Health Law

OIG to Issue Compliance Guidance for Physicians

Jeff Peters, JD* and William A. Sarraille, JD♦

Interventional physicians, like many other small physician practices, are bracing for a soon-to-be released document from the Office of the Inspector General (OIG) for the Department of Health and Human Services that will provide guidance to physician practices interested in developing compliance programs for their practices.

The purpose of these compliance programs is to demonstrate to government authorities that a provider has made an institutional commitment to adhere to all relevant laws as a matter of everyday practice, and may establish a strong basis for minimizing any penalties if a violation actually occurs. Even though these guidances issued by OIG are non-binding, they are particularly useful as they reflect the

OIG's position on a wide range of compliance issues directly impacting physician practices.

Physician compliance documents should include the elements that OIG believes are crucial for an effective plan including: written compliance policies and procedures, compliance officer/compliance committee, effective training and education, effective lines of communication, disciplinary protocols to enforce the plan, monitoring and auditing of the plan/program, and responsiveness to detected offenses and the development of corrective action plans.

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Interventional physician practices and other small physician practices are bracing for a soon-to-be released document from the Office of the Inspector General (OIG) for the Department of Health and Human Services that will provide guidance to physician practices interested in developing compliance programs for their practices. Although OIG insists that its guidance will be practical and appropriately take into account the limited resources of small physician practices, some critics are skeptical of OIG's ability to do that, given a perceived tendency on the part of OIG to address only or primarily the largest of providers in other compliance guidance it has issued.

As part of an ongoing program covering nearly all segments of the health care industry, the OIG plans to publish a draft Compliance Program Guidance document for individual physicians and small group practices this spring.

Some sources suggest that a publication date in late April or early May is the most likely. Upon publication of the draft guidance, the public will have a period of time, presumably thirty days, in which to submit comments. Generally speaking, however, the OIG has not made much in the way of substantive changes to its compliance guidance once issued in proposed form, a fact that has frustrated many in the health care community.

As indicated above, the OIG has previously issued guidance covering hospitals, skilled nursing facilities, Durable Medical Equipment and Prosthetic and Orthotic suppliers, and third-party billing companies, among others. The guidance is intended to assist health care providers seeking to develop internal compliance programs to prevent, detect, and deter violations of federal and state law. Although useful, the OIG guidance for small physician practices will not be a substitute for each physician office developing and implementing a compliance program that is tailored to its individual circumstances. Nor will the guidance be a substitute for subspecialty specific model plans, like the one developed by the Association of Pain Management Anesthesiologists (AOPMA), since the OIG guidance will likely be for all physicians and not for any particular specialty. In its written comments on the issue of compliance guidance, AOPMA raised the possibility of

From Arent Fox Kintner Plotkin & Kahn, PLLC, Washington, DC. *Mr. Peters is an attorney with Arent Fox. ♦Mr. Sarraille is a partner in the Washington, DC and New York, NY law firm of Arent Fox. He serves as AOPMA's General Counsel. Address correspondence: William A. Sarraille, JD, Arent Fox, 1050 Connecticut Avenue, Washington, DC 20036

specialty-specific guidance with the OIG, but it seems unlikely that OIG will depart from its more broad-brush approach.

Purpose

Compliance programs are designed to demonstrate to government authorities that a provider has made an institutional commitment to adhere to all relevant laws as a matter of everyday practice, and may establish a strong basis for minimizing any penalties if a violation actually occurs. The absence of a compliance plan can prove to be costly for providers, since many federal investigations now routinely rely on the False Claims Act, which provides for treble damages and fines of up to \$10,000 per false claim.

In addition to providing recommendations as to how to structure a compliance program, the OIG guidelines are valuable for a different reason as well. Past OIG guidelines have proven useful in alerting providers of the enforcement priorities of the OIG and the Department of Justice. Although non-binding, the OIG guidances are particularly useful because they will reflect the OIG's position on a wide range of compliance issues directly impacting physician practices. Issues of medical necessity, the ordering of ancillary services, supervision of ancillary personnel, compliance with the Federal Anti-Kickback and Self-Referral Laws, and other issues are likely to be mentioned.

