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Important Updates for DMEPOS Suppliers

- Accreditation Deadline and Second Round of Competitive Bidding Announced
- 9th Circuit (in Addition to the 11th and 4th Circuits) holds that CMS Can Require More than a CMN to Deem DME Items Medically Necessary and Reasonable

NOTE: Please see EBG Client Alert entitled "DMEPOS Update: Physicians and Certain Other Professionals Now Exempt from DMEPOS Accreditation Requirements and MIPPA Delays Competitive Bidding, Terminates Round 1 Contracts" to see the current status of the DMEPOS Competitive Bidding Program and related accreditation requirements.

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Deadline for Supplier Accreditation

The Centers for Medicare and Medicaid Services (CMS) has formally announced that **September 30, 2009** is the deadline by which all durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers must be accredited.[1] Suppliers that bill Medicare or have a supplier/National Provider Identifier (NPI) number must be accredited, and as of September 30, 2009, all Part B suppliers will be required to show evidence of accreditation to retain their supplier and NPI numbers. Although September 30, 2009 is the absolute deadline for accreditation, the timing of the accreditation requirement is staggered as described in more detail below.

As background, Section 302 of the Medicare Modernization Act (MMA) required the Secretary to establish and implement quality standards for suppliers of DMEPOS, which suppliers must comply with in order to receive Medicare Part B payments and to retain supplier billing numbers.[2] Section 1847(b)(2)(A)(i) of the MMA requires DMEPOS suppliers to meet these quality standards before being awarded a contract under the DMEPOS Competitive Bidding Program.[3] The quality standards are published on the CMS website (http://www.cms.hhs.gov/medicareprovidersupenroll) and are separated into three sections and three appendices that provide the following information:

- Section I: outlines business standards that apply to all suppliers and focus on standards for administration, financial management, human resource management, consumer services, performance management product safety, and information management
- Section II: outlines service standards, including intake, delivery, and setup, training and instruction of beneficiaries and/or their caregivers, and follow-up service
- Appendix A: deals with respiratory equipment, supplies, and services
- Appendix B: deals with manual wheelchairs and power mobility devices, including complex rehabilitation and assistive technology.
- Appendix C: deals with custom fabricated, custom fitted, and custom-made orthotics, prosthetic devices, somatic, ocular, and facial prosthetics, and therapeutic shoes and inserts

The timing of the accreditation process is as follows: DMEPOS suppliers submitting enrollment applications to the National Supplier Clearinghouse (NSC) on or after March 1, 2008 must be accredited prior to submitting the application.[4] The NSC will not approve any DMEPOS supplier's enrollment application if the enrollment package does not contain an approved accreditation upon receipt or in response to a developmental request. Furthermore, the NSC will reject a DMEPOS supplier's enrollment application unless the supplier provides supporting documentation that demonstrates that the supplier has an approved accreditation.

DMEPOS suppliers enrolled for the first time with the NSC between January 1, 2008 and February 29, 2008 must obtain and submit an approved accreditation to the NSC by January 1, 2009. Existing DMEPOS suppliers enrolled in the Medicare program (prior to January 1, 2008) are required to obtain and submit an approved accreditation to the NSC by September 30, 2009. The NSC will revoke a supplier's billing privileges if the supplier fails to obtain and submit supporting documentation that the DMEPOS supplier has been accredited.

CMS Announces Second Round of DMEPOS Competitive Bidding

On January 8, 2008, CMS announced the Metropolitan Statistical Areas (MSAs) and product categories for the second round of the Medicare DMEPOS Competitive Bidding Program. Health care providers, suppliers, and manufacturers not yet affected by this CMS procurement initiative should become familiar with the program as CMS prepares to roll out this second phase.

CMS announced the initial phase of the competitive bidding program in April 2007, which covered 10 competitive bidding areas (CBAs) and 10 product categories. (Please review EBG's Special Alert, dated July 2007, entitled *Registration and Bidding Period for First Round of the DMEPOS Competitive Bidding Program Extended: Bids Due by July 20, 2007*.) The bidding process for those initial areas and products is scheduled to take place in March 2008, with payment rates for the first phase going into effect July 1, 2008.

