Chapter 1035
Durable Medical Equipment

Overview

The Medicare program provides coverage of durable medical equipment, prosthetics, orthotics, and certain medical supplies (commonly referred to as "DMEPOS") for Medicare beneficiaries. The DMEPOS industry—which includes the supply, delivery, maintenance, and repair of such items—faces unique challenges in complying with Medicare and other with federal health care program rules and regulations.

In addition to billing risk areas and practices that can affect many different types of healthcare providers—such as false or duplicate billing, upcoding, and unbundling—DMEPOS suppliers must be equally mindful of and address other billing risk areas that are specific to the DMEPOS industry, including false or incomplete medical records and physician certifications, unlicensed distribution of drugs and biologicals, miscoding and upcoding of orthotics, excessive billing for delivery, repairs, or maintenance of DMEPOS items, and overbilling for capped rental items.

This chapter discusses the legal requirements and agency guidance applicable to those billing risk areas specific to the DMEPOS industry, as well as related case law. For further discussion of general risk areas in billing, see *Section 600*, Billing Practices—General Risk Areas. Penalties for fraudulent billing practices are covered in *Chapter 210*, Penalties.

1035.10 Law and Regulatory Summary

1035.10.10
The DMEPOS Benefit

Medicare beneficiaries can receive coverage for DMEPOS items.[1] Medicare will reimburse 80 percent of the expenses for the rental or purchase of a covered DMEPOS item if it meets the following criteria:[2]

- *The item is "durable medical equipment."* DMEPOS items are covered by Medicare only if they meet the statutory definition of durable medical equipment (DME). DME is equipment that can withstand repeated abuse,[3] is used primarily and customarily to serve a medical purpose,[4] generally is not useful to a person in the absence of an illness or injury, and is appropriate for use in the home.
- *The item is necessary and reasonable.* DMEPOS items are covered by Medicare only if they are necessary and reasonable for the treatment of an illness or injury, or to improve the functioning of a malformed body member. DMEPOS items are necessary when they can be expected to make a reasonable contribution to the patient's treatment. In most cases, a physician's prescription for a DMEPOS item, along with other medical information available to the carrier, will establish medical necessity. However, it is important to note that even if a DMEPOS item serves a useful medical purpose, it will be covered only to the extent that it would be reasonable for the Medicare program to pay for the item prescribed.[5]
- *The item is appropriate for use in the home.* The DMEPOS benefit is available only for items used in the beneficiary's home, which can be a beneficiary's own dwelling, an apartment, a relative's home, a home for the aged, or some other type of institution. However, an institution cannot be considered a beneficiary's home if it meets the basic definition of a hospital or skilled nursing facility (SNF).[6]

Medicare also covers the expenses associated with certain repairs, maintenance, and delivery of DMEPOS

[1] Social Security Act §§ 1834(a) [42 U.S.C. § 1395m(a)] and 1834(h) [42 U.S.C. § 1395m(h)].

[2] Centers for Medicare & Medicaid Servs. (CMS), U.S. Dep't of Health & Human Servs., Medicare Benefit Policy Manual (Pub. 100-02), ch. 15, § 110.1.

[3] Medical expenses of an expendable nature—such as incontinence pads, lambs-wool pads, catheters, ace bandages, elastic stockings, surgical face masks, irrigating kits, sheets, and bags—are not considered durable. *Id.* at § 110.1A.

[4] Certain items are presumptively medical—such as hospital beds, wheelchairs, hemodialysis equipment, iron lungs, respirators, intermittent positive pressure breathing machines, medical regulators, oxygen tents, crutches, canes (except white canes used by the blind, which Medicare considers more an identifying and self-help device rather than an item that makes a meaningful contribution to treatment of an illness or injury), trapeze bars, walkers, inhalators, nebulizers, commodes, suction machines, and traction equipment. Other items are presumptively nonmedical—such as room heaters, humidifiers, dehumidifiers, electric air cleaners, elevators, stairway elevators, posture chairs, or any other devices used for comfort, convenience, or environmental control. *Id.* at § 110.1B.

[5] *Id.* at § 110.1C.

[6] *Id.* at § 110.1D.

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items. If a DMEPOS item is rented by a Medicare beneficiary (as opposed to being purchased), the rental charge usually includes the supplier's expenses for maintaining the rental equipment; therefore, separately itemized charges for repairs, maintenance, and replacement of rented equipment generally are not covered by Medicare.[7]

If a Medicare beneficiary purchases or owns a DMEPOS item, repairs to the equipment are covered by Medicare if they are needed to make the equipment serviceable. Routine, periodic servicing—such as testing, cleaning, regulating, and checking the equipment—is not covered; such routine maintenance generally is expected to be done by the owner. However, Medicare will cover more extensive maintenance that is performed by authorized technicians in accordance with manufacturer recommendations.[8]

Replacement of DMEPOS items that Medicare beneficiaries own is covered by Medicare in instances of loss, irreparable damage, or wear, or when replacement is required because of a change in the patient's condition.[9]

Reasonable charges for delivery of DMEPOS items, whether rented or purchased by a beneficiary, generally are included in the fee schedule allowance for the item.[10]

Medicare also covers certain drugs and biologicals that must be used in combination with a DMEPOS item in order to achieve the therapeutic benefit of the drug or to ensure proper functioning equipment. For example, oxygen is covered in conjunction with oxygen therapy equipment, tumor therapy agents are covered when used with an infusion pump, heparin is covered when used with a home dialysis system, and albuterol sulfate is covered when administered through nebulizer equipment.[11]

DMEPOS items can be supplied to a beneficiary through a home health agency, hospital, or SNF. However, coverage for this equipment will not begin until the beneficiary has been discharged from the facility or hospital.[12] The decision whether to rent or purchase equipment resides with the beneficiary.

Federal regulations prohibit Medicare Part B payments for DMEPOS items for any beneficiary who resides in a Medicare Part A SNF for an entire month.[13] In such instances, the DMEPOS items are covered by the Medicare Part A reimbursement to the SNF, which in turn is responsible for paying the DMEPOS supplier for the equipment.[14]

1035.10.20
DMEPOS Supplier Enrollments

Before DMEPOS suppliers can bill Medicare for sale or rental of DMEPOS items, they must enroll in the Medicare program. The first step in the enrollment process is to apply for and receive a Medicare billing number and meet certain other requirements.[15] The Centers for Medicare & Medicaid Services (CMS) will issue a National Provider Identifier (NPI) to a DMEPOS supplier, at which time, the supplier may submit an enrollment application using CMS Form-855S or the Provider Enrollment, Chain, and Ownership System (PECOS).[16]

To ensure that applicants for Medicare billing numbers are bona fide businesses, CMS requires that each provider or supplier meet certain standards. Specifically, DMEPOS suppliers must operate in compliance with the standards at 42 C.F.R. § 424.57(c), commonly referred to as the "DMEPOS Supplier Standards," under which suppliers bear the burden of proving that they:[17]

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[7] *Id.* at § 110.2.

[8] *Id.*

[9] Social Security Act § 1834(a)(7)(C) [42 U.S.C. § 1395m(a)(7)(C)].

[10] CMS, Medicare Benefit Policy Manual (Pub. 100-02), ch. 15, § 110.2D. *See* Medicare Claims Processing Manual (Pub. 100-04), ch. 20, § 60, for rules that apply to claiming reimbursement for exceptional cases.

[11] CMS, Medicare Benefit Policy Manual (Pub. 100-2), ch. 15, § 110.3.

[12] Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry, 64 Fed. Reg. 36,368, 36379 (July 6, 1999).

[13] CMS, Program Integrity Manual (Pub. 100-8), ch. 5, § 5.13.

[14] *Id.*A July 2001 OIG audit report uncovered what the OIG called "a major flaw" in DMEPOS claims processing. Despite Medicare rules prohibiting Part B payments for DMEPOS for any beneficiary who resides in a Part A skilled nursing facility (or is a hospital inpatient) for an entire month, the OIG report found that all four DME regional carriers (DMERCs) made Part B payments for such services from 1996 through 1998 and that estimated overpayments totaled approximately $35 million, due, in part, to lack of adequate edits in the DMERCs' claims processing systems. The OIG recommended recovery of the overpayments and also that CMS work with the DMERCs to implement edits to identify and prevent such Part B payments in the future. *See* OIG, Medicare Part B Payments for Durable Medical Equipment Provided to Beneficiaries in Skilled Nursing Facilities (No. A-01-00-00509, July 23, 2001); CMS, Skilled Nursing Facility Manual (Pub. 100-12), ch. 2, § 264.7C.

[15] Social Security Act § 1834(j)(1) [42 U.S.C. § 1395m(j)(1)]; 42 C.F.R. § 424.57(b). *See* Medicare Program; Additional Supplier Standards, 65 Fed. Reg. 60,366 (Oct. 11, 2000).

[16] *See* CMS, Frequently Asked Questions, Who Is Eligible to Receive an NPI? According to CMS,

"An entity who meets the definition of a 'health care provider'–that is, any provider of medical or other health services, and any other person or organization that furnishes, bills, or is paid for health care in the normal course of business–is eligible to receive a provider ID, or NPI. Under HIPAA, a covered health care provider is any provider who transmits health information in electronic form in connection with a transaction for which standards have been adopted. These covered health care providers must obtain an NPI and use this number in all HIPAA transactions, in accordance with the instructions in the adopted Implementation Guides/TR3 Reports. The NPI may also be used on paper claims, but HIPAA does not govern that method of submitting claims."

[17] 42 C.F.R. § 424.57(c).

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- operate in compliance with all applicable federal and state requirements, including licensure requirements;
- provide complete and accurate information on the application for billing privileges and report any changes to such information to CMS within 30 days of the change;
- have the application for billing privileges signed by an individual whose signature binds the supplier;
- fill orders from their own inventory or under a contractual arrangement;
- advise beneficiaries that they may either rent or purchase DMEPOS items, including capped rental equipment;
- honor equipment warranties,
- maintain a physical facility on an appropriate site with space for storing business records (i.e. not a post office box or commercial mailbox);
- permit onsite compliance inspections by CMS, the National Supplier Clearinghouse (NSC) or agents of CMS or NSC;
- maintain a primary business telephone number;
- have comprehensive liability insurance coverage;
- agree not to contact beneficiaries by phone, except under certain limited circumstances;
- be responsible for the delivery of equipment;
- answer Medicare beneficiaries' questions and complaints about DMEPOS items;
- maintain and repair or replace rental equipment;
- accept returns of substandard equipment;
- disclose the DMEPOS supplier standards to beneficiaries;
- comply with ownership disclosure provisions under 42 C.F.R. § 420.206;
- will not convey or reassign a DMEPOS supplier number,
- have a protocol for resolving complaints concerning the DMEPOS supplier standards;
- maintain documentation for all complaints;
- provide Medicare-required information to CMS;
- obtain and maintain accreditation from a CMS-approved accreditation organization;
- notify their accreditation organization when opening a new location;
- meet the DMEPOS quality standards at all locations, whether owned or subcontracted;[18]
- disclose, upon enrollment, all products and services, including addition of new product lines for which the supplier is seeking accreditation;
- meet the surety bond requirements specified at 42 C.F.R. § 424.57(d);
- if applicable, obtain oxygen from a state-licensed oxygen supplier;
- maintain ordering and referring documentation consistent with 42 C.F.R. § 424.516(f);
- do not share a practice location with any other Medicare provider or supplier, except under certain limited circumstances; and
- remain open to the public for a minimum of 30 hours per week, except under certain limited circumstances.

1035.10.30 DMEPOS Claims Processing, Payment and Assignment

1035.10.30.10 DME Medicare Administrative Contractors

There are four DME Medicare administrative contractors (MACs) that process DMEPOS claims for defined geographic areas or jurisdictions.[19] Key objectives for the DME MACs include supplier customer service, increased payment accuracy, supplier education and training leading to correct claims submissions, and realized cost savings resulting from efficiencies and innovation. As of January 2018, the four DME MAC contracts are held by Noridian Healthcare Solutions (Jurisdictions A and D) and Cigna Government Services (Jurisdictions B and C). The Medicare Modernization

[18] In addition to the DMEPOS Supplier Standards, DMEPOS suppliers must also comply with the DMEPOS Quality Standards established by CMS under the Medicare Modernization Act of 2003. Pub. L. 108-173 The DMEPOS Quality Standards address supplier business services requirements, product-specific requirements, and other requirements for certain types of DMEPOS items (respiratory equipment, supplies, and services; manual wheelchairs, power mobility devices, and complex rehabilitative wheelchairs and assistive technology; and custom fabricated and custom fitted orthoses, prosthetic devices, external breast prostheses, therapeutic shoes and inserts and their accessories and supplies, and custom-made somatic, ocular, and facial prostheses). For more information about the DMEPOS Quality Standards, *see* CMS, Medicare Learning Network, DMEPOS Quality Standards (ICN 905709) (Sept. 2016).

[19] Prior to establishing the DME MACs in 2006, the Medicare program relied on more than 30 DMEPOS carriers and subsequently on DMERCs for the processing of all Medicare DMEPOS claims. One of CMS's primary reasons for establishing the DMERC system (i.e. consolidation into a four-carrier system) was to combat growing trends of fraud and abuse in the DMEPOS industry. The DMERC system emphasized uniform documentation of claims and was intended to facilitate early detection of abusive and fraudulent billing practices through data analysis. CMS charged the DMERCs with establishing medical policies for the 100 items that had the highest allowed charges, developing aggressive education and fraud prevention programs, and reducing claims processing costs. CMS required all DMERCs to use a standard claims form. Nevertheless, a 2000 OIG study of the DMERC system found that while DMERCs had assisted federal agents in developing fraud cases involving DMEPOS suppliers, DMERC fraud units had not been using their statistical information to identify fraud. *See*OIG, Office of Evaluation & Inspections (OEI), Durable Medical Equipment Regional Carriers: Meeting HCFA's Objectives (No. OEI-04-97-00330, Feb. 2000).

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Act of 2003 (MMA) requires CMS to reevaluate and recompete these contracts every five years.[20]

1035.10.30.20
DMEPOS Competitive Bidding Program

Traditionally, under Medicare Part B, DMEPOS items have been paid for according to a fee schedule. CMS's Pricing, Data Analysis, and Coding Contractor (PDAC) regularly conducts coding and verification of various DMEPOS items and, with the exception of custom items, a fee schedule amount is calculated for each item or category of DMEPOS that is identified by a code in the Healthcare Common Procedure Coding System (HCPCS).

