

CRAFTING

Your Compliance Plan

Understand the seven key elements of OIG's Compliance Program

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WAY BACK IN 1999, the U.S. Department of Health and Human Services' Office of Inspector General (OIG) created and released a document, *OIG's Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry*. This document would become the framework for most O&P office compliance plans. Although this document is almost 20 years old, the guidance found in it is still relevant—and may be even more important today than when it was written.

Over the last few years, Medicare has increased its focus on finding and stopping fraud and abuse within the Medicare program through various methods (e.g., audits, new supplier enrollment standards, etc.). Medicare also has become more active and proactive in enforcing these and other regulations, like the Health Insurance Portability and Accountability Act (HIPAA). It is vital that you have a viable and useful compliance plan and program in place.

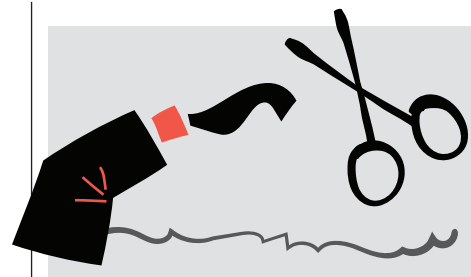
The OIG stated that in order for any compliance plan to be effective it should include seven key elements or components: implementation of written policies; designation of a compliance officer; development of training/education programs; establishment of effective lines of communication; performance of internal audits; consistent enforcement of standards; and prompt response to issues. This month's *Compliance Corner* offers an explanation of these seven elements.



1

Implementing Written Policies and Procedures

The first step in creating your compliance plan is developing of your company's written standards of conduct, or the broad values set in place for your organization to follow. For example, your standards should include your desire to comply with all state and federal regulations and a statement that your facility will conduct business in a professional and proper manner. The standards of conduct will then help you create and frame the specific written policies and procedures that are tailored to meet your company needs—the steps that will show your commitment to compliance.



Your policies and procedures should address specific areas of risk or areas that are prone to potential fraud or abuse. This would include such general areas as the claims development and submission process (establishing medical necessity, orders, proof of delivery, selection of codes, etc.), kickbacks/self-referrals, marketing, and retention of records, among other things.

To help you identify some of these compliance hotspots, OIG published a list of 47 potential risk areas specific to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) in the 1999 report. However, not all of them would apply to O&P or to your specific business model; thus, not all of the 47 would be included in your policy and procedures.

Finally, your standards and your subsequent policies and procedures should be readily available to all employees and well publicized in your company's educational materials. For example, every employee should be required to sign a copy of the standards of conduct, and new hires should be educated on the policy and procedures. You might consider reviewing the policies and procedures on a yearly basis for existing employees.

2

Designating a Compliance Officer and Compliance Committee

You must designate one employee to be the compliance officer, and that individual must serve as the primary point person for all compliance activities and questions. If possible, create a compliance committee whose duties would be to advise and help the compliance officer in implementing, updating, interpreting, and enforcing (including disciplinary actions) the company's compliance program/policies and procedures.

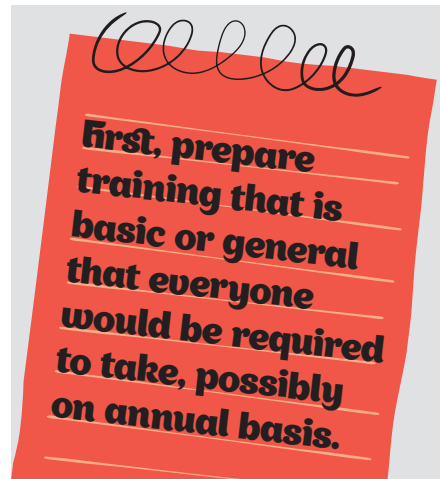
There is no need to hire someone to act solely as a compliance officer; it is acceptable to have a compliance officer who has other duties and functions within the company. However, there are some keys things to think about when appointing your compliance officer. First, the individual should be a high-ranking staff member within your company, or should have direct access to high-ranking personnel or senior management. Second, he or she should have the ability and power to exercise independent judgment and implement policy changes, without fear of any reprisals. Third, if your compliance officer will be performing other duties, those duties should not be in

conflict with the goals of your standards of conduct and your compliance goals.

3

Implementing Training and Education Programs

The *OIG Compliance Program Guidance* for DMEPOS states: "The proper education and training of corporate officers, managers, and employees, and the continual retraining of current personnel at all levels, are significant elements of an effective compliance program." Thus, you must implement education and training programs that are designed for existing employees as well as new hires, including the compliance officer and management staff; and these programs must be routinely revamped to account for current trends.



The type of education or training should be tailored to meet the needs of your employees and your company, but there are several general rules to follow.

First, prepare training that is basic or general that everyone would be required to take, possibly on annual basis. This would be training on the fundamentals, such as state and federal regulations, audit policies, company standards, etc. This session also should include information that ensures that all employees are aware of the compliance program, understand their role in the program, and know the penalties for violating the policies and procedures of the program.