The stated goal of the competitive bidding program is twofold – to reduce fraud and to lower costs. As noted above, under the program, suppliers of specified DMEPOS must be accredited by one of 10 organizations chosen by Medicare, which will eliminate DME suppliers that are merely empty storefronts. As for reducing costs, currently, Medicare pays for items based on a fee schedule based on average payments Medicare has paid for DMEPOS in the past. Under the competitive bidding program, based on bids in a given area, Medicare will determine a market clearing price for the covered products, and will accept any accredited supplier whose rate is below that market clearing price. The process is intended to bring costs for DMEPOS closer to true market prices. This process will help limit the burden on Medicare beneficiaries by reducing their out-of-pocket expenses.

The second round of bidding continues CMS' national expansion of a program that, when fully implemented by 2010, is estimated to save the Medicare program $1 billion annually. The second round of bidding will occur in 70 MSAs, including the three largest: New York, Los Angeles, and Chicago. The program will be expanded into additional areas after 2009.

The specific MSAs subject to bidding in this second round are listed below:

2008 MSAs	2008 MSAs
1. Albuquerque, NM	37. Charleston-North Charleston, SC
2. Bakersfield, CA	38. Chattanooga, TN-GA
3. Colorado Springs, CO	39. Columbia, SC
4. Denver-Aurora, CO	40. Deltona-Daytona Beach-Ormond Beach, FL
5. Fresno, CA	41. El Paso, TX
6. Las Vegas-Paradise, NV	42. Greensboro-High Point, NC
7. Los Angeles-Long Beach-Santa Ana, CA	43. Greenville-Maudlin-Easley, SC
8. Sacramento—Arden-Arcade—Roseville, CA	44. Houston-Sugar Land-Baytown, TX
9. Salt Lake City, UT	45. Jackson, MS
10. San Diego-Carlsbad-San Marcos, CA	46. Jacksonville, FL
11. San Francisco-Oakland-Fremont, CA	47. Knoxville, TN
12. San Jose-Sunnyvale-Santa Clara, CA	48. Lakeland, FL
13. Visalia-Porterville, CA	49. Little Rock-North Little Rock-Conway, AR
14. Akron, OH	50. Louisville/Jefferson County, KY-IN
15. Chicago-Naperville-Joliet, IL-IN-WI	51. McAllen-Edinburgh-Mission, TX
16. Columbus, OH	52. Memphis, TN-MS-AR
17. Dayton, OH	53. Nashville-Davidson-Murfreesboro-Franklin, TN
18. Detroit-Warren-Livonia, MI	54. New Orleans-Metairie-Kenner, LA
19. Flint, MI	55. Ocala, FL
20. Grand Rapids-Wyoming, MI	56. Oklahoma City, OK
21. Huntington-Ashland, WV-KY-OH	57. Palm Bay-Melbourne-Titusville, FL
22. Indianapolis-Carmel, IN	58. Raleigh-Cary, NC
23. Milwaukee-Waukesha-West Allis, WI	59. Richmond, VA
24. Minneapolis-St. Paul-Bloomington, MN-WI	60. San Antonio, TX
25. Omaha-Council Bluffs, NE-IA	61. Tampa-St. Petersburg-Clearwater, FL
26. Toledo, OH	62. Tulsa, OK
27. Wichita, KS	63. Virginia Beach-Norfolk-Newport News, VA-NC
28. Youngstown-Warren-Boardman, OH-PA	64. Allentown-Bethlehem-Easton, PA-NJ
29. Asheville, NC	65. Bridgeport-Stamford-Norwalk, CT
30. Atlanta-Sandy Springs-Marietta, GA	66. Hartford-West Hartford-East Hartford, CT

31. Augusta-Richmond County, GA-SC 32. Austin-Round Rock, TX 33. Baton Rouge, LA 34. Beaumont-Port Arthur, TX 35. Birmingham-Hoover, AL 36. Cape Coral-Fort Myers, FL	67. New Haven-Milford, CT 68. New York-Northern New Jersey-Long Island, NY-NJ-PA 69. Scranton-Wilkes-Barre, PA 70. Syracuse, NY