Section 302 of the MMA[21] authorized HHS to use its competitive acquisition authority to replace the existing payment methodology for certain DMEPOS items with a competitive acquisition process. In May 2006, CMS published an initial notice of proposed rulemaking on competitive bidding and issued a final rule regarding the program in April 2007. While statutorily mandated to begin in July 2007, the DMEPOS competitive bidding program officially began in 2011. The intent of the DMEPOS competitive bidding program is to improve the effectiveness of the Medicare payment methodology for the most commonly utilized DMEPOS items, reduce beneficiary out-of-pocket expenses, and save the Medicare program money while ensuring beneficiary access to quality items and services. DMEPOS items covered by the competitive bidding program include:

- enteral nutrients, equipment, and supplies;
- general home equipment and related supplies and accessories (e.g., hospital beds and related accessories, group 1 and 2 support surfaces, commode chairs, patient lifts, seat lifts);
- nebulizers and related supplies;
- negative pressure wound therapy pumps and related supplies and accessories;
- respiratory equipment and related supplies and accessories (e.g., oxygen and oxygen equipment, continuous positive airway pressure devices, respiratory assist devices, and related supplies and accessories);
- standard mobility equipment and related accessories (e.g., walkers, standard power and manual wheelchairs, scooters, and related accessories);
- transcutaneous electrical nerve stimulation devices and supplies; and
- diabetic testing supplies (mail-order only).

Through the competitive bidding program, CMS conducts a competition among DMEPOS suppliers who operate in particular competitive bidding areas (CBAs) (not all DMEPOS items are subject to competitive bidding) DMEPOS suppliers are required to submit a bid for selected products. Bids are submitted electronically through a web-based application process and required documents are mailed. Bids are evaluated based on the supplier's eligibility, its financial stability and the bid price. Competitive bidding contracts are awarded to the DMEPOS suppliers that offer the best price and meet all applicable quality and financial standards. Contract suppliers must agree to accept assignment on all claims for bid items and will be paid the bid price amount. The bid price amount is derived from the median of all winning bids for a particular DMEPOS item. CMS is required to recompete contracts under the DMEPOS competitive bidding program at least once every three years.

1035.10.30.30
Assignment

A DMEPOS supplier that chooses to participate in the Medicare program voluntarily agrees to accept assignment for all covered items furnished to Medicare beneficiaries. Under Medicare program rules, a DMEPOS supplier that accepts assignment must accept the DME MAC's determination of the allowable, approved charge as full reimbursement for the DMEPOS item provided.[22] Medicare will reimburse 80 percent of this allowable amount if the deductible has been met.[23] The Medicare ben-eficiary is responsible for the 20 percent coinsurance, any portion of the $100 calendar-year deductible satisfied by the claim, and the full charge for any services not covered by Medicare.[24] A DMEPOS item may have certain features that make it more expensive than a lower-cost item that would adequately meet the medical needs of the patient. The charge for the more expensive item cannot exceed the fee schedule amount for the item adequate for the patient's medical needs. Only if a more expensive item or model with special features is medically necessary for the beneficiary will the Medicare allowed amount be based on the more expensive model.[25]

If a DMEPOS supplier accepts an assignment, it cannot bill the beneficiary for the difference between the allowable amount and actual cost of the DMEPOS item. If the beneficiary has supplemental insurance in addition to Medicare coverage, the private insurance carrier can be billed only 20 percent—the extent to which the beneficiary is liable—of the allowable charge. Independent agreements between DMEPOS suppliers and beneficiaries as to reimbursable amounts exceeding the allowable charge are superseded by the Medicare assignment agreement between the DMEPOS supplier and the beneficiary.[26] The Medicare-Medicaid Anti-

[20] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173.
[21] *Id.*
[22] CMS, Program Integrity Manual (Pub. 100-4), ch. 1, § 30.3.
[23] Social Security Act § 1833 [42 U.S.C. § 1395l].
[24] Social Security Act § 1834 [42 U.S.C. § 1395m].
[25] CMS, Program Integrity Manual (Pub. 100-4), ch. 1, § 30.3.4.
[26] CMS, Medicare Benefit Policy Manual (Pub. 100-2), ch. 15, § 40 ("Agreements with Medicare beneficiaries that are not autho-

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Fraud and Abuse Amendments of 1977[27] provide penalties for repeated violations of the assignment agreement, stating that any person who knowingly, willfully, and repeatedly violates the assignment agreement is guilty of a misdemeanor subject to a maximum fine of $2,000 and/or six months' imprisonment.[28]

Once an assignment agreement is made, it cannot be revoked in whole or part without the written consent of both the DMEPOS supplier and beneficiary. An assignment agreement can be revoked only before the claim is processed, and the revocation is effective only when the DME MAC has made and sent notice of its approved change determination. Although the assignment cannot be rescinded after the DME MAC notice of determination has been sent, either party may appeal the DME MAC determination.[29]

Some of the benefits of being a participating DMEPOS supplier (i.e., accepts assignment) include:[30]

- the ability to bill Medicare directly for the full Medicare allowed amount for the covered DMEPOS item;
- the right to appeal claim determinations by the DME MAC;
- publication of the DMEPOS supplier's name in a participating provider/supplier directory provided to senior citizens groups and, upon request, to individual Medicare beneficiaries; and
- for certain types of DMEPOS suppliers, access to Medicare beneficiary eligibility data.[31]

With certain exceptions, nonparticipating suppliers (i.e., do not accept assignments) may accept assignment on a case-by-case basis, but cannot accept assignment for some DMEPOS items and may not bill the beneficiary for other items when the items are supplied for the same incident.[32] The supplier must either accept assignment or bill the beneficiary for all DMEPOS items supplied for the same incident. If a DMEPOS supplier chooses not to accept Medicare assignment, it is still responsible for submitting claims to Medicare on behalf of beneficiaries.[33]

1035.10.30.40 Telemarketing

The direct solicitation of Medicare beneficiaries has been a topic of interest since the Department of Health and Human Services, Office of Inspector General (OIG) released guidance in March 2003 regarding telemarketing by DMEPOS suppliers.[34] In that guidance, the OIG confirmed that DMEPOS suppliers are prohibited from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of covered items, except in three specific situations:

- when the beneficiary gives written permission to the DMEPOS supplier to make contact by telephone;
- when contact with the beneficiary relates to a covered item the DMEPOS supplier has already furnished to the beneficiary; or
- when the DMEPOS supplier has furnished at least one covered item to the beneficiary during the preceding 15 months.[35]

This prohibition applies to situations where contact with a beneficiary is made by the DMEPOS supplier directly, or another party on the supplier's behalf. Under this prohibition, DMEPOS suppliers are responsible for verifying that any marketing activities performed by third parties on the supplier's behalf do not involve this prohibited activity and that any information purchased from such third parties was not obtained or derived from such prohibited activity.

The OIG's guidance was reissued in January 2010. The 2010 guidance did not articulate a new interpretation of the prohibition, rather, served to again highlight what the OIG considers a fraudulent and abusive practice within the healthcare industry. Also in 2010, CMS issued its own guidance in the form of Frequently Asked Questions (FAQs) regarding telemarketing practices by DMEPOS suppliers.[36] Thereafter, in August 2010, CMS

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rized as described in these manual sections and that purport to waive the claims filing or charge limitations requirements, or other Medicare requirements, have no legal force and effect. For example, an agreement between a physician/practitioner, or other supplier and a beneficiary to exclude services from Medicare coverage, or to excuse mandatory assignment requirements applicable to certain practitioners, is ineffective. The contractor will refer such cases to the OIG.").

[27] Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142.

[28] *See* CMS, Medicare Claims Processing Manual (Pub. 100-04), ch. 1, § 30.2.15D.

[29] CMS, Medicare Claims Processing Manual (Pub. 100-04), ch. 1, § 30.3.2.

[30] Durable Medical Equipment Regional Carriers Supplier Manual, Region B (AdminiStar) ch. 3.

[31] CMS, Medicare Claims Processing Manual (Pub. 100-04), ch. 2, § 30.6.

[32] DMEPOS suppliers that have a valid NSC number must accept assignment on all claims for drugs and biologicals that they bill to the DME MACs. *See* Social Security Act § 1842(o)(3) [42 U.S.C. § 1395u(o)(3)]. Per CMS, a DMEPOS supplier may not render a charge or bill to anyone for these drugs and biologicals for any amount other than the Medicare Part B deductible and coinsurance amounts. Additionally, mandatory assignment does not apply to the dispensing fees for nebulizer drugs. CMS, Medicare Claims Processing Manual (Pub. 100-04), ch. 17, § 50.

[33] Compliance Guidance for the DMEPOS Industry, 64 Fed. Reg. 36,368, 36,377.

[34] OIG, Special Fraud Alert: Telemarketing By Durable Medical Equipment Suppliers, 68 Fed. Reg. 10,254 (March 4, 2003), as corrected by 68 Fed. Reg. 11,403 (March 10, 2003).

[35] These prohibitions on telemarketing by DMEPOS suppliers are formally outlined in Section Social Security Act § 1834(a)(17)(A). Further, § 1834(a)(17)(B) specifically prohibits payment to DMEPOS suppliers that knowingly submit claims generated pursuant to prohibited solicitations.

[36] CMS, DMEPOS Telemarketing Frequently Asked Questions *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/DMEPOSTelemarketingFAQs.pdf.

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issued a final rule[37] modifying the DMEPOS Supplier Standards at 42 C.F.R. § 424.57(c) to require a DMEPOS supplier to:

> Agree not to make a direct solicitation (as defined in § 424.57(a)) of a Medicare beneficiary unless one or more of the following applies: (i) [t]he individual has given written permission to the supplier or the ordering physician or non-physician practitioner to contact them concerning the furnishing of a Medicare-covered item that is to be rented or purchased; (ii) [t]he supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item; (iii) [i]f the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

In the preamble to the August 2010 final rule, CMS confronted many of the same issues addressed by the OIG in its guidance. Overall, CMS's position in the August 2010 final rule appeared consistent with the OIG's 2010 (and 2003) guidance.

In March 2012, CMS finalized a rule that removed the definition of and modified the requirements regarding the "direct solicitation" of Medicare beneficiaries by DMEPOS suppliers. Significantly, the revised standard modified the prohibition on DMEPOS suppliers soliciting Medicare beneficiaries by telephone, e-mail, instant message, or in-person, without permission, by leaving in place such a prohibition with respect to telephone solicitation but removing the prohibition with respect to the other forms of communication.

COMMENT: As the issue of soliciting Medicare beneficiaries remains a concern for DMEPOS suppliers, and is one that carries significant operational burdens and implications, suppliers, in turn, must continue taking steps to ensure that day-to-day policies and practices are in line with these modified standards. Generally, the limitation on solicitation raises compliance concerns for DMEPOS suppliers with regard to the common physician practice of asking patients if they have a preference for a supplier. If no preference is stated, the physician generally will fax an order to a DMEPOS supplier, which ideally would then contact the patient by phone to arrange delivery of the ordered DMEPOS item. However, this practice does not fit within one of the three telemarketing exceptions and, as such, remains improper according to the March 2012 final rule. The onus of compliance continues to be on the DMEPOS supplier, not the physician, because the supplier bills Medicare. As a result, DMEPOS suppliers should revisit their business practices to ensure that, for any new customers, suppliers are reaching out in writing, rather than by telephone, to arrange for delivery of DMEPOS items. DMEPOS suppliers also should consider working with physicians' offices to supply the necessary consent forms to new customers, which, in turn, will streamline the delivery process for DMEPOS items.

1035.20 Industry Compliance Guidelines

1035.20.10 In General

1035.20.10.10 Areas of Concern

In its compliance program guidelines for DMEPOS suppliers, the OIG set forth numerous areas of concern with regard to fraudulent billing practices in the DMEPOS industry.[38] As well as detailing industry-specific billing practices, the OIG has outlined fraudulent billing practices that are common among healthcare providers, regardless of their specific industry. These general risk areas include:[39]

- *Bill Submission.* The OIG noted several fraudulent bill submission practices, including billing for items or services not actually provided, billing for items not ordered by the beneficiary, billing for new items and providing used or substandard items, duplicate billing, and billing excessive amounts for items or services. Billing amounts are excessive if they are substantially in excess of the supplier's usual charges for such items or services, unless there is good cause for such charges. (*See Chapter 610*, Billing for Items or Services Not Rendered for more information on these practices).
- *Medical Necessity Monitoring.* The OIG emphasized the duty of a supplier of a rental item to monitor medical necessity on an ongoing basis. Billing for rental items that no longer are medically necessary can be fraudulent (*see Chapter 615*, Billing for Medically Unnecessary Services for more information on the medical necessity requirement).

[37] CMS, Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards, 75 Fed. Reg. 52,629 (Aug. 27, 2010).

[38] Compliance Guidance for the DMEPOS Industry, 64 Fed. Reg. 36,368. For detailed OIG guidance on compliance programs, *see Chapter 207, Compliance Program Basics*.

[39] *Id.* at 36373-75.

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- *Coding Practices.* The OIG cited several fraudulent billing practices arising out of Medicare's product-identification codes, including upcoding, resubmission of denied claims with changed information, inappropriate place of service codes, knowing misuse of supplier numbers, and unbundling (*see Chapter 620*, Upcoding, and *Chapter 635*, Unbundling, for more information on fraudulent coding practices).

- *Coinsurance Waivers.* Routine waiver of a beneficiary's coinsurance or deductible obligations can violate the False Claims Act (FCA). A supplier that routinely waives the Medicare copayment fraudulently misrepresents the actual charge for the item or service. For example, if the Medicare-allowed amount for a piece of equipment is $100, but the supplier routinely waives the copayment, the actual charge for the item is $80. Medicare should be paying only 80 percent of the $80 ($64), rather than 80 percent of $100 ($80).[40] This practice also can violate the anti-kickback statute (*see Chapter 1435, Waiver or Payment of Copayments, Deductibles, or Premiums*, for more information on anti-kickback concerns).

- *Overpayment Practices.* It is fraudulent for a supplier to fail to refund overpayments to a health care program or beneficiary (*see Chapter 640, Credit Balances/Failure to Refund*, for more information on overpayment practices). Sometimes, however, DMEPOS suppliers face overpayment situations that are not of their own making. For example, an OIG audit report [41] found that providers were paid amounts for DME and supplies under Medicaid that exceeded the dollar amount allowed for similar items under the Medicare program because the state agency did not update its reimbursement limits for these items on a timely basis. The suppliers were not required to reimburse the government.