Recommended Components

OIG personnel have indicated that the major components of the physician practice guidelines will be consistent with the major elements contained in previous guidelines. Thus, the physician compliance document will include the elements the OIG believes are crucial for an effective plan. We expect therefore that the OIG will suggest that compliance programs must have or provide for (1) written compliance policies and procedures; (2) a compliance officer/compliance committee; (3) effective training and education; (4) effective lines of communication; (5) disciplinary protocols to enforce the plan; (6) monitoring and auditing of the plan/program; and (7) responsiveness to detected offenses and the development of corrective action plans.

AOPMA Input

The AOPMA submitted written recommendations to the OIG, emphasizing the need for flexibility as well as a recognition of the large variety of size and specialties among

physician practices. Among the many points raised, the AOPMA urged the OIG to keep in mind that smaller providers have vastly different compliance program needs and capabilities than other, larger providers. In addition, the AOPMA recommended that the OIG adopt a user-friendly and practical document, so that physicians or practice administrators would actually be able to use the document as a convenient and comprehensible reference.

The AOPMA further urged the OIG to adopt a flexible approach in proffering guidance to physicians and small practices, because smaller practices and individual physicians must have compliance programs designed to meet their particular needs. Among the suggestions offered by the AOPMA:

Hotline

The OIG typically recommends the use of an anonymous hotline. For small practices, in which the entire staff could consist of as few as three or four people, however, a hotline system simply would be unduly burdensome as well as highly impractical. The AOPMA suggested the OIG approve of the use of a suggestion/concern box where notes may be placed anonymously.

Training

The AOPMA expressed concern to the OIG regarding training issues. AOPMA stressed that training expectations should be commensurate with the size of the practice. The AOPMA recommended to the OIG that it should not state a specific training standard, but rather should articulate a standard that would permit practices to establish training levels appropriate to their resources and needs. In particular, the AOPMA stated its belief that for most small practices, written training materials or perhaps audio-visual training materials, should be sufficient.

Reliance on OIG or Government Advice/Guidance

When providers or practitioners may be unsure about the appropriate course of action with regard to a Medicare or Medicaid issue, the providers or their representatives will exercise sound judgment and caution, and ask the appropriate OIG, Medicare/Medicaid department, agency, intermediary or carrier for guidance. The AOPMA pointed out to the OIG that this is an entirely prudent and laudable practice which the OIG should encourage. Therefore, the AOPMA proposed that the OIG permit reasonable reliance on such advice, if appropriately documented in writ-

ten communications from or to the government agency or agent.

Regulation in the Guise of Guidance

In connection with a number of other OIG guidance publications, critics have asserted that OIG has effectively issued new regulations for health care providers in the guise of providing guidance on existing regulations. These critics contend that the OIG has essentially usurped the Health Care Financing Administration's role and violated the notice and public comment restrictions on regulatory rule-making by proceeding in this fashion. AOPMA has raised its concerns about this issue with the OIG.

Early Indications

The OIG claims to have been receptive to many of the recommendations and concerns of the AOPMA and other physician organizations. In particular, the OIG does seem

to intend to make the guidance document easy to use and not overly legalistic. In fact, the principal drafting attorney has mentioned that she has tried to use layman's language, and not overly burden the document with legal citations and references. Thus, there may be some reason to be cautiously optimistic that the guidance may actually be flexible, practical, and useful.

By the same token, however, certain interests have been lobbying OIG to include burdensome requirements in the guidance. Stung by the OIG's requirements in their guidance for third party billing companies that effectively requires those companies to monitor their clients' billing and coding, some of those companies have urged OIG to adopt standards that would require burdensome internal billing and coding monitoring efforts, in an effort to "off-load" the billing and coding risk, as much as possible, back on physician practices. Only time will tell what the OIG will require.