, suppliers run the risk of having their claims for payment denied or delayed pending the submission of additional documentation. Alternatively, as in the *Maximum Comfort* case, suppliers may be subject to an overpayment assessment at a later time.

Suppliers of PMD and other expensive DME can ensure they will receive full and prompt payment of their Medicare claims by securing from the ordering physician or practitioner a prescription or order and medical documentation, as specified in 42 C.F.R. §410.38. This documentation must be retained by the supplier and furnished to CMS or a contractor upon request.

Suppliers also need to be cognizant of the current political environment regarding health care reform. On November 12, 2008, Senator Max Baucus, Chairman of the Senate Finance Committee, issued a "health care reform blueprint" that includes five principles for "preventing [health care] fraud, waste, and abuse before they happen, and aggressively detecting them when prevention fails."[25] Ongoing governmental discussions and possible legislation aimed at reforming the health care delivery, coverage, and payment system bodes further scrutiny of Medicare coverage and payment policies regarding PMDs, and other expensive DME.

In a new administration, it is likely that DME suppliers will encounter heightened scrutiny of their claims for Medicare payment. By becoming knowledgeable about Medicare regulations and program guidance, and properly training and informing employees, suppliers will be taking steps to ensure that timely payment is received for DME furnished to program beneficiaries.

Endnotes:

1. "CMS Enhances Program Intgrity Efforts To Fight Fraud, Waste and Abuse in Medicare," Oct. 6, 2008, available at http://www.cms.hhs.gov/apps/media, press/release.asp?Counter=3291&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date.
2. Health Lawyers Weekly, Vol. VI, Issue 39, Oct. 10, 2008. Other equipment to receive heightened review include continuous positive airway pressure devices (CPAP), oxygen equipment, glucose monitors, and test strips.
3. *Maximum Comfort v. Leavitt,* 129 S.Ct. 115, Oct. 6, 2008, No. 07-1507 and 512 F.3d 1081 (9th Cir. 2007).
4. *Id. at* 4.
5. *Id. at* 8.
6. *Id.* at 9.
7. *Id. at* 18. The Council also has applied the positions set forth in its *Maximum Comfort* decision in other cases. *See In the case of the Scooter Store*, available at www.hhs.gov/dab/macdecisions.
8. *Maximum Comfort, Inc. v. Thompson*, 323 F.Supp. 1060 (E.D. Cal. 2004).
9. *Id. at* 1074.
10. *Id. at* 1075.
11. *Maximum Comfort v. Leavitt,* 512 F.3d 1081 (9th Cir., 2007). The Court also noted that appeals courts in two other circuits had decided in a similar fashion that the statute does not preclude the Medicare program from requiring additional documentation, beyond the CMN, to establish the medical necessity of claimed DME. See *Gulfcoast Medical Supply, Inc. v. Secretary, Department of Health and Human Services*, 468 F.3d 1347 (11 Cir. 2006) ("[W]hen the Medicare Act is read as a whole, it unambiguously permits carriers and the Secretary to require suppliers to submit evidence of medical necessity beyond a CMN.") and *MacKenzie Medical Supply, Inc. v. Secretary of the U.S. Department of Health and Human Services*, 506 F3d 341 (4th Cir. 2007) ("[T]he plain language of the Medicare Act does not support MacKenzie's position that a DME claim accompanied solely by

a completed CMN is always sufficient to support payment.").
12. Social Security Act §1862(a)(1)(A).
13. *Supra n. 11 at* 1088.
14. *Id. at* 1088–1089.
15. *Supra* n. 4, at 19.
16. 42 C.F.R. §410.38(c)(2).
17. 42 C.F.R. §410.38(c)(4).
18. 42 C.F.R. §410.38(c)(5).
19. Medicare Program Integrity Manual, Pub. 100-08, Chap. 5, §5.7, Feb 3, 2008; effective March 1, 2008, available at www.cms.hhs.gov/manuals.
20. *Id. at* §5.8.
21. Medical Review of Claims for the Fiscal Year 2006 Comprehensive Error Rate Testing Program, A-01-07-00508, Aug. 2008, at 11-12.
22. OIG Semi-Annual Report, April 1, 2008 – Sept. 30, 2008, issued Dec. 3, 2008, available at www.oig.hhs.gov/publicatoins/doc/semiannual/2008/semiannual_fall2008.
23. *Supra* n. 11; MacKenzie Medical Supply Inc. v. Leavitt, 506.
24. Social Security Act §1833(e).
25. "Call to Action – Health Reform 2009," Nov. 12, 2008, finance.senate/gov/healthreform2009/home.

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