- *Telemarketing.* An OIG Special Fraud Alert addressed claims for payment for sales of DME generated by prohibited telemarketing.[42]

1035.20.10.20
General Compliance Considerations

A DMEPOS supplier cannot bill for an item or service unless and until it has been ordered by the treating physician or other authorized person. Such written order must be received before the supplier submits the claim to Medicare.[43] If a supplier does not have a faxed, photocopied, electronic, or pen-and-ink signed order in its records before it submits a claim to Medicare, the claim will be denied.[44] For items that are dispensed based on a verbal order, the supplier must document the verbal order and have the treating physician or other authorized person confirm it in writing prior to billing.[45] A written order prior to delivery is required for pressure reducing pads, mattress overlays, mattresses, and beds; seat lift mechanisms; transcutaneous electrical nerve stimulation (TENS) units; and power operated vehicles.[46]

1035.20.10.30
Certificates of Medical Necessity

For some DMEPOS items and services, the supplier must receive a signed certificate of medical necessity (CMN) from the treating physician or other authorized person. CMNs communicate, either on paper or electronically, proof of the medical necessity of the item or service:[47]

> The CMN may be analogized to a written prescription by a physician. It must contain a certification by the physician that the specific equipment is medically necessary. It must also contain the physician's diagnosis of the medical condition which warrants the equipment.[48]

CMS requires CMNs before Medicare will reimburse certain items.[49] The CMN must be retained in the DMEPOS supplier's records before the supplier can submit a claim for payment to Medicare.

The practice of falsifying or altering CMNs or related medical documents is a frequent form of fraud for DMEPOS suppliers and a clear violation of the False Claims Act (FCA). Such practices have taken the following forms:

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[40] OIG Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B (May 1991), *reprinted in* 59 Fed. Reg. 65,372, 65374 (Dec. 19, 1994).

[41] OEI, Partnership Audit of Medicaid Payments for Oxygen Related Durable Medical Equipment and Supplies - January 1, 1998 through December 31, 2000, Kentucky Department for Medicaid Services, Frankfort, Kentucky (No. A-05-02-00063, March 5, 2003).

[42] *See* OIG, Special Fraud Alert: Telemarketing By Durable Medical Equipment Suppliers, 68 Fed. Reg. 10,254 (March 4, 2003), as corrected by 68 Fed. Reg. 11,403 (March 10, 2003).

[43] Compliance Guidance for the DMEPOS Industry, 64 Fed. Reg. at 36,376.

[44] *See* CMS, Medicare Program Integrity Manual (Pub. 100-08), ch. 5, § 5.1.1.2.

[45] CMS, Medicare Program Integrity Manual (Pub. 100-08), ch. 5, § 5.1.1.

[46] CMS, Medicare Program Integrity Manual (Pub. 100-08), ch. 5, § 5.1.1.2.1.

[47] Social Security Act § 1834(j) [42 U.S.C. § 1395m(j)]; CMS, Medicare Program Integrity Manual (Pub. 100-8), ch. 5, § 5.3.3.

[48] *United States v. Wolk*, No. 93-5773 (E.D. Pa. memorandum and order Jan. 17, 1995).

[49] Medicare requires CMNs for the following items: home oxygen therapy, hospital beds, support surfaces, manual wheelchairs, continuous positive airway pressure devices, lymphedema pumps, osteogenesis stimulators, transcutaneous electrical nerve stimulators, seat-lift mechanisms, infusion pumps, parenteral nutrition, and enteral nutrition. Compliance Guidance for the DMEPOS Industry, 64 Fed. Reg. at 36,376.

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- adding missing information to support the medical necessity of the item or service[50];
- obtaining blank, physician-signed CMNs for the supplier to fill in later[51];
- sending supplier-completed CMNs to physicians for signature[52]; and
- whiting or cutting out and replacing information on the completed CMN.[53]

It is important to note that the veracity of the information added to the CMN is irrelevant to liability under the statute. In *United States v. Wolk*, the supplier-defendant argued that he had not violated the FCA, because the information he added to the CMNs was not false. The court rejected the defendant's interpretation of the statute:

> The CMN form and the physician signature requirement ensure that the physician prescribing the equipment will be held accountable for any frivolous prescriptions. Therefore, an administrator may review the form secure in the knowledge that the CMN embodies only information ratified by the physician who signed the CMN. This court holds that any information added, without authorization, by an individual other than a physician signing the CMN is "false" for purposes of the FCA.[54]

At minimum, the OIG recommends that DMEPOS suppliers set forth written policies and procedures to ensure that they:[55]

- do not forward blank CMNs to the treating physician for signature;
- do not complete the section of the CMN that sets forth medical necessity;
- do not alter or add information on the CMN after receiving the completed and signed CMN from the physician;
- do not sign the CMN for the treating physician;
- do not urge physicians to order equipment or supplies that exceed what is reasonable and necessary for the patient;
- do not deliver an item that requires a written order from the treating physician prior to receiving the written order;
- do not submit a claim for DMEPOS items or services prior to receiving a written order or CMN from the treating physician or other authorized person;
- do not submit a claim for DMEPOS items or services until the CMN is properly and correctly completed by the treating physician;
- maintain completed and signed CMNs in their files;
- consult with the treating physician or other authorized person who signed the CMN when there is a question on the order; and
- submit claims only for services that the treating physician or other authorized person attests are ordered and medically necessary for the patient.

1035.20.10.40

Cover Letters to Physicians

Cover letters commonly are used by DMEPOS suppliers as a method of communicating with treating physicians. The cover letter is not required or regulated by the government. As such, Durable Medical Equipment Regional Carriers (DMERCs) do not base Medicare denials on what can be considered inappropriate use of cover letters.

However, the OIG has expressed concern that cover letters can influence or direct a physician to provide specific answers on a CMN, particularly with regard to questions on the patient's medical condition. Such communication is potentially fraudulent. Fraudulent cover letters have taken the following forms:[56]

- urging a physician to order equipment and supplies that exceed what is necessary and reasonable for the patient;
- supplying specific medical information to the physician to be included in the attached CMN; and
- using a completed CMN as a cover letter, with instructions that the physician photocopy it onto the physician's letterhead[57]

DMEPOS suppliers should avoid providing medical information, suggesting a diagnosis, or requesting that certain items be ordered when drafting cover letters to physicians.

Additionally, the OIG suggests that DMEPOS suppliers include language in cover letters that reminds physicians of their responsibilities to properly complete CMNs.[58]

1035.20.10.50

Medicare Assignment

If a DMEPOS supplier accepts Medicare assignment, it cannot charge beneficiaries more than the amounts

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[50] *See United States v. Wolk*, No. 93-5773 (E.D. Pa. memorandum and order Jan. 17, 1995).

[51] *Id.* This practice also was specifically identified in the OIG Special Fraud Alert: Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services, 64 Fed. Reg. 1813 (Jan. 10, 1999).

[52] OIG Compliance Guidance for the DMEPOS Industry, 64 Fed. Reg. 36,376.

[53] *See United States v. Wolk*, No. 93-5773 (E.D. Pa. memorandum and order Jan. 17, 1995).

[54] *Id.*

[55] OIG Compliance Guidance for the DMEPOS Industry, 64 Fed. Reg. 36,376.

[56] *Id.* at 36,379.

[57] *See, e.g.*, Settlement Agreement Between the United States (U.S. Attorney for the Northern District of New Jersey) and Jalopy Shoppe Inc. d/b/a Mediserv Inc., *United States ex rel. Wells v. Huntleigh Technology PLC*, No. 95-95 (D.N.J. agreement concluded May 23, 1997).

[58] OIG Compliance Guidance for the DMEPOS Industry, 64 Fed. Reg. 36,379.

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allowed under the Medicare fee schedule, including coinsurance and deductibles, nor can the supplier bill the beneficiary for the difference between the allowable amount and actual cost of the item or service.[59]

If the beneficiary has supplemental insurance in addition to Medicare, the private carrier can be billed only 20 percent—the extent to which the beneficiary is liable—of the allowable charge determination. Independent agreements between the supplier and beneficiary as to reimbursable amounts exceeding the allowable charge are superseded by the Medicare assignment agreement.

Suppliers that elect not to execute a participation agreement[60] can accept assignment on a claim-by-claim basis. However, they cannot accept assignment for some items and bill the beneficiary for other items when the items are supplied for the same incident. The supplier must either accept assignment or bill the beneficiary for all items given at the same time and on the same occasion.

If a DMEPOS supplier chooses not to accept Medicare assignment, it still is responsible for submitting claims to Medicare on behalf of beneficiaries.[61]

1035.20.10.60
Delivery, Repairs and Maintenance

A DMEPOS supplier should ensure that it is not submitting claims for rental equipment when the beneficiary is residing in an institution. Some suppliers bring DMEPOS items to beneficiaries living in an institution just prior to discharge to train them on using the item or to fit the item. While this practice can be appropriate, once the supplier has trained or fitted the beneficiary, it should take the item and deliver it to the beneficiary's home on the date of discharge.[62]

The DMEPOS supplier should file the claim for this item using the date the beneficiary is discharged from the institution as the date of service. If the supplier delivers the item to the beneficiary prior to his or her discharge for use in the institution, the item should be included in the institution's costs—the supplier should not submit the claim. The DMEPOS supplier cannot submit a claim prior to the beneficiary's date of discharge.[63]

Suppliers can deliver DMEPOS items to the beneficiary at the facility up to two days prior to discharge if:

- the early delivery is for purposes of fitting or training the beneficiary on its use;
- the equipment is for subsequent use in the beneficiary's home;
- the supplier does not bill for use of the equipment prior to discharge—the date of discharge is deemed to be the date of service;
- the supplier is responsible for any necessary delivery and cannot bill the beneficiary or Medicare for the cost of transporting the equipment from the facility to the beneficiary's home; and
- the facility does not use the supplier's equipment in place of what it is supposed to provide for the beneficiary prior to discharge.

Reasonable charges for delivery of durable medical equipment, whether rented or purchased, are generally included in the fee schedule amount for the item.[64] Medicare also covers the expense of certain repairs and maintenance of rental equipment. Because the rental charge usually includes the supplier's expenses for maintaining the rental equipment, suppliers generally are not permitted to submit itemized charges for repair, maintenance, and replacement of rented equipment.[65]

1035.20.10.70
Capped Rental Items

Certain durable medical equipment that is rented by beneficiaries is subject to a rental cap. The supplier of a capped rental item must offer a purchase option to the beneficiary during the 10th continuous rental month. If the beneficiary does not accept the purchase option, the supplier must provide the item without charge, other than a charge for maintenance and servicing fees, after the 15th continuous month during which rental payments are made.[66]

The OIG compliance guidelines suggest a specific protocol for suppliers of capped rental items including the following:[67]

- the DMEPOS supplier should clearly, accurately, and non-deceptively discuss the pros and cons of different options with the beneficiary;
- if the beneficiary does not accept the 10th-month purchase option, the supplier must continue to provide the item; and
- if the item or service continues to be medically necessary after the 15th continuous month of rental payments from Medicare, the supplier must continue to provide the item without charge to the beneficiary or Medicare.

Although the supplier cannot bill for rental of the item after it reaches its capped limit, it can submit additional claims for maintenance and servicing fees.

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[59] CMS, Medicare Claims Processing Manual (Pub. 100-4), ch. 1, § 30.3.

[60] *Id.*

[61] *Id.*

[62] OIG Compliance Guidance for the DMEPOS Industry, 64 Fed. Reg. 36,379.

[63] *Id.*

[64] CMS, Medicare Benefit Policy Manual (Pub. 100-02), ch. 15, § 110.2D. *See* Medicare Claims Processing Manual (Pub. 100-04), ch. 20, § 60, for rules that apply to claiming reimbursement for exceptional cases.

[65] CMS, Medicare Benefit Policy Manual (Pub. 100-02), ch. 15, § 110.2A-B.

[66] Social Security Act § 1834(a)(7)(A) [42 U.S.C. § 1395m-(a)(7)(A)]; 42 C.F.R. § 414.229(d).

[67] OIG Compliance Guidance for the DMEPOS Industry, 64 Fed. Reg. 36,378.

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1035.20.10.80
Disposition, Acquisition of Equipment

Medicare will pay for the purchase of DME (even though rental payments may have been made for prior months) when a beneficiary's condition convinces him or her that it would be advantageous to purchase the equipment rather than continue to lease it.[68] Beneficiaries also may sell or otherwise dispose of equipment for which they have no further use, and there is no authority for Medicare to repossess the equipment. After disposal, Medicare again may pay to rent or purchase similar equipment should the beneficiary have a renewed medical need for it. If, however, such a transaction is motivated solely by a desire to create artificial expenses for the Medicare program and realize a profit, reimbursement for the expenses will be denied and, after adjudication, referred by the DMERC to the CMS Regional Office program integrity specialist.

When payments stop because the beneficiary's condition has changed and the equipment is no longer medically necessary, the beneficiary is responsible for any remaining non-covered charges. Similarly, when payments stop because the beneficiary dies, the beneficiary's estate is responsible for the remaining noncovered charges. Contractors do not get involved in issues relating to ownership or title of property.

1035.20.10.90
Supplier Billing Numbers Problems

CMS set standards to ensure that each billing number is assigned to a separate operational entity in order to thwart bogus DME suppliers.[69]

An OIG study of the legitimacy of Medicare DMEPOS suppliers found that seven percent of durable medical equipment suppliers with a Medicare billing number either had no physical address or a highly questionable presence at the address provided. The OIG explained that "an address is important to allow beneficiaries a place where they can reach suppliers about DME needs and problems."[70] At least 41 percent of the suppliers examined failed to meet one or more of the 11 DMEPOS standards the OIG studied.

Another OIG study of CMS's program for granting DME supplier numbers found that fewer than one percent of suppliers were not located at and doing business at the address they provided to CMS for the National Supplier Clearinghouse.[71]

As a result of the findings, CMS increased site visits, rewarded suppliers that comply with the standards, assessed the effect of the revised December 2000 supplier standards, and educated suppliers on their duty to give DME beneficiaries a copy of the Medicare supplier standards.

Invalid or inactive provider numbers continued to be a problem, another OIG study found. Medicare pays for medical supplies and equipment only when authorized by a physician; a doctor's unique provider identification number (UPIN) must be submitted with claims for such services.[72]

An OIG report from September 2002 found that 60 percent of a sample of 250 medical equipment claims that physicians billed for Part B beneficiaries in 1999 improperly used a temporary billing number instead of the UPIN.[73] Medicare paid an estimated $61 million for the services.