The specific DMEPOS product categories subject to the second round of competitive bidding are as follows and, as you will see, include 8 of the top DMEPOS product categories, affecting a larger number of suppliers than did the first phase:

1. Oxygen Supplies and Equipment
2. Standard Power Wheelchairs, Scooters and Related Accessories
3. Complex Rehabilitative Power Wheelchairs and Related Accessories
4. Enteral Nutrients, Equipment and Supplies
5. Continuous Positive Airway Pressure Devices (CPAP), Respiratory Assist Devices (RADs) and Related Supplies and Accessories
6. Hospital Beds and Related Accessories
7. Negative pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories
8. Walkers and Related Accessories

CMS expects to begin pre-bidding activities for this second round, including announcing specific zip codes of the CBAs, specific items in each product category, and bidder education and registration for user IDs and passwords, in the spring of 2008. The bidding period is expected to last 60 days, beginning in the summer of 2008. The new prices for the second phase CBAs are likely to be implemented in the summer of 2009.

Over the next few months, announcements and updates containing important information about the second round of the competitive bidding program will be provided on the CMS DMEPOS Competitive Bidding Program web site (http://www.dmecompetitivebid.com). Some of the more significant upcoming updates will include:

- A detailed timeline
- Announcements of CBAs and items in each product category
- Initial registration for suppliers interested in competitive bidding
- Educational opportunities
- Other informational resources/fact sheets about the program.

Maximum Comfort, Inc. v. Leavitt: CMS and its Contractors May Require More than a CMN to be Reimbursed for DME

Certificates of medical necessity (CMNs) provide a mechanism for DMEPOS suppliers to demonstrate that the items they provide meet the minimal medical necessity criteria for Medicare coverage. The Ninth Circuit has recently joined the Fourth and Eleventh Circuits holding that CMS and its contractors may require more than a CMN to be reimbursed for DME.

Recently, in ***Maximum Comfort v. Levitt***, D.C. No. CV-03-01584-LKK (9th Cir. Dec. 21, 2007) the United States Court of Appeals for the Ninth Circuit overturned a lower court's decision and, like the Fourth and Eleventh Circuits, held that *other* documentation, in addition to a CMN, may be required for Medicare reimbursement of DME.[5]

CIGNA Medicare Services, the Medicare Durable Medical Equipment Regional Carrier (DMERC) at the time, initially approved claims submitted by Maximum Comfort but subsequently conducted an audit of 30 of the 236 power-operated wheelchair claims submitted by the company in 1998 and early 1999. CIGNA determined that Maximum Comfort was overpaid because it failed to provide medical necessity documentation in addition to the CMN; CIGNA's examining officer upheld CIGNA's overpayment assessments. Maximum Comfort then appealed the decision pursuant to 42 C.F.R. § 405.855, and two Administrative Law Judges (ALJs) found in favor of Maximum Comfort — (1) that a valid CMN had been completed, certifying that the power wheelchair was reasonable and necessary for the patient's injury or functioning; (2) that the wheelchairs furnished were medical reasonable and necessary and met the requirements of coverage under Part B. The Medicare Appeals Council *sua sponte* reviewed the ALJs' decisions and reversed both of them, concluding that Congress did not intend the CMN to be the only mechanism through which suppliers could establish coverage for DME and that nothing prevented the Secretary from imposing additional documentation requirements on equipment suppliers. The Council also found that certain manuals and newsletters issued by CIGNA instructed Maximum Comfort to retain supporting documentation substantiating its equipment claims in case of an audit; thus, the Council concluded that Maximum Comfort knew or should have known that its claims were deficient.

Maximum Comfort initiated an action in the United States District Court for the Eastern District of California.[6] The district court ruled in favor of Maximum Comfort, finding that based on the plain language of § 1395m(j)(2)(A)(i), "any and all information required from suppliers to make a medical necessity determination must be contained in a CMN."[7] The Ninth Circuit reversed the district court and remanded the case for further proceedings consistent with its opinion.

