An Overview of the Physician Compliance Plan Guidelines

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INTRODUCTION

On September 25, 2000, the Department of Health and Human Services' Office of Inspector General (OIG) issued final guidance (Physician Compliance Plan Guidelines or Guidelines)[1] to assist physicians practicing individually or in small group practices in designing voluntary compliance plans to promote adherence to the requirements of federal health care programs. The OIG has previously issued compliance program guidance for hospitals, clinical laboratories, home health agencies, durable medical equipment suppliers, billing companies, hospices, Medicare + Choice organizations and nursing facilities.[2]

In contrast to the guidelines issued for other industry sectors, the Physician Compliance Plan Guidelines are notable for the tone and posture in which they are presented. OIG appears to recognize a perception in the medical community that OIG may suspect that most physicians are dishonest. Pleading to the contrary, OIG states its belief that "the great majority of physicians are honest and share our goal of protecting the integrity of . . . Federal health care programs"[3] and stresses that OIG is not looking to jail those physicians who inadvertently stumble in the increasingly complex world of health care billing and coding protocols. Further, OIG believes "the great majority of physicians are working ethically to render high quality medical care and to submit proper claims."[4] OIG recognizes that "even ethical physicians ... make billing mistakes."[5]

OIG then clarifies that "physicians are not subject to criminal, civil or administrative penalties for innocent errors, or even negligence." Only "reckless or intentional conduct" (which includes reckless disregard or deliberate ignorance of the falsity of a claim) implicates the Civil False Claims Act or the Civil Monetary Penalties Law,[6] and criminal penalties require proof beyond a reasonable doubt of "criminal intent to defraud," an even higher standard.[7] OIG explains that erroneous claims resulting from honest mistakes or negligence should be remedied by refunding the overpayment and, as appropriate, correcting the problem or process that led to the mistake.

Although OIG claims to understand and be fairly tolerant of innocent errors, it finally reminds us that all providers "have a duty to reasonably ensure that the claims submitted to Medicare and the other Federal health care programs are true and accurate."[8] The development of a compliance plan as contemplated under the Physician Compliance Plan Guidelines is expected to assist physicians in satisfying these obligations. While OIG believes that physician compliance plans will help prevent improper conduct by physicians participating in federal health care programs, it also observes that issues related to private payor claims should also be addressed.[9] This is consistent with common sense and with the expansion of federal criminal jurisdiction to private sector health plans under the Health Insurance Portability and Accountability Act of 1996 (HIPPA).[10]

SEVEN COMPONENTS OF A COMPLIANCE PLAN

The Physician Compliance Plan Guidelines focus on the same seven components which are central to the compliance program guidance issued for the other eight industry sectors identified above: (i) internal monitoring and auditing, (ii) implementation of standards, (iii) designation of a compliance officer, (iv) training and education, (v) corrective action, (vi) open lines of communication and (vii) enforcing disciplinary standards.

The Guidelines suggest that physicians start the compliance plan implementation process by first adopting those components which "appear most likely to provide an identifiable benefit." OIG recognizes that many of the seven components may already be in place at the physician's practice, even if they are not designated as such.[11] Thus, the effort required by a small physician practice to begin the establishment of an appropriate compliance plan may involve little more than identifying and coordinating existing policies and continuing to participate in compliance initiatives called for by hospitals and other providers with which the

physician works. The Guidelines contemplate a "step by step" approach to developing a compliance plan and suggest the following order of development.

Step One: Internal Auditing and Monitoring.[12]

OIG recommends that a practice review its existing standards and procedures to determine if they are current and complete and modify those which are ineffective or outdated. OIG also believes it advisable that self-audits be conducted of a practice's actual coding, billing and documentation performance by individuals with appropriate billing and medical expertise. Importantly, OIG specifically states that each practice should have the flexibility to decide whether self-audits of claims should be performed retrospectively or concurrently with the claims submission.

Although affording each practice the flexibility to develop its own system, OIG does make several specific self-audit recommendations. First, a baseline audit should be performed to establish a benchmark against which the practice can "chart" its future performance, and OIG recommends that the benchmark audit cover the three-month period following the adoption of the plan.

After the baseline audit is performed, OIG recommends that random periodic self-audits be performed at least annually by reviewing at least five medical records per federal payor per physician. The sample could be selected from the pool of all payors, on a payor-specific basis or based on identified risk areas. Self-audits can be used to determine whether:

- bills are accurately coded;
- documentation is complete and correct;
- services or items are reasonable and necessary; and
- any incentives exist for unnecessary services.

If a problem is discovered, it should be addressed as soon as possible. Appropriate responses may include education of staff and prompt overpayment refund to the payor with an explanation. Some circumstances might call for consultation with a billing expert to determine the nature and extent of the problem or to recommend a course of action. In all events, OIG suggests that the practice's discovery of and response to the problem be documented and preserved.