While doctors who have not been assigned a UPIN could submit DME claims using a temporary or surrogate UPIN, the OIG study found that physicians claiming for more than one-third of these services had individual UPINs for at least five years prior to the dates on the claims and physicians for 17 percent of these services had individual UPINs at least 10 years before the dates of service. Furthermore, nearly half the services ordered with a surrogate UPIN (45 percent) had either no written order or certificate of medical necessity or at least one piece of required information missing from the documentation.

Moreover, 17 percent of the claims using a surrogate UPIN had no supporting documentation. For 28 percent, at least one piece of required information was missing from the documentation, usually the beneficiary's height and weight. Documentation for five percent of services did not include the physician's UPIN at all, and documentation for four percent of services did not include the supplier billing number. Elements missing from physician orders were the physician's name or signature, description of the item being ordered, and the date of the order. Another problem was supporting documentation dated more than 31 days after the service date provided on the Medicare claim.

1035.20.10.100
Potentially Denied Charges

The OIG recommends that DMEPOS suppliers avoid submitting claims for items or services that they believe are not covered by Medicare. However, CMS allows a supplier to submit a claim for an item or service that the supplier believes is not covered if the:[74]

- beneficiary insists that the supplier submit the claim; and
- supplier notes on the claim its belief that services are not covered and that the bill is being submitted at the beneficiary's insistence.

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[68] CMS, Medicare Benefit Policy Manual (Pub. 100-02), ch. 15, § 110.4.

[69] OEI, Medical Equipment and Supplies: Assuring Legitimacy (No. OEI-04-96-00240, Dec. 1997).

[70] *Id.*

[71] OEI, Medical Equipment Suppliers: Compliance with Medicare Standards (No. OEI-04-99-00670, Aug. 2001).

[72] OEI, Medical Equipment and Supply Claims with Invalid or Inactive Physician Numbers (No. OEI-03-01-00110, Nov. 2001).

[73] OEI, Durable Medical Equipment Ordered with Surrogate Physician Identification Numbers (No. OEI-03-01-00270, Sept. 2002).

[74] *See* OIG Compliance Guidance for the DMEPOS Industry, 64 Fed. Reg. 36,377.

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To protect itself from such liability, prior to furnishing the item or service, the supplier must inform the beneficiary that it believes the claim will be denied and ask the beneficiary to sign a written notice. The written notice, called an advance beneficiary notice (ABN), must:[75]

- identify the particular item or service clearly;
- state that payment for the particular item or service likely will be denied; and
- give the reason for the belief that payment likely will be denied.

Routine notices to beneficiaries that state only that denial of payment is possible are not considered acceptable evidence of written notice. Notices should not be given to beneficiaries unless there is some genuine doubt regarding the likelihood of payment as evidenced by reasons stated on the written notice. Giving notice for all claims, items, or services is not an acceptable practice.[76]

It is the beneficiary's decision whether to sign the written notice. If the beneficiary does sign the written notice, the DMEPOS supplier should: [77]

- include the appropriate modifier on the claim form;
- maintain the written notice in its files; and
- be able to produce the written notice for the DMERC upon request.

A DMEPOS supplier is not liable for payment on assigned claims where the supplier did not know, and reasonably could not have been expected to know, that payment for such services would be denied. However, when the DMEPOS supplier knew or could have been expected to know that items or services would not be covered, liability for improperly paid items or services rests with the supplier.

Knowledge standards used by intermediaries to determine when a supplier must refund a payment to a beneficiary are described in a CMS program memorandum detailing instructions for use of ABNs.[78]

Upgrades. An upgrade is an item with features that go beyond what the physician ordered. An upgrade may include an excess component—an item, feature, or service in addition to, or more extensive and/or more expensive than that ordered by the physician and what is reasonable and necessary under Medicare's coverage requirements. An upgrade includes an increase in the extent of, number of, duration of, or expense for an item, feature, or service.

A supplier may know or believe that an item of DMEPOS does not or may not meet Medicare's reasonable and necessary rules under the specific circumstances. In these cases, it is the responsibility of the supplier to obtain the beneficiary's signature on an ABN if the supplier wants to collect from the beneficiary should the item or partial expense attributable to an upgrade be denied. This obligation does not apply when a physician orders an upgrade. In such a case, normal operating procedures and appropriate medical review apply.

1035.20.20
Product Specific Areas of Concern

1035.20.20.10
Home Oxygen Therapy

Home oxygen therapy—one of the items requiring a CMN for coverage—accounts for the largest share of Medicare payments for DME. Medicare payments for oxygen more than doubled between 1992 and 1996, increasing from $900 million to $1.9 billion during that period. Medicare allowances for oxygen equipment totaled over $2 billion in 1997.[79]

Medicare covers home oxygen therapy for beneficiaries diagnosed with significant hypoxemia, a deficiency in the amount of oxygen in the blood. This condition is usually associated with severe respiratory problems. Medicare beneficiaries can qualify for home oxygen therapy if:[80]

- a treating physician determines the beneficiary's ability to breathe is severely impaired and prescribes oxygen therapy;
- the beneficiary's blood gas study, as performed by a physician or qualified provider or supplier of laboratory services, meets certain criteria; and
- alternative treatments have been tried or considered and deemed clinically ineffective.

Medicare reimburses suppliers for home oxygen equipment based on a monthly fee schedule allowance, which varies by state.[81] The monthly allowance covers the oxygen equipment, oxygen contents (including all refills, system setup, and maintenance), and patient training.

Reimbursement for oxygen equipment is made on a rental basis only. The total number of continuous rental months for which Medicare will pay for oxygen equipment is limited 36 months.[82]

After the 36-month rental period, the title of the equipment remains with the supplier. A new rental period does not start following the completion of the 36 month rental period unless the equipment is replaced

[75] 64 Fed. Reg. at 36,378.

[76] *Id.*

[77] *Id.*

[78] CMS, Program Memorandum Intermediaries/Carriers, Transmittal AB-02-163 at 31 (Nov. 8, 2002).

[79] OEI, Usage and Documentation of Home Oxygen Therapy (No. OEI-03-96-00090, August 1999).

[80] *Id.* at 5; Durable Medical Equipment Regional Carriers Supplier Manual, Region C (Palmetto GBA), ch. 19. Manuals issued by CMS's four regional carriers are *available at* cms.hhs.gov/suppliers/dmepos.

[81] Social Security Act § 1834(a)(5) [42 U.S.C. § 1395m(a)(5)].

[82] Durable Medical Equipment Regional Carriers Supplier Manual, Region C, ch. 5 *available at* www.cgsmedicare.com/jc/pubs/pdf/chpt5.pdf.

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because it is lost, stolen, or irreparably damaged or is replaced after the reasonable, useful lifetime expires.[83]

According to Medicare guidelines, oxygen suppliers must maintain certificates of medical necessity to support oxygen claims using Form CMS-484 (Certificate of Medical Necessity: Oxygen). Home oxygen CMNs must contain sufficient medical information, including diagnoses and results of laboratory tests, to establish that beneficiaries meet Medicare coverage requirements.

DMEPOS suppliers must ensure that initial CMNs for oxygen therapy include the written results of an arterial blood gas study or oximetry test. The study or test must have been ordered and evaluated by a treating physician prior to the DMEPOS supplier's claim. Further, the DMEPOS supplier should maintain such test results and any other independent diagnostic treatment facility documents necessary to support the patient's medical necessity for the oxygen.[84]

The OIG recommends that the DMEPOS supplier have the facility from which it receives test results submit all raw test results—not just a summary of the results—to the treating physician.

The OIG guidelines specifically note that a DMEPOS supplier is not qualified to conduct the blood gas study or prescribe the oxygen therapy.[85]

Oxygen coverage is determined by results of an arterial blood gas or oximetry test. A CMN for oxygen equipment must include results of the testing before coverage can be determined. The medical necessity of home oxygen is evidenced by the results of a blood oxygen test. The oxygen testing process has very strict deadlines. For initial certification, Group I and II[86] must be tested within 30 days prior to the date of initial certification. If the oxygen is begun immediately following discharge from an acute care facility, the test must be within two days prior to discharge.[87] To recertify for Group I, retesting requirements are determined by the DME MAC. However, Group II must be retested between the 61st and 90th day after the date of the initial certification. If a certification needs to be revised, the test must be taken within 30 days prior to the date of the revised certification if the initial certification specified a length of need that is less than lifetime.

A physician evaluation must be completed within 30 days prior to the date of the initial certification. For recertifications, Group I and Group II must be re-evaluated by the treating physician within 90 days prior to any recertification date.

Although a beneficiary who was previously enrolled in a Medicare Advantage Plan and returns to traditional fee for service Medicare is subject to the same benefits, rules, and requirements for coverage, there is an exception for home oxygen therapy. The supplier must obtain an initial CMN and submit it to the DME MAC at the time that fee for service coverage begins.[88] The beneficiary does not have to obtain the blood gas study on the CMN within 30 days prior to the date on the CMN, but the test must be the most recent study the beneficiary obtained while in the Medicare Advantage Plan under guidelines in a Local Coverage Determination (LCD).[89]

Common reasons for denial of claims for home oxygen therapy are:[90]

- the only qualifying test results came from oximetry tests conducted by a DME suppliers other than a hospital;
- claims lack information necessary to justify coverage;
- hard copy claims lack the treating physician's signature; or
- electronic claims fail to indicate that the treating physician's handwritten signature is on file in the supplier's office.

1035.20.20.20
The Orthotics Industry

Orthotics are rigid devices—often called braces—that are applied to the outside of the body as a means of support. An orthotic device differs from a prosthetic in that, rather than replacing a body part, it supports and rehabilitates existing body parts. Orthotic devices usually are customized for an individual's use and are not appropriate for use by anyone else.[91]

An orthotic can be supplied in many ways. Typically, a physician prescribes the orthotic and refers the patient to an orthotist or orthotic supplier. Orthotic devices also can be supplied by a clinic, hospital, or nursing home. Some orthosis prescriptions are very specific, while others are general. [92]

A DMEPOS supplier uses the prescriptions provided, as well as its own examination of the patient, to determine the specific device needed. If a device needs to be fabricated, the patient is likely to return to the supplier to have the device fitted. Ideally, the supplier also instructs the patient on how to put on, take off, and maintain the device and provides follow-up care.[93]

As with all Medicare Part B services, in order to receive coverage, the orthotics must be reasonable and

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[83] *Id.*

[84] OIG Compliance Guidance for the DMEPOS Industry, 64 Fed. Reg. 36,379.

[85] *Id.*

[86] Group I: An arterial PO2 at or below 55mm Hg, or arterial blood oxygen saturation at or 88 percent; Group II An arterial PO2 is 56 to 59 mm Hg or arterial blood oxygen saturation is 89 percent.

[87] *See* CMS, Medicare Claims Processing Manual (Pub. 100-04), ch. 20.

[88] Durable Medical Equipment Regional Carriers Supplier Manual, Region C, ch. 5 *available at* www.cgsmedicare.com/jc/pubs/pdf/chpt5.pdf.

[89] *Id.*

[90] *See* CMS, Medicare Claims Processing Manual (Pub. 100-04), ch. 20.

[91] Social Security Act § 1861(s)(9) [42 U.S.C. § 1395x(s)(9)].

[92] OEI, Medicare Payments for Orthotics: Inappropriate Payments (No. OEI-02-99-00120, March 2000).

[93] *Id.* at 7.

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necessary for the diagnosis or treatment of illness or injury. Orthotic devices are classified into one of 465 different codes in the common procedure coding system used for billing.[94] The devices are listed as three different types:[95]

- custom fitted, which require substantial adjustments to a prefabricated item by a specially trained professional to meet the needs and/or unique shape of an individual patient;
- custom fabricated, which are made for a specific patient from his/her individualized measurements and/or pattern; or
- molded to patient model, whereby a cast is made of the specified body part and used to create an orthotic device.

An OIG study found a significant level of inappropriate Medicare reimbursement for orthotics. According to the study, one-third of Medicare beneficiaries owned or rented miscoded orthotics, a figure that represents $33,071,800 in excessive Medicare payments when projected to the total Medicare population.[96]

The most common reasons for denial of coverage include the following:

- the device did not meet the specifications of the code billed;
- the device was not custom-fabricated or -molded, as indicated by the code billed;
- the amount billed was already included in the base code for a larger device; and
- there was inadequate documentation and limited physician involvement.[97]

1035.20.20.30
Nebulizer Drug Therapy

A nebulizer is a type of DME through which prescription inhalation drugs are administered. Nebulizers and associated drugs are covered by Medicare "if the patient's ability to breathe is severely impaired."[98]

Medicare guidelines stipulate that the prescribed drug must be used to deliver respiratory therapy and the nebulizer must be the means to deliver that therapy. LCDs provide information to determine if the item is "reasonable and necessary." For example, one LCD states that for a small volume nebulizer, related compressor and FDA-approved inhalation solution of albuterol is deemed reasonable and necessary for the management of obstructive pulmonary disease.[99] A large volume nebulizer is covered when it is reasonable and necessary to deliver humidity to a beneficiary with thick, tenacious secretions, who has cystic fibrosis, bronchiectasis, a tracheostomy, or a tracheobronchial stent.[100]

If these conditions are met, Medicare will reimburse for both the drug and equipment for as long as nebulizer drug therapy is necessary. If inhalation drugs are not being used with the nebulizers, Medicare should not be billed for the nebulizer equipment.[101]

An OIG study found that, while payments for nebulizer equipment increased during the preceding years, Medicare payments for the drugs used with nebulizers diminished. The most common improper billing issues with nebulizers included:[102]

- claims for nebulizer equipment without corresponding claims for nebulizer drugs and
- claims for drugs associated with nebulizer use that were never dispensed to beneficiaries.

Providers should keep in mind that only entities licensed to dispense prescription drugs can bill Medicare for the provision of those drugs. As such, a DMEPOS supplier must have a valid pharmacy license to bill for the prescription drugs provided in conjunction with DME or prosthetic devices. CMS has said that its reasoning is that if the supplier does not have a valid pharmacy license, CMS cannot be assured of the drug's safety and effectiveness. As such, the drug is not reasonable and necessary for patient treatment.

1035.20.20.40
Osteogenesis Stimulators

Osteogenesis stimulators apply electric currents or ultrasounds to the spine or a long bone to help fuse a fracture that failed to heal or after multilevel spinal fusion.[103] Someone other than the ordering physician may produce the detailed written order.[104] However, the ordering physician must review the content and sign and date the document. Osteogenesis requires a written order prior to delivery. The supplier must receive the completed written order before dispensing the item. Generally, osteogenesis requires in-person or face-to-face documentation that the beneficiary was evaluated or treated for a condition that supports the need for the DME ordered as specified in policy specific documentation. The reasonable and necessary criteria are specific to each code. For example, both NCD and LCD for a non-spinal electrical osteogenesis stimulator for a nonunion of a long bone fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days, each including

[94] Orthotic devices are classified by codes L0100 through L4380.