Second, create plans or modules that are more specific and detailed-orientated for specific audiences, such as billers and coders.

Finally, be sure you have an avenue to ensure that your education and training remains up-to-date on all changes; and that these changes are disseminated in a timely manner, via staff meetings, emails, memos, etc. Also make sure you are registered to receive all announcements from the durable medical equipment Medicare administrative contractors, read all of the trade magazines, belong to the appropriate associations, and attend yearly seminars when appropriate.

4

Developing Effective Lines of Communication

Your compliance program and company are expected to have effective, open lines of communication, both internally and externally, in place between the compliance officer/committee and all people associated with the company; with the purpose of receiving clarification about the company's policy and procedures; and to encourage the reporting of any potential areas or incidents of fraud and abuse. These lines of communication could include hotlines, emails, memos, newsletters, suggestion boxes, and posters.

Whichever methods of communication you use, there are two areas to focus on. First, be sure that your employees are encouraged to use the established lines of communication, and communicate that they should not fear any retaliation or repercussions if they use the lines of communication to report fraud or abuse (these are whistleblower protections). Second, make sure that all questions and responses in regard to policies and procedures are documented, as they can be used in updating future versions of the policies and procedures.

5

Internal Auditing and Monitoring Systems

The goal of the audit program is to monitor ongoing operations to ensure that policies and procedures are being observed and that necessary corrective action can be taken to correct any deficiencies.

When designing or reviewing the effectiveness of an audit program, the following issues should be considered:

- Frequency (how often the audits are conducted: monthly, semimonthly, etc.)
- Number of charts to be reviewed (what number provides you with a strong cross sample)
- Particular issues to be monitored (be sure to audit for the right issues, using current guidelines)
- Documentation of the results
- Personnel involved (who is conducting the audits: staff, compliance officers, third parties, etc.)
- Discussion of the results of the audits and the actions taken as a result with all those involved (this should be performed as often possible but, at a minimum, annually).

Keep in mind that the extent of your auditing/monitoring program should be in line with your available resources and the identified risk areas that are pertinent to your company. The OIG report points out that if a “supplier failed to develop an adequate audit program, given its resources, the government will be less likely to afford the DMEPOS supplier favorable treatment under its various enforcement authorities.” What you do or don’t do may affect your liability.

6

Well-Publicized Disciplinary Directives

Your compliance plan must include written guidance regarding disciplinary action for anyone who has failed to follow the company’s standards of conduct and written policies and procedures for compliance, regardless of his or her position in the company.

These well-publicized disciplinary directives should include information on who is in charge of handling disciplinary problems. For example, you should document whether minor issues may be handled by a manager or compliance officer, or if all issues will be handled by upper management (such as an owner, president, chief executive officer, etc.).



The consequences of noncompliance and disciplinary action must be consistently applied and enforced, with all employees subject to the same types of disciplinary action for similar offenses. This must be done for the disciplinary actions to have any effect as a deterrent. For example, each employee could be subject to varying levels of discipline depending on the action, using disciplinary tactics such as additional education, verbal warnings/write-ups, demotion, and, in extreme cases, termination.

7

Responding Promptly/Taking Corrective Action


Once an individual has been identified as having violated your code of conduct or been otherwise noncompliant, regardless of the scope and size, you must have procedures in place that allow you to act rapidly to assess the issue and correct the action through the proper channels.

Ensure your compliance plan includes a standardized process or format that can be used by your compliance officer/committee, or any other management officials, for investigations. The scope and breadth of your investigation will depend on the size of your company, but consider including the following 10 steps in your investigations:

1. Put an immediate halt to the issues/actions/questionable actions that resulted in the investigation.
2. Determine the scope of the issue, i.e., is it an ongoing issue, or was it a one-time mistake?
3. If it is a large issue, consider involving others in the investigation.
4. If it is a large or complex issue, consider involving outside counsel (such as your company’s attorney).
5. Sort through all the information you gathered and determine the relevant facts.

6. Task the investigative team (compliance officer, compliance committee, etc.) with creating a report outlining the causes of the investigation, and what the investigation revealed. This leads into steps seven and eight, which also should be included in the report.
7. Review the findings to determine your exposure/liability. For example, are you required to self-report anything? Are there any overpayments involved?
8. Determine what you will do to correct the issue, and your corrective action plan.
9. Consider monitoring the issue and determine if your corrective action plan was effective, or if more action is required.
10. Keep and file copies of the information compiled as a result of the investigation in a secured location.

The presence or absence of a compliance plan, and your adherence to that plan, can help you stay clear of certain Medicare trouble areas—and it can mean the difference between receiving a warning or receiving stiff fines or other dire consequences. Take time today to review your facility’s compliance plan, and update it if necessary.

To learn more on this topic, view the full OIG report on the OIG website at <https://oig.hhs.gov/authorities/docs/frdme.pdf>. 



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