Step 2: Establish Practice Standards and Procedures.[13]

OIG recommends that a practice develop a formal compliance plan which includes written standards and procedures that are suitable for dealing with risk areas identified in the practices internal self-audit. For some practices, many of these standards already exist and may simply need to be compiled. If resources are lacking, a practice could narrow its focus to a few important risk areas and borrow and tailor compliance plan standards from other providers and from publicly available sources. Regardless of how the standards are compiled, regular education of existing and new employees on the standards is critical. Potential risk areas which OIG believes should be covered by a physician-compliance plan include: (a) coding and billing, (b) reasonable and necessary services, (c) documentation, and (d) improper inducements, kickbacks, and referrals. The Guidelines suggest certain strategies which may assist the physician in developing a compliance plan which addresses each of these risk areas. For example, with respect to coding and billing, the most frequent areas of investigations and audits by OIG include:

- billing for items or services not rendered;
- submitting claims for equipment, supplies or services that are not reasonable and necessary;
- double billing;
- misuse of provider identification numbers;
- unbundling (billing for components of services that are covered by all-inclusive codes);
- improper use of coding modifiers;
- clustering (exclusive use of middle level service codes); and
- upcoding.

OIG also advises that each practice should develop record retention protocols for compliance records, business records and medical records. The protocols should include the time frame for retention of each type of record and should ensure that medical records are not improperly lost, destroyed, or disclosed. The protocols should also ensure that compliance documents relating to educational activities, internal investigations, self-audits, remedial action, and communications with payors and carriers are retained.

Step Three: Designation of a Compliance Officer/ Contact.[14]

The third step in the compliance plan implementation process recommended by OIG is to identify one or more persons in the practice to be responsible for compliance functions.[15] While OIG recognizes that the level of oversight may vary based on the circumstances of the practice, it appears to view as most critical the designation of one or more persons who will be

responsible for preparing written standards and procedures, overseeing audit functions, investigating allegations of wrongdoing, developing and monitoring adherence to any necessary corrective action plan, regularly updating the plan, developing and coordinating appropriate training programs, and performing appropriate background checks on employees and contractors.

Step 4: Conducting Appropriate Training and Education.[16]

OIG views appropriate training and education of all practice staff as critical to the implementation of a successful compliance plan. To establish training objectives, the practice should determine who in the practice needs to be trained, what type of training is best for the practice (e.g., seminars, self-study, newsletters, etc.), and what frequency of training is most suitable for the practice.

Compliance training should occur on a recurring basis and should focus on the operation and importance of the compliance plan, the consequences of violating the standards, and the role of each employee in the plan. Each employee should be made to understand how to perform his or her job in compliance with the plan and that violating the standards may result in disciplinary action. Individuals who are directly involved with billing and coding should receive extensive education specific to their responsibilities, and OIG recommends at least annual training updates for such employees. The Guidelines summarize a variety of training methods, and recognize that those formats may vary depending on the needs and resources of the practice.

Step Five: Responding to Detected Offenses and Developing Corrective Action Initiatives.[17]

OIG counsels that, upon detecting a possible violation, the practice's compliance officer should promptly investigate the allegations and take decisive steps to correct any problems. Although the Guidelines do not discuss the protocols which should be followed to establish and maintain the attorney/client or work-product privileges to protect the practice during an investigation, the Guidelines do suggest that the physician practice consider seeking advice from its legal counsel to determine the extent of the practice's liability and to plan the appropriate course of action.

The Guidelines recommend that the practice:

- develop and monitor "warning indicators" which will show significant changes in relevant claims processing information which may signal a violation;
- avoid actions which may compound a violation once it is discovered; and
- promptly identify and repay overpayments.

OIG cautions that potential criminal violations may warrant prompt disclosure to an appropriate governmental authority, and that use of the Provider Self-Disclosure Protocol established by the OIG should be considered in the case of suspected fraud.[18]

Step 6: Developing Open Lines of Communication.[19]

OIG believes that "an open line of communication is an integral part of implementing a compliance program." While hotlines and e-mail may work for larger provider organizations, OIG recognizes that small physician practices likely require less formalized processes for communicating compliance matters. OIG recommends that the practice implement a clear "open door" policy between the physicians and practice employees and that conspicuous notices be posted in the practice to provide up-to-date compliance information. OIG also specifically recommends that physician practices post the HHS-OIG Hotline telephone number.