[95] OEI, Medicare Payments for Orthotics: Inappropriate Payments (No. OEI-02-99-00120, March 2000).

[96] *Id.* at 11.

[97] *Id.* at 14.

[98] OEI, Questionable Practices Involving Nebulizer Drug Therapy (No. OEI-03-94-00391 , March 1997).

[99] Local Coverage Determination: Nebulizers, Nordian Health Care Solutions, *available at* med.noridianmedicare.com.

[100] *Id.*

[101] OEI, Questionable Practices Involving Nebulizer Drug Therapy (No. OEI-03-94-00391, March 1997) at 10.

[102] *Id.*

[103] OIG, Fiscal Year 2017 work plan at 13.

[104] Osteogenesis Stimulators-Coverage Reminders, Celerian Group Company *available at* cgsmedicare.com.

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multiple views of the fracture site, and with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.[105]

1035.20.20.50
Therapeutic Shoes

Although therapeutic footwear for diabetics is not considered DME, it is covered under Medicare Part B, often provided by DME suppliers, and reimbursed by DMERCs.

Medicare will cover therapeutic footwear for vulnerable beneficiaries who meet certain requirements. Therapeutic shoes and inserts are covered under the Therapeutic Shoes for Individuals with Diabetes benefit. Beneficiaries must be receiving treatment for diabetes and have one or more of the following conditions:[106]

- peripheral neuropathy with evidence of callus formation;
- a history of pre-ulcerative calluses;
- a history of previous foot ulceration;
- foot deformity;
- previous amputation of a foot or part of a foot; or
- poor circulation.

A physician must certify that the beneficiary suffers from one or more of the six qualifying conditions cited above. In addition, the physician must certify that they are treating the beneficiary under a comprehensive plan of care for his or her diabetes and that the beneficiary needs diabetic shoes.[107] The certifying physician must have a face-to-face visit with the beneficiary to address diabetes management within six months prior to delivery of the shoes or inserts and sign the certification statement on or after the date of the in-person visit. The signature must be made within three months prior to delivery of the shoes or inserts.[108]

Prior to selecting the specific item that will be provided, the supplier must conduct and document an in-person evaluation of the beneficiary.[109]

At the time of in-person delivery to the beneficiary, the supplier must conduct an objective assessment of the fit of the shoe and inserts and document the results. A beneficiary's subjective statements regarding fit as the sole documentation of the in-person delivery do not meet this criterion.[110]

An order for therapeutic footwear that has been signed and dated by the prescribing physician—similar to a CMN—must be kept on file by the supplier.

Some of the most common reasons for claim denials for therapeutic shoes are:[111]

- missing medical documentation;
- illegible documentation; and
- documentation that does not support coverage criteria.

1035.20.20.60
Blood Glucose Test Strips

Medicare covers home blood glucose monitors and test strips for beneficiaries who must periodically test their blood sugar levels as part of their diabetes management. To be eligible for Medicare coverage of diabetic testing strips (DTS) and other diabetes testing supplies, the beneficiary must have diabetes and be treated by a physician. Additionally, they must use the testing strips in their homes.[112] Suppliers must use the appropriate diagnosis code and can bill Medicare for DTS for up to three months at a time. Suppliers must identify the number of the DTS and the start and end date associated with the claim.[113]

Medicare can cover up to 100 DTS per month for insulin-dependent beneficiaries and up to 100 DTS every three months for non-insulin-dependent beneficiaries. However, Medicare allows the purchase of additional strips if deemed medically necessary and documented by a physician.[114]

A supplier can only refill orders of DTS when beneficiaries have nearly exhausted their supply and specifically request the refill. Suppliers may not automatically dispense a quantity of DTS on a predetermined basis. Suppliers must contact the beneficiary before to verify the quantity requested.[115] In 2011, Medicare replaced fee schedule amounts with a competitive bidding program. Mail order DTS was included in the first year of its implementation, but not non-mail order. The most common errors in diabetes test strips claim submissions are:[116]

- failure to include a documented diagnosis code for diabetes; and
- submitting claims for DTS during a time period when beneficiary is an inpatient at a hospital or SNF.

In 2012, the OIG investigated inappropriate and questionable billing for diabetes test strips and found that in 2011, Medicare inappropriately allowed $6 million for DTS claims billed for beneficiaries without a documented diagnosis code for diabetes, or that inappropriately overlapped with an inpatient hospital

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[105] *Id.*; CMS, National Coverage Determination for Osteogenic Stimulators available at www.cms.gov.

[106] *Id.*

[107] Local Coverage Determination: Therapeutic Shoes for Persons with Diabetes , Nordian Health Care Solutions, *available at* med.noridianmedicare.com.

[108] *Id.*

[109] *Id.*

[110] *Id.*

[111] OEI, Medicare Payments for Therapeutic Shoes (No. OEI-03-94-00391, Mar. 1997).

[112] OEI, Inappropriate and Questionable Medicare Billing for Diabetes Test Strips (No. OEI-04-11-00330, Aug. 2013).

[113] *Id.* at 3.

[114] *Id.*

[115] *Id.*

[116] OEI, Inappropriate and Questionable Medicare Billing for Diabetes Test Strips (No. OEI-04-11-00330, Aug. 2013).

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stay,[117] or an inpatient skilled nursing facility stay. The results of the stated that suppliers in 10 geographic areas nationwide were responsible for 77 percent of questionable billing.[118]

1035.20.20.70

Power Wheelchairs

CMS uses the term "power mobility devices" (PMDs) to comprise power wheelchairs and power operated vehicles (POVs or scooters). In 2003, in response to a surge in Medicare reimbursement for the most expensive of these vehicles and evidence that "inflated and falsified billings [were] a serious problem among certain DME suppliers," it undertook a comprehensive overhaul of Medicare's coverage approach to these devices.[119] The result was a final rule, published in 2006, that changed PMD payment and documentation requirements.[120]

The rule:

- eliminated the requirement that a prescribing physician transcribe medical record information onto a "certificate of medical necessity" form, substituting instead the transmission of pertinent parts of the existing medical record to the durable medical equipment supplier;
- allowed treating practitioners, including physician assistants. nurse practitioners, or clinical nurse specialists, to prescribe PMDs, expanding the list of those permitted to assess their medical necessity beyond specialists in physical medicine, orthopedic surgery, neurology, or rheumatology, who originally had that exclusive authority;
- required a face-to-face examination of the beneficiary by the physician or treating practitioner before a PMD may be prescribed; and
- established an add-on code to allow the physician or treating practitioner to be paid for the work and resources involved in compiling and submitting the information from the medical record needed to document medical necessity.

CMS requires that PMD equipment be prescribed only after a face-to-face examination of the beneficiary.[121] A beneficiary who has had a face-to-face examination during an inpatient hospital stay will not need a separate face-to-face examination, as long as the physician or treating practitioner who performed the face-to-face examination during the hospital stay prescribes the PMD within 45 days after the date of discharge.[122] Payment for the history and physical examination is made through the appropriate evaluation and management code. The face-to-face requirement does not apply when only PMD accessories are being ordered.[123]

The physician or treating practitioner must submit a written prescription for the PMD to the supplier that must be received by the supplier within 45 days after the face-to-face examination,[124] or in the case of a recently hospitalized beneficiary, within 45 days after the date of discharge from the hospital.[125] Included must be the beneficiary's name, the date of the face-to-face examination, the diagnoses and conditions that support the claim for the PMD, a description of the specific type of PMD required, and the expected length of time the beneficiary will need the equipment. The physician or treating practitioner must sign and date the prescription.[126] All PMDs must meet CMS safety requirements.[127]

A May 2005 national coverage determination on mobility assistive equipment (MAE), including power wheelchairs and scooters,[128] adopted a function-based determination of medical necessity based on a beneficiary's ability safely to accomplish mobility-related activities of daily living in customary locations within the home, with and without the use of mobile equipment. Among other clinical criteria was whether a beneficiary or caregiver demonstrates a consistent capability and the willingness to operate the MAE safely.[129]

In a decision memo, CMS made clear that the "in the home" restriction does not mean beneficiaries may not use their wheelchairs outside the home. It means only that for DME, including wheelchairs, to be covered, a beneficiary must have a medical need to use the DME in the home. Thus, the requirement excludes DME from coverage if there is a medical need to use the equipment only outside of the home. However, if DME is determined to be medically necessary in the home, the equipment is covered by Medicare even if the beneficiary also uses the equipment outside the home.

Because the coverage criteria refer more explicitly to standard clinical evaluative methods, beneficiaries' medical records were expected to more accurately reflect patient evaluations, the agency said in a press release announcing the decision.

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[117] *Id.*

[118] *Id.*

[119] The final rule also implemented § 302(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, which added Social Security Act § 1834(a)(1)(E)(iv) [42 U.S.C. § 1395m(1)(E)(iv)] to establish certain legal requirements for federal payments for motorized or power wheelchairs.

[120] Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles, 71 Fed. Reg. 17,021 (April 5, 2006) (final rule).

[121] 42 C.F.R. § 410.38(c)(2)(i).

[122] 42 C.F.R. § 410.38(c)(3)(i).

[123] 42 C.F.R. § 410.38(c)(3)(ii).

[124] 42 C.F.R. § 410.38(c)(2)(ii).

[125] 42 C.F.R. § 410.38(c)(3).

[126] 42 C.F.R. § 410.38(c)(1).

[127] 42 C.F.R. § 410.38(c)(6).

[128] CMS, Decision Memo for Mobility Assistive Equipment (No. CAG-00274N, May 5, 2005).

[129] CMS, Medicare National Coverage Determinations Manual (Pub. 100-03), ch. 1, § 280.3.

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1035.30 Enforcement

According to a 2011 OIG report, DMEPOS suppliers have had significant program integrity problems. The report pointed out some of the most common problems among DMEPOS suppliers during their first year in Medicare, including:

- billing for services not ordered by physicians or not rendered;
- having unusual billing patterns and failing to respond to CMS or contractor requests for information;
- nonpayment of the required surety bond;
- omitting ownership or management information; and
- omitting information regarding criminal records or any adverse legal actions taken against owners or managers.

In addition, because of its susceptibility to bad actors defrauding Medicare, Medicaid, and other federal health care programs, DMEPOS has been and continues to be at the forefront of government investigations, audits, and enforcement actions. As shown below, many of the enforcement actions taken against DMEPOS suppliers involved owners, operators, or managers of DME supply companies falsifying documents purporting medical necessity of the equipment supplied to the beneficiaries.

But apart from bad actors, Medicare overpayments for DMEPOS are also often tied to the absence or incomplete documentation that is required when billing for equipment supplied to beneficiaries. According to a September 2017 OIG report, DMEPOS claims represent one of the largest portions of Medicare overpayments at 26 percent of overall overpayments.[130] In addition, particular DMEPOS supplies continue to be vulnerable to fraud, waste, and abuse (e.g., diabetes test strips, home oxygen equipment, power wheelchairs, orthotics, and drug nebulizers) and therefore, continue to be under the watchful eye of the OIG and its enforcement teams.

1035.30.10
Enforcement Priorities

1035.30.10.10
OIG Work Plans

Through its work plan, the OIG highlights its current focus areas under the Medicare and Medicaid programs. Historically, the OIG announced its work plan annually or semi-annually; however, in June 2017, the OIG announced its intent to update its work plan on its website monthly, instead, in order to allow providers to more timely identify and respond to emerging fraud and abuse issues.[131] The work plans give insight on areas the OIG prioritizes and will allocate its resources in particular fiscal periods, which are often tied to areas with increased risk of federal health care program abuse. The work plans are products of investigations and reports conducted by the OIG, often initiated and reported by DME MACs, Zone Program Integrity Contractors (ZPICs), and other contractors tasked to report signs of suspicious activity of fraud, waste, or abuse of Medicare, Medicaid, and other Federal health care programs.

Healthcare attorneys should utilize work plans to provide their clients some foresight regarding particular DMEPOS areas under the OIG's scrutiny. Additionally, the OIG will often make recommendations to federal health care programs in lieu of completed studies and projects. Generally, the changes are to reimbursement payment systems. Thus, healthcare attorneys are most likely able anticipate upcoming change and advise their clients accordingly.

In its 2017 work plan, the OIG announced two DME-related projects that it completed:[132]

- *Medicare's Flawed Payment System for DME Infusion Drugs*. Approximately three years prior, the OIG first reported that Medicare was reimbursing DME infusion drug suppliers at exceedingly high costs because it was reimbursing at 95 percent of the average wholesale prices (AWPs), in contrast to the way most Part B-covered prescription drugs are reimbursed via average sale price (ASP) based payment methodology.[133] It has been undisputed that the AWP benchmark is a flawed basis for setting provider reimbursement rates. However, despite the OIG's report and recommendations, the OIG found that DME infusion drugs were still being reimbursed at AWP-based Medicare payment amounts in 2015.[134] In its 2016 follow-up report to CMS, the OIG concluded that it was necessary for CMS to change its reimbursement payment system for DME infusion drugs to prevent incentive for overutilization of particular drugs and ensure continued access to life-saving medicine for Medicare beneficiaries.
- *Escalating Medicare Billing for Ventilators*. In a report to CMS, the OIG found that Medicare payment for E0464 ventilator claims in 2015 was 85 times more than the claims it had paid just six years before; this translates to Medicare expendi-

[130] OEI, Enhancements Needed in the Tracking and Collection of Medicare Overpayments Identified By ZPICs and PSCs (No. OEI-03-13-00630, Sept. 2017).

[131] *See* Office of Inspector Gen., U.S. Dep't of Health & Human Servs., work plan webpage.

[132] OIG, Fiscal Year 2017 work plan at vii-viii.

[133] OEI, Escalating Medicare Billing for Ventilators Raises Concerns (No. OEI-12-16-00340 , Sept. 2016) at 1-2.

