The business and regulatory climate for healthcare practitioners overall has changed and continues to change. Until recently, compliance programs for physician practices were recommended yet still voluntary according to the OIG Compliance Program Guidelines for Individual and Small Group Practices. The Affordable Care Act (ACA) requires physicians who treat Medicare and Medicaid beneficiaries to have a compliance program. Private practices in particular are overwhelmed by the compliance mandates of the ACA, yet they must comply to avoid the significant risks and costs associated with non-compliance. They must find mistakes before the government does!

HHS/OIG has not yet published the core elements or timeline of a mandatory compliance program. However, all indicators point to the seven elements set forth in chapter 8 of the Federal Sentencing Guidelines Manual as the basis for establishing one under § 6401 of the PPACA. In fact, OIG advises providers to make compliance plans now and has compliance training tips and videos that apply to small group providers available on their website.

**Private practices must take ownership for compliance**

There is mounting pressure to reduce medical costs, making audits increasingly common. These audits identify overpayments and demand physicians to repay. To avoid the hefty
Establishing an effective compliance program for a physician practice

Understanding the seven elements listed below and how a practice can address each area is critical to establishing an effective compliance program.

1. Written Policies, Procedures and Standards of Conduct:
   Demonstrate a commitment to compliance and ethical practices, and have written policies that are regularly distributed to all staff members.

   The practice should develop written standards such as a code of conduct and procedures for a staff manual that is specific to the practice. This work may be performed internally or by hiring a consultant or attorney to assist in drafting the policies. Once established, these policies must be followed and updated regularly or additional problems can arise.

2. Compliance Officer, Compliance Committee and High Level Oversight: Designate a compliance officer and/or compliance committee to directly report to the physician owner(s), and who are separate from the legal and financial roles in the practice. The guidelines emphasize that the owner(s) be engaged in the compliance program, mandating that the owners be “knowledgeable” of the content and operation of the program, “exercise reasonable oversight” of implementation and effectiveness, and receive training and education on the program structure and operation.

   The perfect scenario is for the practice to appoint one individual with the educational background and the inclination to handle the many details of this position who is to be responsible for the oversight and daily implementation of the compliance program.

3. Effective Training and Education: Provide compliance training at least annually and at new employee orientations and include the owner(s) and designated Compliance Officer. All staff members involved in the administration or delivery of benefits should also receive fraud, waste and abuse (“FWA”) training on a regular basis.

   Ultimately, the practice’s Compliance Officer or committee determines which employees need training and when. The training may be delivered in a variety of ways. A guideline that can be used for the amount of training needed is through CIAs (Corporate Integrity Agreements) which typically require 1-3 hours of education annually. The primary goals of training are to ensure that all employees:
   - know how to perform their jobs in compliance with regulations such as HIPAA and OSHA
   - understand that compliance is a condition of continued employment.

4. Open Lines of Communication: Have an effective manner of communicating from the owners to the entire practice staff. The written policies and procedures must require all employees to report any compliance concerns and violations that exist or are suspect. Therefore, it is important for employees to feel that they may report suspected fraud, waste or abuse without fear of retribution. Providing this means of communication should enable the practice to catch errors or potential fraud in the early stages preventing larger problems and diminishing whistleblower liability in the future.

   To have open lines of communication, it is most effective to allow employees to maintain anonymity whenever possible. There is a much greater likelihood that an employee will report if they can do so anonymously and after work hours. Hotlines used often by hospitals and larger organizations are a good solution, but not always practical for physician practices.

5. Well-Publicized Disciplinary Standards: Establish and publicize disciplinary policies and procedures for all employees stipulating expectations for compliance issue reporting and resolution, and for participation in required training. Ideally, these will be included in the practice’s policies and procedures and the code of conduct.

   While establishing these guidelines and regularly educating the staff about them is important, a practice must also ensure that all employees perceive these disciplinary standards as being carried out in a fair, equitable and consistent manner.

6. Effective System for Monitoring, Auditing and Identifying Compliance Risks: Create and implement an effective system for routine, internal monitoring and internal and external audits to ensure program compliance. The most critical areas for any practice involve billing, coding, documentation and relationships with third parties. Other areas that require regular monitoring by the practice involve OSHA, HIPAA, and...
screening employees against the OIG LEIE (List of Excluded Individuals and Entities) in order to comply with the Exclusion Statute.

It is important that a practice conducts self-auditing and monitoring on a continual basis. Staff should be trained and responsible for the process of evaluation. At least once annually, the results of the audit should be documented and reported to the governing body or partners of the practice.

7. Procedures and System for Prompt Response to Compliance Issues: Conduct timely, well-documented and reasonable inquiries into any potential non-compliance issue within 2 weeks after it was identified. Actions must focus on correcting the root cause of the non-compliance issue.

If a problem is detected, it means the compliance program is working and there is no reason for alarm. However, follow up is important as the issue must be investigated and corrected. In some cases, it may be advisable to proceed under attorney-client privilege. A valuable resource when addressing such issues is the updated OIG’s Provider Self-Disclosure Protocol issued on April 17, 2013.

While all physician practices are required to adopt compliance programs, the expectation is that the program that each develops is tailored to the specific needs and resources of the practice.

Practices taking the offensive lead

The benefits of a compliance program extend beyond fine avoidance. Implementing a comprehensive compliance program minimizes mistakes and possibly enhances revenue through improved coding and documentation. The business side of the practice will become more streamlined providing for increased staff communication and improved patient care.

Maxed out Time and Resources Too Costly of an Excuse

Physician practices must demonstrate that their practice is committed and invested in effective compliance programs guarding against Medicare fraud. Enforcement initiatives are underway and increasing, demonstrating that physician practices will be subject to further scrutiny and fines (see graph). The potential consequence of not having a compliance program as mandated by the ACA is exclusion from participating in Medicare and Medicaid.

Another example of a potential consequence is related to the Civil False Claims Act. This act states it is illegal to submit claims that a provider knows or should know are false or fraudulent. No specific intent is required to violate the FCA. In fact, “knowingly” may be defined by acting in deliberate recklessness or disregard for the truth. Some examples of a false claim include a service that is:

1) not actually rendered to a patient
2) provided but covered under another claim
3) coded incorrectly
4) unsupported by documentation

Potential fines are $11,000 per claim plus treble damages (three times the government programs’ loss).

Compliance with ACA rules and regulations may be cumbersome, yet here are some of the options for physician practices to address them. Mitigating the practice’s risks by adopting a comprehensive compliance program is not only the best defense but the greatest offense.

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