OIG Releases Final Compliance Program Guidance for Physicians

On September 25, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued its final compliance program guidance (Guidance) for solo-practitioner and small-group practice physicians. This Guidance joins the list of compliance programs released by the OIG in the past few years covering various types of health-care providers (e.g., clinical laboratories, hospitals, home health agencies).

Overview
Like the other compliance programs, this Guidance is not mandatory but is designed to help the small physician practice comply with complicated billing rules and avoid hefty fines and other penalties under the federal False Claims Act and other laws. The Guidance focuses on seven areas, drawn from the federal sentencing guidelines:

• Conducting internal monitoring and auditing through the performance of periodic audits.
• Implementing compliance and practice standards through the development of written standards and procedures.
• Designating a compliance officer or contact to monitor compliance efforts and enforce practice standards.
• Conducting appropriate training and education on practice standards and procedures.
• Responding appropriately to detected violations through the investigation of allegations and the disclosure of incidents to appropriate government entities.
• Developing open lines of communication, such as discussions at staff meetings regarding erroneous or fraudulent conduct issues and community bulletin boards, to keep practice employees updated regarding compliance activities.
• Enforcing disciplinary standards through well-publicized guidelines.

The Guidance, however, differs significantly from other model compliance programs in that compliance measures may be implemented incrementally. In addition, the OIG recognizes that some compliance measures may never be implemented by some practices at all, depending on the circumstances and resources of the individual physicians. This departure from the norm seeks to reduce the monetary and time burden a compliance program may impose on small physician practices, recognizing the unique characteristics of such practices compared to other types of providers.

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In this vein, the Guidance emphasizes flexibility in developing a culture of compliance within a practice, rather than the institution of formal procedures. This emphasis is more evident in the final Guidance than in the proposed guidance released earlier by the OIG. For example, in the final Guidance, no formal code of conduct is recommended, the word “effective” is not used to describe small-group practice compliance programs, informative appendices are included, and the overall language is simplified to enhance user-friendliness.

According to the Guidance, innocent billing errors will not be prosecuted, but the OIG expects physicians and their employees to act in good faith to ensure that false or erroneous claims are not submitted to the government. The OIG indicates that larger group practices should develop their compliance activities using both this Guidance and the Third-Party Medical Billing Compliance Program Guidance released earlier. Finally, the Guidance identifies certain high-risk areas where physicians should be especially vigilant.

What Should Physicians Do?
Solo practitioners and small group practices should take action to ensure that a basic compliance infrastructure exists within their practices. Because the OIG permits great flexibility in implementation of compliance, no one specific action is required. Nonetheless, physicians should, at a minimum, (1) audit their practices to identify historical or existing billing issues, with particular attention to the high-risk areas identified by the OIG, and (2) develop written compliance policies, either using existing practice policies, or borrowing compliance policies from other entities, such as their medical billing companies or independent practice associations (IPAs) with which they affiliate. Employees should be trained to understand that compliance is part of the culture of the practice, and that no retribution will result from reports of compliance issues. Finally, when compliance problems are discovered, physicians should take prompt action to address them.

Larger practices are expected to develop somewhat more sophisticated compliance programs, utilizing both this Guidance and the Third-Party Medical Billing Compliance Program Guidance released earlier by the OIG.

Why Implement a Compliance Program?
The OIG believes that implementation of a compliance program helps to detect billing errors before an improper claim is submitted, to reduce the chance of an audit and to avoid fraud and abuse law violations. The existence of a compliance program also likely puts the physician in a more favorable position in dealings with the government should a billing problem arise. The OIG likens implementation of a compliance program to preventive medicine—it makes the practice healthier and avoids future problems.

Incremental Approach
Physician practices are encouraged to use a step-by-step approach to implement the seven standard components of a full-scale compliance program. “Piggy-backing” on compliance programs of other providers (such as hospitals) or entities (such as physician practice management companies (PPMCs)) to augment the physician practice compliance program is permitted. Likewise, sharing training and education programs or using another entity's policies and procedures as a template is also encouraged. Finally, physician practices may simply build on their existing infrastructure to create a more focused compliance program. While providing these alternatives, the OIG recognizes that each practice group will ultimately be guided by its own circumstances and resources in developing a compliance program.