[134] *Id.*

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tures rising from $3.8 million to $340 million.[135] The OIG suggested the reasons for the escalating Medicare claims for the E0464 ventilators were two-fold: (1) the rental rates for noninvasive pressure ventilators were higher than volume ventilators, CPAP devices and RADs, and (2) there were no monthly rental payment caps for ventilators, in contrast with 13 month caps for CPAP devices and RADs. According to further investigation, there was possible program abuse via incorrect billing and upcoding.[136] For example, over a four-year period, the increased Medicare claims of E0464 ventilators were attributed to three suppliers. These suppliers supplied a combined total of 196 beneficiaries in 2012 and then supplied a combined total of 16,073 beneficiaries in 2015.[137] Additionally, the OIG found that some beneficiaries had claims for accessories that were paid for separately instead of being bundled, violating Medicare payment policies for ventilators.

In the 2017 work plan, the OIG announced the following reviews and activities it initiated that would impact DME suppliers:[138]

- *Part B Services During Non-Part A Nursing Home Stays: Durable Medical Equipment*. July 2009 OIG report found that Medicare Part B inappropriately made $30 million in payments for DMEPOS during non-Part A stays in SNFs. The OIG will study the extent of this inappropriate payment.
- *Medicare Market Share of Mail-Order Diabetic Testing Strips: April 1-June 30, 2016-Mandatory Review*. The OIG will begin a three-part examination of the market share of diabetic testing strips (DTS). The first three-month period will determine the market share before the implementation of the National Mail Order Recompete on July 1, 2016. The second three-month period will determine the market share after the implementation; while the third period will be the six-month time frame after the implementation.
- *Positive Airway Pressure Device Supplies—Supplier Compliance with Documentation Requirements for Frequency and Medical Necessity*. The OIG will review claims of positive airway pressure or respiratory assist device therapy (PAP) supplies from suppliers that shipped PAP devices in the absence of physician orders for refills.
- *Power Mobility Devices Equipment—Portfolio Report on Medicare Part B Payments*. The OIG will provide a summary of its evaluations, audits, and investigative work regarding Medicare Part B payments of power mobility devices (PMDs) equipment. The OIG will include key recommendations for protecting beneficiaries and improving the program.

Additionally, the OIG planned to continue the following reviews and investigations from prior work plans:

- *Orthotic Braces—Reasonableness of Medicare Payments Compared to Amounts Paid by Other Payers*. The OIG will determine the reasonableness of Medicare fee schedule amounts for orthotic braces. It also will compare payments made by Medicare and non-Medicare payers to identify wasteful spending.
- *Osteogenesis Stimulators—Lump-Sum Purchase Versus Rental*. The OIG will determine whether there are potential savings to Medicare and its beneficiaries if osteogenesis stimulators are rented over a 13-month period instead of a lump-sum purchase.
- *Power Mobility Devices—Lump-Sum Purchase Versus Rental*. The OIG will determine whether there are potential savings to Medicare and its beneficiaries if PMDs are rented over a 13-month period instead of a lump-sum purchase.
- *Competitive Bidding for Medical Equipment Items and Services – Mandatory Review*. The OIG will review CMS's competitive bidding proceedings, as well as its ability to make subsequent pricing determinations for certain medical equipment items and services.
- *Orthotic Braces—Supplier Compliance with Payment Requirements*. The OIG will investigate Medicare Part B payments for orthotic braces to determine whether they were medically necessary and supported by the required documents, in accordance with Medicare requirements.
- *Nebulizer Machines and Related Drugs – Supplier Compliance with Payment Requirements*. The OIG will investigate Medicare Part B payments for nebulizer machines and related drugs to determine whether they were medically necessary.
- *Access to DME in Competitive Bidding Areas*. The OIG will investigate and determine whether DMEPOS transitions from fee schedule to competitive bidding program have reduced beneficiaries' access to DMEPOS and compromised quality of care.

In its 2016 work plan, the OIG planned to review the following DME issues:[139]

- *Diabetes Testing Supplies.* The OIG reported that it had found inappropriate payments to multiple medical equipment suppliers for test strips and lancets dispensed to the same beneficiaries with overlapping service dates. Therefore, the OIG stated that it would review Medicare's claims processing edits designed to prevent payments to

[135] OEI, Escalating Medicare Billing for Ventilators Raises Concerns (No. OEI-12-15-00370 , Sept. 2016) at 4-5.
[136] *Id.* at 3.
[137] *Id.* at 6.
[138] OIG, Fiscal Year 2017 work plan.
[139] OIG, Fiscal Year 2016 work plan.

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multiple suppliers of home blood glucose test strips and lancets to determine whether the controls were effective in preventing inappropriate payments.

- *Physicians—Referring and Ordering Medicare Services and Suppliers.* The OIG also reviewed select Medicare DMEPOS ordered by physicians and non-physician practitioners to determine whether the payments were made in accordance with Medicare requirements.

In the 2015 work plan, the OIG focused on the following DME issues:[140]

- *Power Mobility Devices—Supplier Compliance with Payment Requirements.* The OIG reviewed Medicare payments for suppliers of PMDs to determine whether payments were made in accordance with Medicare requirements (e.g., medical necessity and supportive documentation).
- *Power Mobility Devices—Add-on Payment for Face-to-Face Examination.* The OIG also found that many of the PMD claims were unallowable because prescribing physicians failed to bill Medicare for the face-to-face examination as an E/M service as well as an add-on payment for the sole purpose of documenting the need for the PMD.
- *Lower Limb Prosthetics—Supplier Compliance with Payment Requirements.* A national OIG review of supplies of lower limb prosthetics found that 267 suppliers had questionable billing. Some suppliers were found submitting claims that did not meet certain Medicare requirements (i.e., claims for beneficiaries who had no claims from referring physicians and billing for lower limb prostheses for beneficiaries who had no history of amputations or missing limbs). Therefore, the OIG reviewed Medicare payments for claims submitted by suppliers for lower limb prosthetics to determine whether requirements of CMS's Benefit Policy Manual (Pub. No. 100-02), ch. 15, § 120, were being met.
- *Diabetes Testing Supplies—Supplier Compliance with Payment Requirements for Blood Glucose Test Strips and Lancets.* After finding that suppliers of diabetic-related supplies did not always comply with federal requirements, the OIG reviewed Medicare payments for home blood glucose test strips and lancet supplies.

1035.30.10.20
OIG Semiannual Reports

The OIG releases a semiannual report to Congress, describing its progress in identifying significant problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations. One of the largest bodies of work involves investigating matters tied to the Medicare and Medicaid programs such as patient harm; billing for services not rendered, lack of medical necessity, upcoding; solicitation and receipt of kickbacks, and illegal referral arrangements between providers and medical companies. In its spring 2017 semiannual report to Congress,[141] the OIG mentioned some DMEPOS-related offenses:

- Several New Jersey businesses entered into settlement agreements after allegations that they knowingly caused false claims to be submitted in connection with cardiac monitoring services. The defendants allegedly marketed the cardiac monitoring services and designed a web-based registration system that led to or caused the submission of false claims by funneling physicians to select telemetry that provided the highest rate of reimbursement for all Medicare patients. The defendants agreed to a pay a total of $13.4 million and agreed to a five-year CIA.
- In Georgia, a manager of a diabetic footwear Medicaid provider was sentenced to three years and five months in prison and ordered to pay $948,361 in restitution and forfeiture after investigations found that she had submitted fraudulent claims to Medicaid. The manager submitted claims for medical equipment that was not medically necessary, not prescribed by a physician, and for the most part, never provided to a patient.

In the October through March 2017 semiannual report, the OIG reported a settlement agreement with a Pennsylvania medical device company to resolve allegations that it knowingly caused false claims to be submitted to Medicare and Medicaid. This is distinct from the usual DME cases in that the issue surrounded improper marketing and use of a medical device without proper FDA clearance. While the company's medical device had been cleared as an embolization device to be placed in blood vessels to block or reduce blood flow to certain types of tumors and arteriovenous malformations, it was never cleared by the FDA as a drug-device combination product or for use as a drug-delivery device. Yet the company loaded the device with chemotherapy drugs, thereby making it into a new combination drug device product, not approved by FDA and therefore, not covered by Medicare and Medicaid. The defendant agreed to pay $25 million dollars to resolve its False Claims Act liability. It was also ordered to pay a $8.75 million criminal fine for misbranding its product and a criminal forfeiture of $2.25 million.

In its 2016 semi-annual reports,[142] the OIG reported the following DME-related cases:

- A Utah DME supplier, specializing in power wheelchairs, was found conspiring to bill Medicare for power wheelchairs for beneficiaries that did

[140] OIG, Fiscal Year 2015 work plan.
[141] OIG, Semiannual Report October 1, 2016 - March 31, 2017.
[142] OIG, Semiannual Report October 1, 2015 - March 31, 2016; Semiannual Report April 1, 2016 - September 30, 2016.

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not qualify. Investigations of the owner and sales representatives found that they were altering physician records and signatures in order to qualify beneficiaries for the power wheelchairs, thereby allowing the company to receive Medicare payment. The defendants were sentenced to a combined five years and 10 months in prison and ordered to pay restitution of $6.2 million.

- In North Carolina, an individual was sentenced to three years and six months in prison and ordered to pay $2.6 million in restitution for submitting false claims to Medicare for reimbursement of DME items that were never provided to beneficiaries. In fact, investigations found that he had set up sham DME companies and purchased lists of personally identifiable health information, which he used to submit false claims without the beneficiaries' knowledge.

In 2015,[143] the OIG reported the following cases related to DMEs:

- An owner of a California DME supplier was sentenced to six years and six months in prison and ordered to pay $3.4 million in restitution after being convicted of conspiracy to commit healthcare fraud, healthcare fraud, and illegal remunerations for healthcare referrals. Investigations found that the owner paid marketers to solicit beneficiaries. The owner and co-conspirators then offered the beneficiaries medically unnecessary power wheelchairs, hospital beds, orthotics, and other DME for free. The owner and co-conspirators directed the beneficiaries to physicians who would create fraudulent patient files. The patient files included DME prescriptions and false statements that face-to-face examinations were conducted, purporting to support the medical need for the DME. The physicians would then direct the beneficiaries back to the DME supplier to fill the prescription. Finally, the supplier and physicians billed Medicare for the DME, office visits, or diagnostic tests that were either medically unnecessary or were not provided.
- Another California DME supplier was sentenced to four years in prison and ordered to pay $4.3 million in restitution. A registered nurse and owner of a DME supply company used cash and checks to pay illegal kickbacks to recruit Medicare beneficiaries for power wheelchairs and other DME, which were not medically necessary. The owner and co-conspirators also paid illegal kickbacks to a physician who wrote false prescription and documents for the DMEs, which were used to fraudulently bill Medicare.
- A New Jersey medical device company was ordered to pay $34.4 million in fines and $5.1 million in forfeiture after pleading guilty to distributing, with the intent to defraud and mislead, adulterated medical devices into interstate commerce in violation of the Food, Drug, and Cosmetic Act. The CEO of the medical device company had submitted a premarket notification to the FDA seeking clearance to market a total knee replacement device product. Even though the product was never cleared or approved as safe and effective, the CEO continued to market and distribute the product to surgeons throughout the United States. Apart from the criminal fines, the company agreed to pay $41.2 million settlement to resolve its civil FCA liability arising from the marketing and distribution of the product. It also agreed to be excluded from participation in Medicare, Medicaid, and all other federal health care programs for 20 years.
- The manager of a DME supplier, who also operated a medical billing business, was sentenced to one year and three months in prison and ordered to pay $3.4 million in restitution after pleading guilty to healthcare fraud. The manager paid marketers to solicit Medicare beneficiaries. The manager and co-conspirators paid illegal kickbacks to physicians and medical clinics in exchange for false prescriptions and documents purporting the beneficiaries' need for power wheelchairs and other DME and then billed Medicare for DME that were medically unnecessary.

In 2014,[144] the OIG's semiannual reports to Congress reported the following DME-related cases:

- The owner of a DME supplier and the office manager of a clinic, along with co-conspirators, including a physician's assistant, solicited Medicare beneficiaries by offering free DMEs. The owner and co-conspirators would prescribe the beneficiaries medically unnecessary DMEs, including PMDs and orthotics, along with medically unnecessary examinations. The owner would then use the beneficiaries' patient information to bill for medically unnecessary DME prescription through her DME company. The owner pled guilty and sentenced to six years and four months in prison and ordered to pay $9.6 million in restitution. The owner was also excluded from participating in any Federal health care programs for 30 years.
- Two New York owners and operators of DME companies pleaded guilty to health care fraud and were sentenced to 2 years and 6 months of incarceration, and ordered to pay $1 million in restitution. Investigations found that these owners billed Medicare and Medicaid for DMEs that were either never provided to patients, or if actually provided to patients, billed for the more expensive DME than was actually provided to patients. Investigations also found that the owners and co-conspirators forged fraudulent medical prescrip-

[143] OIG, Semiannual Report October 1, 2014 - March 31, 2015; Semiannual Report April 1, 2015 - September 30, 2015.

[144] OIG, Semiannual Report October 1, 2013 - March 31, 2014; Semiannual Report April 1, 2014 - September 30, 2014.

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tions for DME along with medical documentation that appeared to legitimize the false claims.

- A Texas DME supply company owner submitted claims for DME items that were medically unnecessary, were not provided at all, and were intentionally miscoded. The owner submitted 157 unpaid claims on behalf of deceased beneficiaries. He was sentenced to four years in prison and ordered to pay approximately $1.5 million in restitution following his conviction for conspiracy to commit healthcare fraud and health care fraud aiding and abetting.
- Two owners of mail-order diabetic supply companies allegedly caused the companies to enter into marketing contracts with insurance brokerage and other companies most likely to have a high percentage of diabetes patients. The owners allegedly paid the companies based on the number of patients referred to them for diabetic supplies in violation of the anti-kickback statute. They agreed to pay $7 million to resolve the allegations, a 20-year exclusion period from participating in Medicare, Medicaid, and all other federal health care programs, and paid $5 million to settle civil allegations under the FCA.

In its 2013 semiannual reports,[145] the OIG reported the following DME cases:

- An owner and operator of several DME companies in Nevada was sentenced to four years and three months in prison and ordered to pay over $12 million in restitution after pleading guilty to charges of health care fraud. The owner allegedly paid marketers to obtain patients for her companies. The marketers would pay Medicare beneficiaries for their Medicare information, which would then be used to bill Medicare for items not provided. The owner also forged or caused to be forged fraudulent DME prescriptions along with medical documents purporting DME to be medically necessary, as if a physician had prescribed the DME for her customers.
- Owners of a New York DMEPOS supplier that specialized in high-end wound care supplies, braces, and orthotic shoes were sentenced to 12 years in prison and ordered to pay $4.4 million in restitution for defrauding Medicare by billing for DME that were never provided. The owners entered nursing homes under the false guise of providers, stole medical records, altered and manufactured records, and then utilized these records to justify the company's claims to Medicare for DME that were never provided to the residents.
- The owner of a Louisiana-based DME supply company that billed Medicare for orthotics, heat pads, power wheelchairs, and other medical equipment, was sentenced to eight years and one month of incarceration and ordered to pay $2.5 million in restitution after being convicted on charges of health care fraud. Although the owner submitted almost $467,000 in claims to Medicare for equipment purportedly prescribed by a physician in Texas, investigations showed that the physician never prescribed any equipment for which the owner billed Medicare. The owner also submitted more than $6.7 million in claims to Medicare for equipment that were not medically necessary and, in some cases, never actually provided.