The first question decided by the Ninth Circuit was whether the CMN was conclusive proof of medical necessity or whether the Secretary could request additional documentation from a DME supplier. The Ninth Circuit rejected the district court's interpretation of § 1395m(j)(2), finding that the statutory provision does not state that the CMN is the *sole* vehicle for claims reimbursement, nor does it state that a completed CMN, by itself, establishes a right to reimbursement.[8] The Court instead found that the Secretary may require, as a condition of reimbursement, information in addition to that provided by the CMN.

The second question addressed by the Ninth Circuit was whether Maximum Comfort was on notice that payment would be denied. It noted that a company may not be held liable for repayment under 42 U.S.C. § 1395pp(a)(2) if it "did not know, and could not reasonably have been expected to know, that payment would not be made" for the DME it supplied.[9] Like the Council, the Court noted that under the regulations,

Maximum Comfort was deemed to have constructive notice of manual issuances, bulletins, and other written guidance and directives indicating that certain items of DMEPOS would not be covered by Medicare.[10] According to the Ninth Circuit, the CIGNA manual and certain other documents provided Maximum Comfort with sufficient notice that the Secretary might require additional documentation, *and* as such, Maximum Comfort could be held liable for repayment.

The ruling in this case is consistent with the Eleventh Circuit's 2006 holding in ***Gulfcoast Medical Supply, Inc. v. Secretary***, 468 F.3d 1347 (11th Cir. 2006) and the Fourth Circuit's 2007 holding in ***MacKenzie Medical Supply, Inc. v. Leavitt***, 506 F.3d 341 (4th Cir. 2007).

In ***Gulfcoast***, the supplier argued that as a matter of statutory construction, Part B of the Medicare Act does not give carriers or the Secretary discretion to require a supplier to submit additional medical documentation beyond the CMN to prove medical reasonableness and necessity; rather, the CMN signed by a physician is legally sufficient to validate a claim under Part B. Gulfcoast's argument relied on the definition of "certificate of medical necessity" under 42 U.S.C. § 1395(m)(j)(2)(B). Gulfcoast asked the Eleventh Circuit to follow the district court's ruling in ***Maximum Comfort,*** that § 1395m(j)(2)(B) "plainly specifies that Congress intended that whatever information may be required by carriers from suppliers to show the medical necessity and reasonableness of DME must be contained in a CMN."[11] The Eleventh Circuit found that, contrary to the district court holding in ***Maximum Comfort***, the Medicare statute did not unambiguously preclude the Secretary from requiring a supplier to submit information beyond a CMN to prove medical reasonableness and necessity[12] — (1) § 1395m(j)(2)(B) does not state that a CMN is the *only* documentation that may be required of suppliers to show medical necessity; (2) Gulfcoast failed to cite to another section of the Medicare Act that states or suggests that the Secretary may not require that a supplier supplement a CMN with other documentation. The court opined that the CMN is an optional prepayment tool designed primarily to reduce paperwork and to streamline the processing of claims.[13] The court cited the auditing provisions of Medicare Part B, noting that "Congress unambiguously contemplated the Secretary's authority to require suppliers to submit medical documentation beyond a CMN to prove medical reasonableness and necessity."[14]

In ***MacKenzie***, the supplier similarly relied on the plain language of 42 U.S.C. § 1395m(j)(2)(A) and (B) and the district court's ruling in ***Maximum Comfort***.[15] Following ***Gulfcoast***, the Fourth Circuit concluded that 42 U.S.C. §§ 1395m(j)(2)(A)(i) and (j)(2)(B), when read in combination, do not unambiguously provide that a completed CMN is always sufficient to entitle a DME supplier to reimbursement on a DME claim.[16] The court concluded that the plain language of the Medicare Act, specifically the use of the permissive word "may" in the provision at issue, did not support MacKenzie's position that a DME claim accompanied solely by a completed CMN mandates payment to a DME supplier. Quoting ***Gulfcoast,*** the court found that the Act "simply does not contain any explicit or unambiguous words of exclusivity" and concluded that a CMN need not represent the only worthy documentation of medical necessity for CMS.[17] The Fourth Circuit agreed with the Eleventh Circuit that the CMN is best

viewed as "an optional pre-payment tool designed primarily to reduce paperwork and to streamline the processing of claims," not as a complete standardization of the DME claim process which eliminates all flexibility of the Secretary to require further support for DME claims initially made via a CMN.[18]

Conclusion

DMEPOS suppliers must be aware of the looming accreditation requirements and plan accordingly. Because of the new product categories and scope of the MSAs involved, more suppliers will be part of the competitive bidding (and accreditation) process and will need to have familiarity with the related rules. EBG can assist with that education.

