

compliance

Compliance Programs—No Longer Voluntary?

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Healthcare remains one of the most heavily regulated industries in the United States. Physicians, hospitals, and other healthcare organizations are subject to a variety of statutes, regulations, and program requirements. In addition, the Centers for Medicare & Medicaid Services (CMS) has determined that most improper payments in the Medicare program occur because a provider did not comply with Medicare's coverage, coding, or billing rules.

The Affordable Care Act (ACA), as it matures, has increasing requirements for providers and one of these is the establishment of an effective compliance program. While many healthcare entities have already implemented compliance programs, a compliance plan will no longer be voluntary or optional. The mandate is set forth in Section 6401 of the ACA, which established a requirement that all enrolled providers and suppliers must revalidate their enrollment information under new screening provisions, and states that a "provider of medical or other items or services or supplier within a particular industry sector or category" shall establish a compliance program as a condition of enrollment in Medicare, Medicaid, or the Children's Health Insurance Program (CHIP).

The new screening process is required to include a licensure check, and may include a criminal background check, fingerprinting, unscheduled and unannounced site visits, and database checks. The statute requires the Secretary of Health and Human Services (HHS) to establish procedures to provide for a provisional period of not less than 30 days and not more than one year during which

new providers and suppliers, as the Secretary determines appropriate, would be subject to enhanced oversight, such as prepayment review and payment caps.¹

In addition, Section 6401 states that regardless of provider size, implementation of a formal compliance plan is mandatory and that a new practice will not be able to enroll in Medicare or Medicaid without a compliance program in place. Last, the ACA requires that the HHS Secretary work in conjunction with the Office of the Inspector General (OIG) to delineate "core elements" of an acceptable program, and set a deadline for implementation of the program.

At the time this article was completed, HHS had not yet set the final guidelines or a deadline for certifying effectiveness for healthcare providers, including hospitals and physician practices, but a compliance program is still technically mandated by law. The consequences for not having a compliance program in place could be severe, including civil penalties, criminal prosecution, and exclusion from the Medicare, Medicaid, and CHIP programs.²

Don't Assume You Have One

Even if you believe the healthcare organization, at a corporate level, has a compliance program in place, do you know how it affects your department, your electronic health record (EHR), or your employees? Does Compliance audit your department, providing ongoing materials and presentations, or do they generally leave you alone to work without ongoing support? Ensuring compliance with the myriad of coding and billing regulations is everyone's job, so

make sure you are connected to your Compliance Department, or take the responsibility for compliance into your own hands. A successful compliance plan sends a message to the staff, physicians, payers, and regulators that the cancer program is trying to prevent errors. According to the Jan. 16, 2009, Federal Register:³

"Coding is the assignment of a code to a specific clinical condition or procedure; the mechanism used to do this, whether electronic or manual may differ, but codes are still assigned."

This means that every individual who captures a charge in an EHR, checks a code on a fee slip, or uses coding references to report a procedure or diagnosis code on an insurance claim is "coding." As a result, every individual who codes must be trained to ensure compliance with coding and billing guidelines and regulations.

Why Comply?

An effective compliance program is more than just obedience to laws, regulations, and policies. If an ethics and compliance program is to permeate the healthcare organization, it must speak to the concerns of providers who may not link the relevance of charge capture (electronic or via paper charge ticket) to Medicare reimbursement. In addition to complying with the law, there are other good reasons for implementing a compliance program. An effective compliance program can:

- Identify potential lost revenue issues
- Strengthen operational efficiencies
- Reduce denial rates and error correction
- Improve medical record documentation

- Enhance the organization’s professional reputation
- Identify existing or new problems before they are too complicated or expensive to correct
- Reduce the risk of lawsuits, fines, and penalties
- Enhance the quality of care.

In addition, the implementation of an effective compliance plan can foster better communication between billing and clinical staff, ensuring increased understanding of coding and billing rules.

An effective compliance plan is an active compliance plan, and an active compliance plan will keep pace with rapidly changing government regulations, payer requirements, office operations, and changes in technology. According to *Above Reproach: Developing a Comprehensive Ethics and Compliance Program*:⁴

“Fundamentally, an ethics and compliance program has two purposes: to ensure that all individuals in an organization observe pertinent laws and regulations in their work; and to articulate a broader set of aspirational ethical standards that are well-understood within the organization and become a practical guideline for organization members making decisions that raise ethical concerns.”