1035.30.20

Settlement Agreements

Settlement	Alleged Misconduct	Resolution and Penalties
United States ex rel. John Doe v. Spectocor Enterprise Services, LLC, No. 14-1387 (D.N.J., settlement announced June 26, 2017).	A DME company billed Medicare for higher and more expensive levels of cardiac monitoring services than requested by ordering physicians. Although the DME was marketed to allow physicians to run three separate types of cardiac monitoring services, the DME allegedly only allowed physicians to enroll in the service that provided the highest rate of reimbursement by the patient's insurance.	The company agreed to pay $13.45 million to resolve the allegations.

[145] OIG, Semiannual Report October 1, 2012 - March 31, 2013; Semiannual Report April 1, 2013 - September 30, 2013.

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Settlement	Alleged Misconduct	Resolution and Penalties
United States v. Biocompatibles, Inc., No. 16-710M-01 (D.D.C., settlement announced Nov. 7, 2016).	A DME company marketed a device that was cleared by the FDA as an embolization device. However, the company marketed and sold the device as a drug-delivery device, loading its device with chemotherapy drugs, making it a new combination drug device product, not approved by the FDA and not covered by Medicare and Medicaid.	The company agreed to pay $25 million to resolve the FCA allegations and was ordered to pay a $8.75 million criminal fine for misbranding and to forfeit $2.25 million. See 216 *BNA's Health Care Daily Report*, (Nov. 8, 2016).)
United States ex rel. Clyde et al. v. Orbit Medical et al., No. 2:10-cv-00297 (D. Utah, settlement announced May 27, 2015).	A DME company falsified prescriptions and documentation, which included altering documents to establish the medical necessity of power wheelchairs, to support fraudulent claims submitted to Medicare, the Federal Employees Health Benefits Plan and the Defense Health Agency.	The company agreed to pay $7.5 million to resolve the allegations. See 104 *BNA's Health Care Daily Report*, (June 1, 2015).
United States ex rel. Ballentine v. International Rehabilitative Sciences, No. 6:11-cv-370 (D.S.C., case dismissed May 16, 2013).	A DME company submitted claims to Medicare for DME that lacked physician orders, the required supporting documentation, or medical necessity. Company employees also allegedly falsified claims documentation and improperly gave prescribing providers gifts.	The company agreed to pay $1.2 million to resolve the allegations.
Hill-Rom Company, Inc. (E.D. Tenn. agreement announced Sept. 27, 2011).	The company knowingly submitted false claims to Medicare for bed support surfaces for treatment of bed sores for patients who did not qualify for such treatment. It submitted claims for patients for whom the equipment was not medically necessary, including patients who had died or were no longer using the equipment, prosecutors said. The company had a practice of automatically billing for patients over long periods of time without making any reasonable effort to determine if the patients continued to meet Medicare conditions for payment.	The company agreed to pay $41.8 million to settle the alleged FCA violations. Qui tam relators were to jointly receive $8 million of the settlement. The company also entered into a five-year Corporate Integrity Agreement (CIA) with the HHS OIG.
Mobility Products Unlimited LLC (M.D. Fla. agreement announced May 26, 2006).	The company improperly billed Medicare for used wheelchairs and scooters as if they were new. Other issues included whether the company separately billed for unbundled wheelchair and scooter accessories, particularly seatbelts and adjustable-height armrests, and whether it offered Medicare beneficiaries manual wheelchairs for free or at drastically reduced prices in order to secure the sale of a motorized wheelchair.	The company and its CEO agreed to pay more than $2.77 million to resolve the matter. They also entered into a five-year corporate integrity agreement that requires the company to retain an independent review organization to conduct a comprehensive claims review, including a review of the medical necessity of equipment being provided.

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Settlement	Alleged Misconduct	Resolution and Penalties
Group II Medical Supports LLC (S.D. W. Va. agreement announced May 15, 2006).	A DME supplier and its owner submitted false claims to Medicare and Medicaid. It routinely supplied high-cost inflatable mattresses, developed to treat the most advanced and serious forms of pressure ulcers or bed sores, to patients who did not have the required ulcers and otherwise did not qualify. The company misrepresented individual patient conditions and diagnoses and created false documents to support the payment claims.	The company agreed to pay the United States almost $1.6 million to resolve the allegations. The supplier, owner and former owner also were permanently excluded from future participation in the Medicare and Medicaid programs. The former vice president of sales was excluded for a minimum of five years.
United States v. Novartis Nutrition Corp., No. 05-30013 (S.D. Ill., settlement Feb. 11, 2005).	A pharmaceutical manufacturer offered free enteral feeding pumps to induce others to purchase different enteral nutrition products. The company gave 95 feeding tube pumps to Southern Medical Distributors before advising the phony supply company to submit charges of $162 per pump per month to Medicare for reimbursement. It then provided fake invoices for pump rental fees and a credit memo for the purpose of presenting the phony documents to federal auditors in the event of a Medicare audit.	The companies settled with the federal government, agreeing to pay $49.2 million in civil and criminal penalties. Novartis also entered into a five-year corporate integrity agreement to reform the sales and marketing practices of its enteral feeding operations, while its subsidiary was excluded permanently from participation in the Medicaid and Medicare programs. 09 *BNA's Health Care Fraud Rep.* 185,(Mar. 2, 2005).
Abbott Laboratories Inc. (S. D. Ill., settlement announced July 23, 2003).	A manufacturer of enteral feeding products was charged with counseling DME suppliers, contrary to Medicare policy, to submit bundled claims for reimbursement for feeding pumps and tubing. This resulted in the two products' being billed as one and at a higher price than if the items were billed separately. It also marketed the pumps and tubing sets at no additional charge to DME providers in exchange for an agreement from the provider to purchase a minimum amount of plastic tubing sets and/or food per month.	Without admitting any wrongdoing, the company agreed to pay a $400 million civil settlement and $200 million in criminal fines. A wholly owned subsidiary pleaded guilty to obstructing a criminal investigation and was ordered to pay a $200 million criminal fine. It was permanently excluded from the Medicare and Medicaid programs and the parent entered into a five-year corporate integrity agreement with the OIG. 7 *BNA's Health Care Fraud Rep.* 593, (Aug. 6, 2003).
United States ex rel. Nieber v. Kapi'olani Home Health Servs., No. 97-00989 SOM (D. Haw. agreement concluded Aug. 18, 1999).	A DME supplier billed Medicare for medical equipment without maintaining documentation to establish whether or when equipment was provided. They also allegedly provided equipment to patients without a physician's order or signed certificate of medical necessity.	Without admitting any wrongdoing, the company agreed to pay state and federal governments $3.4 million to settle all charges against it and enter into a corporate integrity agreement.

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Settlement	Alleged Misconduct	Resolution and Penalties
United States ex rel. Frisco v. Home Americair of Calif. Inc., No. CV 93-7186 (C.D. Calif. agreement concluded Apr. 1, 1998); *United States ex rel. Penizotto v. Bates East Corp.*, No. CV 96-5824 (C.D. Calif. agreement concluded Apr. 1, 1998).	A company licensed franchises to nearly three dozen suppliers of home oxygen equipment nationwide. The parent, two of its franchises, and other related parties allegedly provided home oxygen equipment to beneficiaries who did not qualify for the service. The parties then allegedly submitted false information to Medicare to receive payment for the equipment.	The parties agreed to pay $5 million and enter into a corporate integrity agreement to settle all allegations.
United States ex rel. Wells v. Huntleigh Tech. PLC, No. 95-95 (D.N.J. agreement concluded May 23, 1997).	The DME supplier sold pneumatic compressors and sleeves used with the compressors to Medicare beneficiaries for home use. The supplier submitted its claims to Medicare using a procedure code reserved for compressors that are more expensive than the pumps it actually sold. The company also used television commercials to tell beneficiaries that they could order the $4,000 lymphedema pump and be fully insured by Medicare, and it provided treating physicians with directions to photocopy a pre-written prescription, supplied by the company, onto the physician's own letterhead. In the alternative, the doctors were advised to send the company blank letterhead so it could create the prescription.	The company and its president agreed to pay $1.35 million to settle all allegations. The company also agreed to enter into a corporate integrity agreement.
Geriatric Medical and Surgical Supply Company Inc. (D. Mass., settlement announced May 16, 1997).	The company sold a product called "skin barrier paste"—used primarily by patients suffering from urinary incontinence—to nursing homes in amounts that greatly exceeded the legitimate medical needs of patients. The product also allegedly was sold in quantities larger than that ordered by physicians for patient use.	The company agreed to pay $200,000 up front, and agreed that the government could keep another $290,518 in claims payments that Medicare had withheld pending resolution of the overbilling charges.

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Court Rulings

Facts	Outcome
An owner of a medical supply company billed Medicare for services that were not medically necessary and paid kickbacks to patient recruiters in exchange for patient referrals. The owner also paid kickbacks to physicians in exchange for fraudulent prescriptions for medically unnecessary power wheelchairs for which the owner then billed Medicare.	The owner was sentenced to 97 months in prison and ordered to pay $1,866,260 in restitution. *(United States v. Walter-Eze*, No. 2:14-cr-00259-RGK (C.D. Cal. sentencing June 29, 2015). See 126 *BNA's Health Care Daily Report* (July 1, 2015).
An owner of a medical supply company paid kickbacks to patient recruiters in exchange for referrals and to physicians for prescriptions for medically unnecessary DME, including power wheelchairs. The owner used the prescriptions to support fraudulent claims submitted to Medicare.	The owner was sentenced to 4 years in prison and ordered to pay $4,372,466 in restitution. *United States v. Fadojutimi*, No. 2:13-cr-00324-CAS (C.D. Cal. sentencing May 13, 2015). See 94 *BNA's Health Care Daily Report* May 15, 2015).

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Facts	Outcome
An owner of a medical supply company illegally obtained protected health information of Medicare beneficiaries and then supplied the beneficiaries with medical devices from the company, which were not prescribed nor wanted by the beneficiaries. The owner forged physicians' signatures on documents submitted to Medicare to support fraudulent claims and submitted claims in the names of beneficiaries who were deceased.	The owner was sentenced to 87 months in prison. *United States v. Yusef,* No. 6:11-cr-00028 (E.D. Tex. sentencing Feb. 2, 2015). See 24 *BNA's Health Care Daily Report* (Feb. 5, 2015).
A physician accepted kickbacks for referring Medicare beneficiaries to a DME supply company for power wheelchairs and other DME. The beneficiaries were recruited and taken to see the physician for a single exam, after which the physician made the referrals. The beneficiaries did not need and often never used the prescribed DME.	The physician was sentenced to 24 months in prison and ordered to pay $931,118 in restitution. *United States v. Okoye,* No. 2:13-cr-00789-MMM (C.D. Cal. sentencing Dec. 8, 2014). See 240 *BNA's Health Care Daily Report* (Dec. 15, 2014).
The vice president of a company providing medical equipment and services on an Indian reservation provided Medicaid beneficiaries with less expensive, one-time use catheters but billed Medicaid for more expensive, long term use closed catheters. In total, Medicaid was defrauded of over $1.4 million.	The vice president was sentenced to 12 months and 1 day in prison. *United States v. Tope,* No. 9:14-cr-00008 (D. Mont. sentencing Nov. 26, 2014). See 231 *BNA's Health Care Daily Report* (Dec. 2, 2014).
A DME company owner had physician assistants at three medical clinics sign prescriptions and orders for medically unnecessary DME and for diagnostic tests that were later referred to other Medicare providers that billed for the equipment and tests. The owner also caused the three clinics to bill Medicare for medically unnecessary services. She billed Medicare on behalf of her own DME supply company for medically unnecessary equipment based on referrals from one of the three clinics. In total, the owner caused more than $24.8 million in fraudulent claims to be submitted to Medicare, which paid more than $9.6 million on the bogus bills.	The company owner was sentenced to 76 months in prison and ordered to pay $9.6 million in restitution. *United States v. Artsruni,* No. CR 13-00052 (C.D. Cal. sentencing Apr. 14, 2014). See 18 *BNA's Health Care Fraud Rep.* 378 (Apr. 30, 2014).
The owner of a durable medical equipment company hired recruiters to solicit Medicare and Medicaid beneficiaries and their personal identification information in five states. He filed more than 500 fraudulent claims. Recruiters told beneficiaries that Medicare was "giving away" motorized wheelchairs and scooters, and secured their personal information including names, dates of birth, and Medicare and Medicaid identification numbers. The owner billed for an expensive model of motorized wheelchairs but instead delivered less expensive scooters to the beneficiaries. In other instances, neither power wheelchairs nor scooters were delivered although Medicare and Medicaid had paid the claims. The owner and his co-conspirators created false Certificates of Medical Necessity for 16 beneficiaries listed in the indictment by drafting, without authorization, prescriptions from doctors who had never examined the beneficiaries. The scheme submitted more than $4.1 million in fraudulent claims to the Medicare and Medicaid programs.	The company owner was sentenced to 87 months in federal prison and fined $12,500. He was also ordered to pay $1.63 million in restitution and serve three years of supervised release. *United States v. Egede*, No. 4:06-cr-00163 (E.D. Tex. Feb. 6, 2014). See 18 *BNA's Health Care Fraud Rep.* 152 (Feb. 19, 2014).

