The current regulatory environment affects the operation of health care providers and suppliers and the provision of patient care, and complex regulations have affected durable medical equipment companies and sleep disorder centers.

Government agencies and third-party payers are conducting more and more audits. This trend has caused health care providers and suppliers, including DME companies and sleep disorder centers, to revisit their regulatory compliance efforts and programs.

The national growth and expansion of DME companies and sleep disorder centers aligns with new and advancing technology as well as evolving regulations and enforcement efforts. Compliance programs have become an effective tool to demonstrate adherence to regulatory requirements in the event of an audit, investigation or other enforcement activity.

Additionally, the utilization of telemedicine by DME companies and sleep disorder centers with multiple locations in different jurisdictions, and the availability of CPAP for purchase on the internet without a prescription or documented polysomnography (sleep study) and diagnosis of obstructive sleep apnea, have given rise to additional regulatory concerns and compliance issues.

DME companies and sleep disorder centers should consider implementing compliance programs to demonstrate regulatory compliance — and as a preventative measure for risk management in case of an audit or investigation.

A compliance program is a system designed to ensure continuous adherence to all applicable laws, regulations, industry standards, organizational standards, governance principles, and community and ethics standards.

Corporate compliance is a term used in the health care industry to indicate that a provider or supplier runs a clean operation and does not engage in fraud, waste or abuse of health care funds.

Compliance programs increase staff awareness and demonstrate commitment to regulatory compliance. In addition, they may be a mitigating factor during an audit or investigation. Such programs should be designed, implemented and enforced in a manner that effectively prevents and detects fraud, abuse and criminal conduct.

**LAW OR CONTRACT MAY REQUIRE COMPLIANCE PROGRAMS**

Third-party payer agreements may require the provider or supplier to have a compliance program. The Health and Human Services Department’s Office of Inspector General has developed a series of compliance program guidance documents directed at various health care industry segments, including hospitals, nursing homes, physician practices, hospices, home health agencies, clinical laboratories, third-party billers and DME suppliers.

These OIG model programs encourage development and use of internal controls to monitor adherence to regulations and program requirements. The OIG developed and published the model programs to promote ethical and lawful conduct throughout the health care industry. However, use of the programs is voluntary.

The OIG published the Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Implementation of voluntary compliance programs by health care providers and suppliers, including DME companies, may prevent fraud, abuse and waste in health care plans while providing quality patient care, equipment and supplies.

In recent years, there have been an increasing number of government and insurance company audits and investigations regarding DME companies and sleep disorder centers that supply DME, including CPAP supplies, to patients with obstructive sleep apnea.

Most DME companies and sleep disorder centers bill Medicare, Medicaid and other third-party payers, including commercial insurance companies, for the provision of patient care, DME, and related services and supplies.

The recent rapid growth in the number of sleep disorder centers and DME companies nationwide has sparked increased payments by third-party payers, including reimbursement by the Medicare and Medicaid programs.

With this growth, sleep medicine providers and suppliers are on the radar of government agencies and third-party payers for regulatory compliance and related enforcement efforts.

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Industry in the Federal Register, Volume 64, No. 128 (July 6, 1999).

It identified the following seven fundamental elements applicable to an effective compliance program:

• Implementing written policies, procedures and standards of conduct.
• Designating a compliance officer and compliance committee.
• Conducting effective training and education.
• Developing effective lines of communication.
• Enforcing standards through well-publicized disciplinary guidelines.
• Conducting internal monitoring and auditing.
• Responding promptly to detected offenses and developing corrective action.

These seven elements identify specific areas of the durable medical equipment, prosthetic, orthotics and supply, or DMEPOS, industry operations that may be vulnerable to fraud and abuse.

The OIG’s compliance program guidance is intended to assist suppliers of DME, prosthetics, and orthotics, and their agents and subcontractors, in developing effective internal controls that promote adherence to applicable state and federal regulations as well as state, federal and private health plan program requirements.

Compliance programs are critical as an internal quality assurance control in reimbursement and payment areas, where claims and billing operations are often the source of fraud and abuse.

The OIG has identified certain areas of concern for DMEPOS suppliers, including:

• Billing for items or services not provided.
• Billing for services that the DMEPOS supplier believes may be denied.
• Billing patients for denied charges without a signed written notice.
• Duplicate billing which occurs when more than one claim for payment is submitted for the same patient for the same service, for the same date of service.
• Billing for items or services not ordered.
• Upcoding, which involves selecting a code to maximize reimbursement when such code is not the most appropriate descriptor of the service.
• Unbundling items or supplies, which involves billing for individual components when a specific HCFA common procedure coding system code provides for the components to be billed as a unit.
• Billing for new equipment and providing used equipment.
• Resubmission of denied claims with different information in an attempt to be improperly reimbursed.
• Refusing to submit a claim to CMS for which payment is made on a reasonable charge or fee schedule basis.