The cases out of the 11th, 4th and 9th Circuits demonstrate that CMS may require more medical documentation that just a CMN to prove that a DME item was medically necessary and reasonable. As such, suppliers should plan to gather that information at the order stage, not waiting until the auditor walks through the door. Again, EBG can assist with planning what documentation should be present in patient files to prevent later problems.

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Endnotes:

[1] *See* CMS, Press Release, "Medicare to Provide Better Oversight of Suppliers of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies" (Jan. 8, 2008), *available on* http://www.cms.hhs.gov/apps/media/press_releases.asp.

[2] Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified at 42 U.S.C. §§ 1395l, 1395m, 1395u, 1395w-3).

[3] *Id*. (codified at 42 U.S.C. § 1395w-3).

[4] *See* CMS, Fact Sheet, "DMEPOS Accreditation" (Jan. 8, 2008), *available on* www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditiationDeadline.pdf.

[5] D.C. No. CV-03-01584-LKK (9th Cir. Dec. 21, 2007) (citing *Mackenzie Medical Supply* and *Gulfcoast Medical Supply*). *See also Gulfcoast Medical Supply, Inc. v. Secretary*, 468 F.3d 1347 (11th Cir. 2006); *MacKenzie Medical Supply, Inc. v. Leavitt*, 506 F.3d 341 (4th Cir. 2007).

[6] *Maximum Comfort, Inc. v. Thompson*, 323 F. Supp. 2d 1060 (E.D. Cal. 2004).

[7] *Maximum Comfort*, D.C. No. CV-03-01584-LKK (9th Cir. Dec. 21, 2007) (quoting *Maximum Comfort*, 323 F. Supp. 2d at 1075.

[8] *Id.* (quoting *MacKenzie,* 2007 WL 3173302 at *6; *Gulfcoast*, 468 F.3d at 1351).

[9] *Id.*

[10] *See* 42 C.F.R. § 411.406(e).

[11] 323 F. Supp. 2d 1060, 1067-68 (E.D. Cal. 2004), *rev'd*, *Maximum Comfort, Inc. v. Leavitt,* D.C. No. CV-03-01584-LKK (9th Cir. Dec. 21, 2007)

[12] *Gulfcoast*, 468 F.3d at 1351.

[13] *Id.* at 1352.

[14] *Id*.

[15] 323 F. Supp. 2d 1060, 1067-68 (E.D. Cal. 2004), *rev'd Maximum Comfort, Inc. v. Leavitt,* D.C. No. CV-03-01584-LKK (9th Cir. Dec. 21, 2007).

[16] 506 F.3d 341, 347 (4th Cir. 2007).

[17] *Id.* at 348.

[18] *Id.* (quoting *Gulfcoast*, 468 F. 3d at 1352). The Fourth Circuit found without merit MacKenzie's challenge to the district court's rejection of its argument that, under the waiver mechanism set forth in 42 U.S.C. §§ 1395gg(c) and 1395pp(a), it was exempt from liability to repay any and all monies that it received for the power wheelchairs at issue. With regard to the argument on appeal that the Paperwork Reduction Act (PRA) prevents the Secretary from requesting medical records in addition to CMNs to substantiate its DME claims for the power wheelchairs at issue, the Fourth Circuit rejected MacKenzie's argument as without merit based on the reasoning of the district court, i.e., that the government is exempted from the requirements of the PRA "during the conduct of – (ii) an . . . investigation involving an agency against specific individuals or entities. . . ." *Id.* at 350 (quoting 44 U.S.C. § 3518(c)(1)(B)(ii)).