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Facts	Outcome
A clinic owner submitted DME claims to Medicare for equipment that was neither medically necessary nor prescribed and falsely used physician identification numbers for filings worth about $11.3 million over the course of five months.	The owner was sentenced to 70 months in prison and ordered to pay $1.7 million in restitution, in addition to three years of supervised release. *United States v. Chavez*, No. 1:11-cr-20099 (S.D. Fla. sentencing order filed Feb. 12, 2014). See 18 *BNA's Health Care Fraud Rep.* 150 (Feb. 19, 2014).
Owners of two sham DME companies submitted $4 million in fraudulent claims on behalf of Florida patients, both living and deceased, supposedly treated by Kentucky physicians. In fact, neither the patients nor the physicians had any knowledge of one another. When inspected by investigators, the owners' two businesses were almost devoid of any medical products that were billed to Medicare. The owners recruited other men to serve as fronts for the companies, and later took them to Mexico to avoid prosecution.	The owners were sentenced to 54 months in prison and ordered to pay $1.9 million in restitution. *United States v. Lopez,* No 3:11CR-106-1 (W.D. Ky. sentence announced Jan. 23, 2014). See 19 *BNA's Health Care Daily Report* (Jan. 29, 2014).
The owner of a DME company worked with a co-conspirator to submit approximately $4.4 million in false claims to Medicare. Most items billed to Medicare and Medicaid, including "Artho kits" and power wheelchairs, either were not delivered at all, not medically necessary, not prescribed by a physician or upcoded from what was actually delivered. The kit was composed of 10 different braces that were not recognized nor authorized to be provided as a kit. The conspirators obtained Medicare beneficiary information by paying recruiters, then created paperwork and patient files to give the appearance of a valid claim. Of those claims, 157 were submitted for dead beneficiaries.	The owner was sentenced to 48 months in prison, and ordered to pay $1.5 million in restitution. His co-conspirator was sentenced to 72 months in prison and ordered to pay $9.9 million in restitution. *United States v. Orji,* No. 4:13-cr-00128 (S.D. Tex., sentencing Nov. 25, 2013).
The owner of a DME company paid patient recruiters and physicians for Medicare beneficiary information and fraudulent prescriptions for power wheelchairs. He then billed Medicare for power wheelchairs that the Medicare beneficiaries either didn't receive or didn't need.	The owner was sentenced to 87 months in prison and ordered to repay Medicare $5.8 million. *United States v. Agbu,* No. 2:11-cr-00134 (C.D. Cal. sentencing Oct. 17, 2013).
A former officer of a DME company paid cash kickbacks to co-conspirator physicians for fraudulent prescriptions for DME, including power wheelchairs. The DME company used the prescriptions to bill Medicare $1.5 million for medically unnecessary DME. Several Medicare beneficiaries were lured to medical clinics with the promise of free items, only to receive power wheelchairs they did not need or want. Their attempts to reject delivery of the power wheelchairs from the DME company were unsuccessful.	The company officer was sentenced to 51 months in prison and three years of supervised release, in addition to restitution to be determined. A co-defendant physician convicted of participation in the scheme was sentenced to 27 months in prison, three years of supervised release and $87,846 in restitution. *United States v. Onyeabor,* No. 2:12-cr-905 (C.D. Cal. sentenced Sept. 9, 2013).
The owner and operator of a DME supply company conspired to provide unnecessary power wheelchairs and other equipment to Medicare beneficiaries and then submit false claims. He also paid owners and operators of fraudulent medical clinics to provide him with prescriptions and other supporting medical documentation for the equipment billed to Medicare. He knew the prescriptions and documents produced by the clinics were fraudulent, yet he certified to Medicare that the equipment provided was medically necessary.	The owner was sentenced to 24 months in prison, three years of supervised release, and ordered to pay restitution of $653,461. *United States v. Aklyan,* No. CR 12-904 (C.D. Cal., July 30, 2013).

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Facts	Outcome
The owner of a now-defunct DME business unlawfully used the identity of a beneficiary to bill Medicare and Medicaid $5,000 for a power wheelchair that was not requested, prescribed, needed, or delivered. His company also submitted more than $11 million in false claims for power wheelchairs, incontinence supplies, hospital beds, mattresses, and other durable medical equipment. The scheme used marketers to obtain Medicare and Medicaid identification numbers and other information from beneficiaries that they in turn used to submit bogus claims for DME that was either not prescribed or prescribed but not delivered. He also attempted to obtain referrals of patients or DME orders from doctors in exchange for gifts.	The owner was sentenced to 144 months in prison, three years of supervised release, and ordered to pay $6.1 million in restitution. The sentence includes a 120-month prison term for his conviction in a conspiracy to defraud Medicare and Medicaid, in addition to a mandatory 24-month term for aggravated identity theft, to be served consecutively. He also forfeited power wheelchairs, scooters, and other DME discovered in his leased storage facility. A biller for the DME company was sentenced to 110 months in prison for conspiracy to defraud Medicare and Medicaid plus 24 months for aggravated identity theft, followed by three years of supervised release. The biller was also ordered to pay $5 million in restitution. A co-owner was sentenced to 80 months in prison, two years of supervised release, and ordered to pay $5.5 million in restitution. *United States v. Herrera,* No. 7:12-cr-01036 (S.D. Tex., sentencing July 11, 2013).
The owner and operator of a DME company paid cash kickbacks for fraudulent DME prescriptions for such items as power wheelchairs and hospital beds. A co-conspirator physician was paid for every fraudulent prescription he wrote for the DME and used the prescriptions to bill Medicare for the DME. Several Medicare beneficiaries were lured to medical clinics with the promise of a free recliner sofa, only to receive power wheelchairs that they did not need or want. The owner also billed Medicare for DME supposedly provided to Medicare beneficiaries who were deceased at the time of service. During the course of the scheme, the owner submitted more than $8.4 million in fraudulent claims to Medicare and received more than $4.5 million on those claims.	The owner was convicted of one count of conspiracy to commit health care fraud and 12 counts of health care fraud. He was sentenced to five years in prison, three years of supervised release, and to pay restitution of almost $4.6 million. *United States v. Adetola,* No. CR 12-382-GU (C.D. Cal. sentenced July 1, 2013).
The owner/operator of a DME retail business participated in a scheme where co-conspirators rounded up elderly patients who did not meet the standards for wheelchair reimbursement and wrote false prescriptions for the DME. The patients were promised free wheelchairs. The owner's DME company submitted claims and received reimbursements based on the prescriptions, for which the owner paid a kickback. A total of $1.3 million in false and fraudulent Medicare claims were filed and $830,000 was run through the owner's company.	The owner pleaded guilty to one count of conspiracy to pay and receive health care kickbacks and defraud Medicare. He was sentenced to 18 months in prison and ordered to pay $593,429 in restitution. A physician co-conspirator was sentenced to five months in prison, followed by five months in a halfway house, and ordered to pay $593,429.81 in restitution and to forfeit $55,800 in kickbacks for his role in the scheme. Another co-conspirator physician was sentenced to five months in prison and ordered to pay $650,000 in monetary penalties. *United States v. Melendez,* 12cr02599 (S.D. Cal. judgment entered June 27, 2013).
A former DME business owner filed bogus reimbursement claims for power wheelchairs, adult continence products, and enteral feeding supplies. He submitted fraudulent claims that falsely represented that legitimate and qualifying supplies were provided and that falsely represented the medical necessity of the supplies. In one instance, he billed Texas Medicaid $870 for feeding tube supplies but only provided oral nutritional supplements to the patient.	The DME company owner pleaded guilty to one count of health care fraud. He was sentenced to 35 months in prison, one year of supervised release, and ordered to pay $484,000 in restitution. *United States v. Odoemena,* No. 3:12-cr-00128 (N.D. Tex. sentencing June 26, 2013).
The owner and operator of a DME company fraudulently billed Medicare $6.7 million for power wheelchairs and "arthritis kits" that were medically unnecessary or never provided to beneficiaries.	The owner was convicted of eight counts of health care fraud, and sentenced to 97 months in federal prison. He was ordered to pay $2.5 million in restitution to Medicare and to serve three years of supervised release following his prison term. *United States v. Msiakii,* No. 4:12-cr-00009 (S.D. Tex. June 17, 2013).

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Facts	Outcome
The owner of a DME business delivered medically unnecessary power wheelchairs and accessories, prosthetics, and orthotic supplies, including wrist, back, foot, ankle, knee, elbow, and shoulder braces, to Medicare and Medicaid beneficiaries that sat unused for years after the defendant was paid. The owner purchased physician orders that often contained forged signatures from at least five recruiters for $200 to $300 per order.	The owner was sentenced to 81 months in prison, 57 months for conspiring to commit health care fraud, and 24 months for aggravated identity theft for unauthorized use of the National Provider Identification and Universal Provider Identification of doctors whose signature were forged on the physician orders. He was also ordered to pay $597,865 in restitution to Medicare and Medicaid and serve three years of supervised release. *United States v. Shittu*, No. 4:12-cr-00457 (S.D. Tex., sentenced June 6, 2013).
The owner of a DME supply business submitted fraudulent claims to Medicare for power wheelchairs, hospital beds, and related accessories for home use, and other supplies that were medically unnecessary or not provided to beneficiaries. He received referrals of beneficiaries with a purported need for DME from home health agencies. The company then contacted the beneficiaries' physicians to obtain prescriptions for the DME. If the company was unable to obtain a signed prescription for medical equipment, the company either forged a signature on a prescription or delivered the equipment without a physician's approval.	The owner was sentenced to a 30-month prison term and ordered to pay $691,175 in restitution, and to serve three years of supervised release. *United States v. Sorunke,* No. 3:12-cr-00311 (N.D. Tex., sentencing May 29, 2013).
A patient recruiter for a DME business provided patients and took kickbacks in a health care fraud scheme that billed Medicare more than $1 million for power wheelchairs and other durable medical equipment that was medically unnecessary. The kickback was based on a percentage of the reimbursement value of the equipment to the price of the particular item. The recruiter procured the names and personal information of Medicare beneficiaries in the area and delivered the names to a co-defendant family physician. The recruiter subsequently delivered the fraudulent prescriptions to co-defendant owners of the DME business.	The recruiter was convicted of 15 counts of health care fraud involving the DME business and one count of conspiracy to pay and receive illegal kickbacks. She was sentenced to 18 months in prison and three years of supervised release. Co-defendant owners of the DME business were sentenced to 27 and 36 months in prison, followed by two years of supervised release. The physician who wrote the fraudulent prescriptions was sentenced to 15 months in prison and ordered to pay $360,000 in restitution. *United States v. Anyanwu*, No. 3:10-cr-00101 (M.D. La. sentenced March 14, 2013).
The owner/manager of six companies that ostensibly sold DME, such as motorized wheelchairs and powered pressure-reducing mattresses, submitted more than $15 million in fraudulent claims to Medicare, which paid more than $8.1 million on the bogus claims. The owner paid marketers to recruit Medicare beneficiaries who would allow their identities and Medicare numbers to be used for the submission of false claims. She paid kickbacks to marketers, who in turn paid kickbacks to doctors who fraudulently wrote prescriptions, even though the physicians had not examined the patients, or an examination revealed that the medical equipment was not medically necessary.	A federal judge sentenced the owner to 13 years in prison. In handing down the sentence, the judge said the defendant was motivated by greed, and thus the lengthy sentence was necessary, in part to send a message to others who might commit crimes against the Medicare program. *United States v. Rush*, (C.D. Cal., No. CR 09-679-GHK, sentencing March 27, 2013).

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Facts	Outcome
The owner of a DME company used fraudulent certificates of medical necessity (CMNs) to falsely bill Medicare $14 million for power wheelchairs and accessories. Medicare paid the company approximately $5.6 million over the course of a scheme that involved payment of kickbacks by DME companies to recruiters who solicited Medicare beneficiaries for evaluation by complicit doctors. Recruiters transported the beneficiaries to the physicians in order to secure false CMNs. The companies then submitted the fraudulent CMNs to Medicare for medically unnecessary motorized wheelchairs, while delivering less-expensive scooters instead.	The owner pleaded guilty to conspiracy to defraud Medicare, health care fraud, and money laundering. He was sentenced to 51 months in prison and required to pay restitution of $5,632,509. He specifically agreed that the $5.6 million in restitution included his personal home, $758,000 from his business bank account, a Hummer, and a Land Rover. *United States v. Skripka,* No. CR-H-04-0349 (S.D. Tex., convicted Oct. 13, 2006). Physician co-defendants Jayshree Patel and Charles Skripka were both sentenced to 78 months in prison and ordered to pay $9.5 million and $6.6 million, respectively, in restitution. Two recruiters were sentenced to 80 and 87 months in prison.
The owner of a DME company steered Medicare patients who wanted or needed less expensive wheelchairs to power wheelchairs that garnered him about $4,000 profit per sale and failed to inform patients they had the right to lease the wheelchairs. He also offered illegal kickbacks in connection with wheelchair sales, and billed certain standard wheelchair equipment, such as the wheels, as extra-cost options; charged $300 for $60 wheelchair seat cushions; billed more than twice the actual time needed for wheelchair repair; and changed the company's patient files by creating back-dated forms and removing documentation.	The owner was convicted on 22 felony counts, including health care fraud, mail fraud, illegal kickbacks, and money laundering charges. The jury also returned a forfeiture verdict of more than $1 million. He was sentenced to 63 months in prison. The verdict was affirmed on appeal. *United States v. Amr,* No. 03-2131 (6th Cir., May 25, 2005).
The owner of at least 16 DME companies fraudulently billed Medicare and Medicaid for wheelchairs, alternating pressure mattresses, and other DME. Claims were submitted for DME not provided, for DME costing more than that actually provided, and for DME not medically necessary.	The owner pleaded guilty in May 2002 to conspiracy to commit Medicare and Medicaid fraud and to launder the proceeds, and to conspiracy to commit Medicare fraud, to obstruct justice, and to launder the proceeds. He also pleaded guilty on behalf of six of his companies to charges that included one count each of conspiracy to commit Medicare and Medicaid fraud and one count each of submitting a false claim. He was sentenced to nearly seven years in prison and ordered to pay more than $14.4 million in restitution to CMS. *United States v. Haught,* No. 8:02-CR-19-T-27EAJ (M.D. Fla., sentencing March 18, 2003).
A physician ran medical clinics in a low-income area of Los Angeles, signed prescriptions and certificates of medical necessity for expensive durable medical devices for hundreds of patients whom he never even examined. Salespeople working for a medical equipment supply company recruited hundreds of Medicare beneficiaries from Filipino communities, telling them they would receive free medical examinations and equipment. The salespeople then transported the patients to one of the physician's clinics, where they underwent a series of expensive tests and examinations conducted by physicians under contract. The salespeople filled out prescriptions and CMNs for lymphedema pumps, back braces, vacuum erection systems, and other equipment, and the physician signed them without examining the patients or consulting with the contract doctors.	The physician was convicted on 39 charges. He was sentenced to five years in prison and ordered to pay $2.8 million in restitution to the federal and state health agencies he defrauded. *United States v. Perry*, No. CR-98-366-TJH (C.D. Calif., sentencing Oct. 22, 2001).

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