The adoption and implementation of voluntary compliance programs by health care providers and suppliers, including DME companies and sleep disorder centers, may prevent fraud, abuse, and waste in health care plans while providing quality patient care, equipment and supplies.

Compliance efforts should establish an internal corporate culture that promotes prevention, detection and resolution of conduct that violates state or federal regulations. The program should effectively articulate and demonstrate the DME company’s ethical and business policies.

The health care provider or supplier should establish benchmarks showing that implementation and achievements are essential for an effective compliance program.
• Providing or billing for substantially excessive amounts of DMEPOS items or supplies.
• Failure to monitor medical necessity on an ongoing basis.
• Delivering or billing for certain items or supplies prior to receiving a physician's order and/or appropriate certificate of medical necessity, or CMN.
• Falsifying information on the claim form, CMN, and/or accompanying documentation.

It is imperative that DME companies and sleep disorder centers conduct their own risk assessment to determine areas of concern and vulnerabilities specific to their operations. Often, improper billing results from a lack of communication between health care professionals who provide patient services and improper coding and claims submissions.

DME companies and sleep disorder centers have received claims submission and reimbursement denials when medical necessity is not established and documented by the ordering physician or other health care providers authorized to order items or services to be paid by Medicare or Medicaid. DME companies and sleep disorder centers should take steps to ensure they are not submitting claims for services that are not covered.

Most actions are filed under the FCA's whistleblower provisions, which are also known as the statute's qui tam provisions. Qui tam FCA lawsuits are civil actions filed on behalf of the government by whistleblowers, who are called relators. A whistleblower who exposes fraud on the government can receive a share of the recovery.

Given the increasing number of qui tam lawsuits, sleep disorder centers and DME companies must ensure that coding and billing practices as well as claims submissions comply with Centers for Medicare & Medicaid Services regulations.

They must also see that entries meet coverage guidelines and applicable national coverage decision and local coverage decision guidelines for their Medicare administrative contractor's jurisdiction.

Each state is assigned to a specific MAC jurisdiction and MAC. For example, Illinois is assigned to MAC 6, and National Government Services Inc. is designated as its MAC.

By voluntarily implementing a compliance program, a DME company or sleep disorder center may realize the following benefits:

• The formation of effective internal controls to ensure compliance with state and federal statutes, rules and regulations as well as state, federal and third-party payer health care program requirements and internal guidelines.
• An increased likelihood of identification and prevention of criminal and unethical conduct.
• The ability to obtain an assessment of employee and contractor behavior relating to fraud and abuse.
• Improvement of the quality, efficiency, and consistency of providing services.
• A centralized source for distributing information on health care statutes, regulations, policies, and other program directives regarding fraud and abuse and related issues.
• Procedures that require the prompt, thorough investigation of alleged misconduct by corporate officers, managers, representatives, employees, and independent contractors, consultants, clinicians and other health care professionals.
• Early detection and reporting, which may minimize the loss to the government from false claims, and therapy reducing the DME companies’ and sleep disorder centers’ exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusion.

Every compliance program should require the distribution of written policies and practices that identify specific areas of risk.

DME companies should keep the treating physician’s or other authorized person’s signed and dated order or CMN on file for all DMEPOS items and services, including CPAP.

Upon a third-party payer’s request, the DME company should be able to provide documentation, such as physician orders, completed original CMNs, proof of the DME delivery, and written confirmation of verbal orders.

It should also be ready to produce any other documentation supporting the medical necessity of an item or service the DME company has provided and billed to a federal or private health care program.

Health care providers and suppliers have a legal duty to ensure false or inaccurate claims are not submitted to government or private payers, including the Medicare and Medicaid programs and commercial insurance companies.

Health care fraud cases under the False Claims Act, 31 U.S.C.A. § 3729, have increased significantly in recent years. The FCA is the government’s primary civil remedy to redress false claims for federal money or property, including false claims relating to incorrect billing for the provision of health care services.
• Initiation of immediate and deliberate corrective action.

• Enhancement of the structure of the DME companies’ or sleep disorder centers’ operation and consistency between any related entities and service locations.

Implementation of a compliance program will not completely eliminate the potential for fraud and abuse.

Such a program will, however, significantly reduce the risk of unlawful or improper conduct by the health care provider or supplier and also reduce the risk of a potential audit, investigation or other enforcement activity, including a qui tam action.

A compliance program can be the foundation on which a DME company or sleep disorder center can build and develop the process necessary for an effective program that demonstrates compliance with applicable regulations and requirements.

An effective and well-developed program should incorporate the OIG’s identified seven fundamental elements.

DME companies and sleep disorder centers should strive to provide the highest level of patient care while reducing fraud, abuse and waste in state, federal and private health programs.

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