Although permitted to be implemented incrementally, the Guidance still incorporates the seven standard components of a compliance program based on the federal sentencing guidelines and present in model compliance programs for other provider types:
Conducting internal monitoring and auditing through the performance of periodic audits.

The OIG believes that an audit is the best way to identify risk areas for a physician practice and to determine if a compliance program is actually working. It recommends two types of audits—standards and procedures audits (are the practice’s standards and procedures current and complete?) and claim submission audits (are bills and medical records in compliance with coding, billing and documentation requirements?). Audits should be conducted at least once per year, preferably following an initial baseline audit for use as a benchmark for future compliance effectiveness. More focused review may be warranted if problems are identified. The OIG suggests that five or more medical records per federal payor, or five to 10 medical records per physician, be reviewed. Physician practices should also create a system to ensure appropriate and timely response to problems once identified and should retain information related to identification and resolution of compliance issues.

Implementing compliance and practice standards through the development of written standards and procedures.

Written standards and procedures are crucial to a compliance program, and often these exist within practice group policy statements or practice standards. Physician practices should also update clinical forms periodically to ensure they facilitate complete documentation of care. Practices that do not have adequate standards and procedures in place should consider adopting and tailoring those of other entities (e.g., IPAs, PPMCs) or management service organizations (MSOs). Practices may also create, and update, a resource manual from publicly available information (e.g., from HCFA, the OIG and other government entities). Finally, standards and procedures, and any updates to them, should be effectively communicated to new and existing employees in a timely manner.

Designating a compliance officer or contact to monitor compliance efforts and enforce practice standards.

Given the small size of many physician practices, the OIG suggests that compliance responsibilities be divided up among “compliance contacts” rather than handled by a single compliance officer. Alternatively, the practice can outsource the compliance officer role to a third party, such as a consultant, PPMC, IPA or MSO. Ideally, this third party should have enough interaction with the practice to understand its inner workings and should have access to a liaison within the practice to provide a tie to daily operations. If a compliance officer is designated, such officer’s duties should include: (1) overseeing and monitoring the implementation of the compliance program, (2) establishing methods to improve the practice’s efficiency and quality of services and to reduce the practice’s vulnerability to fraud and abuse, (3) periodically revising the compliance program to reflect changes in the needs of the practice, the law, or standards and procedures of government and private payor health plans, (4) developing, coordinating and participating in a training program for compliance, (5) ensuring that employees, medical staff and contractors are not excluded or debarred from federal programs, and (6) investigating allegations of unethical or improper business practices and monitoring corrective action.

Conducting appropriate training and education on practice standards and procedures.

Training should be provided on both coding and billing and compliance issues. Compliance programs should determine who needs training, how often and how much, and what kind of training best fits the practice (e.g., seminars, inservices, self-study). Compliance training should explain the compliance program, the consequences of violating it, and the role of the employee in its operation. Compliance should be emphasized as a condition of employment. Coding and billing training should be provided to anyone involved in billing, coding or other aspects of federal health care programs and should cover coding, documentation and billing requirements, the claim develop-
ment and submission process, the implications of signing a form for a physician without authorization and the legal sanctions for submitting false claims. Training may be provided in-house or through outside sources like colleges, Medicare Carriers or third party billing companies. ICD-9, HCPCS and CPT manuals should be available at the practice site. Training should occur at least annually, with new billing and coding employees trained immediately and subject to supervision until their training is completed.

Responding appropriately to detected violations through the investigation of allegations and the disclosure of incidents to appropriate government entities.