Compliance Guidelines

Although the OIG has provided guidance for various healthcare entities when developing a compliance program, there is no “one-size-fits-all” compliance plan. Therefore, consider using the OIG guidance as a foundation

when developing a more customized program to meet physician, facility, or cancer program needs. For example, here are the OIG’s “Seven Fundamental Elements of an Effective Compliance Program,” which were first published in a 1998 Federal Register:⁵

1. Implement written policies, procedures, and standards of conduct. These standards, policies, and procedures should be easily accessible to everyone in the department or cancer center and should be based on your organization’s unique risk areas. Remember that a compliance plan constitutes more than filling out a series of templated forms, placing them in a binder, and letting the resulting product gather dust on a shelf.
2. Designate a compliance officer and Compliance Committee. Every cancer program employee should know who their compliance representative is and how to contact that individual if there is a concern regarding a current practice. Compliance Department staff is empowered to audit billed services, educate other employees, update physicians, and initiate corrective actions should an error be detected.
3. Conduct ongoing training and education. At a minimum this means that all new employees receive general and/or specialized training, based on their job function. In addition, there should be annual refresher classes for all staff. Training should be tracked to include the date, content of each session, delivery method (such as webinar, in-person training), and signatures of all employees who attended the training.
4. Develop effective lines of communication. An open, user-friendly process should be established to report any questionable conduct. The anonymity of those reporting the problems should be maintained, and methods to accomplish this can include a compliance bulletin board, drop box, or posting the compliance hotline number in a prominent location.
5. Conduct internal monitoring and auditing. Monitoring uses the control systems, as designed and implemented by management, to direct and correct day-to-day operations. Auditing, in contrast, predominantly consists of retrospectively testing the established monitoring systems to ensure they are functioning as prescribed. Periodic chart audits should be scheduled to ensure that the medical record documentation supports all diagnosis and procedure codes billed to insurance. The date of service, level of service, performing provider, medical necessity, and other elements to ensure correct billing should be monitored and education performed when deviations are detected.
6. Enforce standards through well-publicized disciplinary guidelines. Any violations of the tenets of the compliance program should be dealt with through disciplinary actions, including reprimands, probation, demotion, suspension, and even termination, depending on the severity of the violation.
7. Respond promptly to detected offenses and undertake corrective action. Once you find a problem, it is essential that there be swift investigation and if

necessary, immediate corrective action. Corrective action may also include the return of any federal program or other payer overpayments and voluntary self-disclosure to appropriate agencies when warranted. It may also be necessary to retain legal counsel to ensure that all legal issues are considered when evaluating and implementing corrective actions.

In addition, the OIG offers “Five Practical Tips for Creating a Culture of Compliance:”⁵

1. Make compliance plans a priority now.
2. Know your fraud and abuse risk areas.
3. Manage your financial relationships.
4. Just because your competitor is doing something doesn’t mean that you can or should.
5. When in doubt, ask for help.

The OIG’s guidance to individual and small physician practices emphasizes that compliance plans must be active programs:⁶


“Compliance programs are not just written standards and procedures that sit on a shelf in the main office of a practice, but are an everyday part of the practice operations. It is by integrating the compliance program into the practice culture that the practice can best achieve maximum benefit from its compliance program.”

In other words, the compliance effort is about individuals on a day-to-day basis knowing what is expected of them and doing it and about never compromising integrity—regardless of the pressures faced. It is by integrating the compliance program into the practice culture that the organization can best achieve maximum benefit from its compliance program.

Reduce Fraud, Waste & Abuse

A key objective of the ACA is to rein in federal healthcare spending, so providers that accept Medicare payments should expect increased efforts to identify overpayments and fraud. The mandate to institute a formal compliance plan shifts part of the burden of preventing fraud, waste, and abuse from the federal govern-

ment to healthcare providers. This means that CMS will try to minimize the need to “pay and chase” and expect physicians and facilities to more closely monitor their compliance with coding, billing, and anti-kickback regulations. For example, if there is a problem with code assignment, the federal government can in the future point to the compliance program requirement and state that the provider violated their own compliance plan.

It is inevitable—at any time HHS or the OIG can publish the mandated core elements and the timeline for implementation as required by section 6401. But rather than procrastinate, now is the time for all cancer programs to start structuring an effective compliance program. A healthy compliance program is like a living organism that continues to grow and evolve over time, becoming better and stronger at managing risks and continuing to inspire the highest ethical goals for practice employees. The more a cancer program invests in the development and implementation of an effective compliance program, the more likely it is that the program will go beyond mere compliance and become a driver of continuous improvement throughout the entire organization. 

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