Among the communication protocols recommended by OIG are for the practice to:

- require employees to report possibly erroneous or fraudulent conduct;
- create user-friendly processes such as anonymous drop boxes for effectively reporting improper conduct;
- make the failure to report improper conduct a violation of the compliance plan;
- develop a simple procedure to process reports of improper conduct;
- if a billing company is used, coordinate activities with the billing company;
- attempt to protect the anonymity of persons who report a possible violation and of the persons to whom the report relates; and
- adopt standards to ensure no retribution for good faith reporting of misconduct.

Step 7: Enforcing Disciplinary Standards Through Well Publicized Guidelines.[20]

As a final step, OIG recommends that a physician practice incorporate measures which will ensure that employees understand the consequences of

noncompliant behavior. Enforcement and disciplinary provisions add credibility and integrity to the plan. OIG recommends that violations result in consistent and appropriate sanctions; however, the disciplinary procedures should be sufficiently flexible to account for mitigating or aggravating circumstances. Failure to detect or report violations should also be subject to discipline. The range of suggested disciplinary actions include oral warnings, written reprimands, probation, demotion, suspension, termination, restitution of damages and referral for criminal prosecution. The disciplinary guidelines should be well publicized in the practice's training and procedure manuals.

APPENDICES

The Physician Compliance Plan Guidelines contain six separate appendices to assist physicians in understanding the laws and standards applicable to their practices and to help them develop and implement appropriate compliance plans.

Appendix A is entitled "Additional Risk Areas," and describes a variety of risk areas which a physician practice may wish to address during the development of its compliance plan. Among the areas identified are:

- *Reasonable and Necessary Services.* Specific risk areas include application of appropriate local medical review policies, provision of appropriate advance beneficiary notices, certification in providing DME and home health services, and billing for non-covered services.
- *Physician Relationships with Hospitals.* Risk areas include the physician's role in EMTALA, billings of teaching physicians, gain-sharing arrangements, and physician recruitment and retention incentive arrangements.
- *Physician Billing Practices.* Risk areas include use of third-party billing services, billing by non-participating physicians, and professional courtesy discounts.
- *Additional.* Other risk areas include rental of space in physician offices by referral sources and unlawful advertising.

Appendix B summarizes the most frequently utilized criminal statutes relevant to health care fraud, and provides examples of possible violations.

Appendix C similarly summarizes and provides examples of the most frequently utilized civil and administrative statutes related to health care fraud and abuse matters.

Appendix D provides information for communicating with OIG, including the OIG Hotline information and the Provider Self-Disclosure Protocol.

Appendix E provides information which will facilitate a physician's communications with Medicare and Medicaid carriers.

Appendix F provides a summary of certain Internet resources relevant to compliance plan activities.

CONCLUSION

Carefully tailored compliance plans can afford physicians a degree of protection in an increasingly complex and adversarial reimbursement environment, and the adoption of a straight-forward and easy to follow compliance plan may well become the standard in preventive medicine for physician practices. Physicians and their counsel may not fully agree with all of the analyses and recommendations of OIG relevant to compliance plan matters. Nevertheless, prudent medical practice management suggests that physicians should understand the OIG's Guidelines and determine whether some or all of the recommended measures can be implemented without undue hardship or cost.[21]

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[1] 65 FR 59434 (October 5, 2000). On September 8, 1999, the OIG issued a solicitation notice seeking information and recommendations for developing formal guidance for physician compliance plans (64 FR 48846) to which 63 comments were received, and on June 12, 2000, the OIG published for comment the draft Physician Compliance Plan Guidelines (65 FR 36818).

[2] Those programs can be reviewed in the Electronic Reading Room for the OIG's web site at http://www.hhs.gov/oig.

[3] 65 FR 59435.

[4] 65 FR 59436.

[5] Id.

[6] 31 USC §3729 and 42 USC §1320a-7a.

[7] 65 FR 59436.

[8] Id.

[9] Id. at 59435. See also Andrew B. Wachler, Abby Pendleton and Robert S. Iwrey, "OIG Softens Its Overall Approach in Releasing the Final Compliance Guidance for Individual and Small Group Physician Practices," 13 The Health Lawyer 1,

at 31 (October, 2000).

[10] Id. See 18 USC 1347.

[11] Id. at 59436.

[12] Id. 59437-38.

[13] Id. at 59438-441.

[14] Id. at 59441-42

[15] OIG advises that a practice may outsource this compliance officer function; however, such an approval may raise a variety of legal and practical problems

[16] Id. at 59442-43.

[17] Id. at 59443

[18] See Appendix D of the Guidelines for further information on the Provider Self-Disclosure Protocol.

[19] 65 FR 59443-44.

[20] Id. at 59444.

[21] For information regarding a physician compliance plan checklist developed by Mark F. Schaff and William H. Maruca, see the Publications section of the American Health Lawyers Association web site at www.healthlawyers.org.

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