Practices should investigate reports of suspected noncompliance immediately upon receipt of such reports and take appropriate action to correct any problem. Ignoring reports undermines the compliance program. Appropriate action may include corrective action plans, return of overpayments, reports to government entities or referral to law enforcement. The OIG suggests that practices develop their own warning signs for compliance problems, such as significant changes in the number or type of claim rejections, challenges to the medical necessity of claims, changes in the pattern of code utilization or high volumes of payment adjustments. Finally, compliance programs should be reviewed periodically and modified accordingly to ensure that they do not fail to detect, fail to prevent, or compound violations.

Developing open lines of communication, such as discussions at staff meetings regarding erroneous or fraudulent conduct issues and community bulletin boards, to keep practice employees updated regarding compliance activities.

Compliance programs have clear and open lines of communication to permit frank reporting and discussion of compliance issues. Due to the small size of physician practices, less formal lines of communication are preferable to those used by other provider types, such as an “open-door” policy, conspicuous posting of notices related to compliance and compliance bulletin boards. While anonymity will be much more difficult to maintain in the small practice setting, employees should understand that they can report compliance issues without fear of retribution.

Enforcing disciplinary standards through well-publicized guidelines.

A compliance program includes enforcement of compliance standards and procedures and discipline of noncompliant employees, including termination if necessary. Mitigating and aggravating circumstances should be considered in enforcement and disciplinary actions. Employees should understand that failure to report compliance issues may also result in disciplinary action. Finally, findings of noncompliant actions should be well documented.

The OIG’s approach recognizes that small practices may be overwhelmed by the resources required to implement a full-scale compliance program. By providing for significant flexibility in design, the OIG hopes that more practice groups will develop and use compliance programs, reducing instances of billing and other fraud and abuse.

Innocent Mistakes Will Not Be Prosecuted

The OIG makes clear that it believes that most physicians are “honest.” Nonetheless, it is charged with ensuring the integrity of government programs, which includes ensuring that all claims submitted to the government are true, accurate and otherwise proper. The OIG emphatically notes that it does not prosecute innocent errors or negligence. Physicians must act with actual knowledge, reckless disregard, or deliberate ignorance of the falsity of a claim for civil penalties to apply, and criminal intent must exist for criminal penalties to apply. The OIG, however, does expect physicians and their employees to act reasonably and in good faith to ensure that all claims submitted to government programs are true and accurate, as even innocent errors drain government coffers.
Large v. Small Groups

Because of their small size and limited resources, the OIG acknowledges that solo practitioner and small physician practices may never implement all seven compliance standards, or may implement them in stages as resources permit. The OIG recommends that such practices focus on historical billing and compliance issues to mold their compliance program to their individual risk.

Larger physician practice groups are advised to take a more systematic approach, given their greater resources, and to utilize both the Guidance and previously released guidance for other provider types (such as Third-Party Medical Billing Compliance Program) in developing appropriate compliance programs for their practices.

Assessing Your Compliance Program

Physician practice compliance programs are assessed by their day-to-day activities—ideally, compliance is fully integrated into the practice through internal controls and procedures that promote compliance. The OIG believes that many compliance measures are already in place within the existing infrastructure of small physician practices, and that implementing additional compliance protocols makes good business sense. Good compliance programs work—compliance is not simply window-dressing or words on a page, actions are taken and compliance is part of the workplace culture.

High Risk Areas

To assist physician practices in identifying potential areas of risk, the OIG has identified four high risk areas that physicians and their employees should be familiar with: (1) coding and billing, (2) reasonable and necessary services, (3) documentation, and (4) improper inducements, kickbacks and self-referrals. Standards and procedures should be developed to decrease the practice’s vulnerability with respect to these compliance areas.

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4 In addition, in an Appendix, the OIG identifies additional risk areas as high-priority for its enforcement actions:
   1. Physician billing practices (third party billing services, nonparticipating physicians, professional courtesy);
   2. Physician relationships with hospitals (EMTALA, teaching physicians, gainsharing, physician incentives);
   3. Reasonable and necessary services (local medical review policies, advance beneficiary notices, DME and home health physician certification, billing for noncovered services);
   4. Rental of office space to/from referral sources;
   5. Unlawful advertising

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