

Small Group Physicians and Other Health Care Providers: Now is the Time to Structure Your Mandatory Compliance Programs

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Pre-PPACA: Background History on Health Care Compliance Programs

The Patient Protection and Affordable Care Act of 2010 (PPACA)¹ imposes mandatory compliance programs for all sectors of the health care industry.² Before the PPACA, health care compliance programs were generally implemented on a voluntary basis, if at all. The limited numbers of health care providers that had mandatory compliance programs in place were typically those that operated under corporate integrity agreements³ with the Office of Inspector General (OIG) within the Department of Health and Human Services (HHS).

The OIG's mission is to protect the integrity of over 300 programs administered by HHS, including federally funded health care programs⁴ such as Medicare and Medicaid. Approximately 80 percent of OIG's resources are dedicated to promoting the efficiency and effectiveness of federal health care programs and protecting these programs and their beneficiaries from fraud, waste, and abuse.⁵ The OIG takes the position that health care providers and suppliers have a duty to ensure the claims they submit to federal health care programs are true and accurate.⁶

In 1997, the OIG initiated voluntary compliance programs to help health care providers and suppliers avoid submitting erroneous claims and engaging in fraudulent conduct

¹ Patient Protection and Affordable Care Act ("PPACA"), Pub. L. 111-148, 124 Stat. 119 (Mar. 23, 2010).

² Corporate compliance in the context of health care means satisfying the statutory and regulatory requirements for providing particular health care activities. See U.S. Dep't of Health and Human Services (HHS), Office of the Inspector General (OIG), *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors*, available at <http://www.oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf>.

³ A Corporate Integrity Agreement (CIA) is an enforcement tool used by the OIG to promote compliance with health care regulations and improve the quality of the delivery of health care. Similarly, the term, Integrity Agreement (IA), is used for smaller health care providers such as physicians. The CIA or IA is usually entered into contemporaneously with a civil settlement agreement between the government and a health care provider who has been the subject of investigations arising under civil false claims statutes, such as the False Claims Act, or who has been found guilty in acts of defrauding federal health care programs, such as Medicare or Medicaid. The health care provider or entity consents to the obligations outlined in the CIA or IA as part of the civil settlement and in exchange for the OIG's agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid and other federal health care programs. See OIG, *Corporate Integrity Agreements*, <http://oig.hhs.gov/fraud/cias.asp>; See also American Health Lawyers Ass'n, *Corporate Integrity Agreements (CIAs)*, June 26, 2009, available through <http://www.healthlawyers.org/resources/>.

⁴ Gerald T. Roy, Deputy Inspector General, HHS, OIG, *Testimony on Perspective on Fraud, Waste, and Abuse with Medicare and Medicaid Programs*, Apr. 5, 2011, at p.2, available through http://www.oig.hhs.gov/testimony/docs/2011/roy_testimony_04052011.pdf.

⁵ *Id.*

⁶ 65 Fed. Reg. 59435 (Oct. 5, 2000) (OIG Compliance Program for Individual and Small Group Physician Practices).

involving federal health care programs.⁷ To further that initiative, between 1998 and 2008, the OIG published a series of guidance documents for creating voluntary compliance programs for health care providers and suppliers. Specifically, the OIG issued guidance materials for physician practices, clinical laboratories, hospitals, home health agencies, hospices, nursing facilities, ambulance suppliers, and suppliers of durable medical equipment, prosthetics, and orthotics.⁸

In response to the many physicians and professional health care providers who expressed interest in protecting their practices from potential erroneous and fraudulent conduct, the OIG published its “OIG Compliance Program Guidance for Individual and Small Group Physician Practices” (2000 Physician Practice CPG)⁹ in October 2000. The OIG intended this publication to be used to help physicians develop voluntary compliance programs that would help them comply with Medicare and Medicaid program requirements, and at the same time, help streamline their business operations.¹⁰ Although this particular guidance document expressly addressed physician practices, it was also geared for other small health providers and ancillary health care professionals as well, including dentists, chiropractors, podiatrists, optometrists, psychologists, physical and occupational therapists, and speech language pathologists.¹¹

PPACA Mandates Health Care Compliance Programs for Providers

The era of voluntary health care compliance came to an end with PPACA’s mandate for formal compliance programs. Section 6102 of the PPACA requires nursing facilities (NF) and skilled nursing facilities (SNF) to have compliance and ethics programs in place, pursuant to HHS/OIG regulations. Section 6401 of the PPACA, contains some overlap language, requiring *all* health care providers—regardless of their size and including NFs and SNFs—to implement formal health care compliance programs as a condition of their enrollment in Medicare, Medicaid and CHIP.¹² Section 6401 imposes a duty on the Secretary of HHS and OIG to establish the “core elements” for a mandatory compliance program for health care providers and suppliers within each sector of the health care industry.¹³ Moreover, under § 6401, HHS/OIG has the discretion to designate

⁷ 62 Fed. Reg. 9435 (Mar. ch 3, 1997) (OIG Compliance Program Guidance for Clinical Laboratories).

⁸ *See, e.g., id.*; 63 Fed. Reg. 8987 (February 23, 1998) (OIG Compliance Program Guidance for Hospitals); 63 Fed. Reg. 42410 (August 7, 1998) (OIG Compliance Program Guidance for Home Health Agencies); 64 Fed. Reg. 36389 (July 6, 1999) (OIG Compliance Program Guidance for Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry); 65 Fed. Reg. 59434 (October 5, 2000) (OIG Compliance Program Guidance for Individual and Small Group Physician Practices); 68 Fed. Reg. 14245 (March 24, 2003) (OIG Compliance Program Guidance for Ambulance Suppliers); 73 Fed. Reg. 56832 (September 30, 2008) (OIG Supplemental Compliance Program Guidance for Nursing Facilities).

⁹ 65 Fed. Reg. at 59434 – 59552.

¹⁰ *Id.* at 59435.

¹¹ *Id.* at 59435, at nn. 1, 2.

¹² PPACA, *supra* note 1, at Subtitle E, §6401(a)(7)(A)(*to be codified in* Section 1866(j) of the Social Security Act (42 U.S.C. 1395cc(j)); §6401(b)(5) (*to be codified in* Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by Section 4302(b)).

¹³ PPACA, §6401(a)(7)(B).

the timeline under which providers and suppliers must implement their compliance programs.¹⁴

Although it has been over one year since PPACA was enacted, HHS/OIG has not yet formally published the § 6401 core elements and implementing timeline for compliance programs applicable to small group physician practices and ancillary health care professionals and suppliers. However, in February 2011, HHS/OIG provided notice of its proposed approach for establishing compliance programs, in general, as required by §§ 6201 and 6401.¹⁵ Specifically, HHS/OIG advised that it intends to use the seven (7) elements described in Chapter 8 of the 2010 U.S. Federal Sentencing Guidelines Manual (FSG),¹⁶ as the basis for establishing the requisite core elements mandated by §6401.¹⁷ According to HHS/OIG, the FSG elements instill a commitment to prevent, detect and correct inappropriate behavior and ensure compliance with all applicable federal laws, regulations and requirements.¹⁸

HHS/OIG claims it will consider the numerous comments that it has already received regarding its proposed approach using the FSG elements and will finalize the compliance plan requirements for all health care providers enrolled in Medicare, Medicaid, and CHIP sometime in the future through Notice of Proposed Rule Making (NPRM), with opportunity for further public comment.¹⁹ HHS/OIG has eluded that it may establish reasonable timelines for implementation based on the various types and sizes of providers and suppliers within given industry sectors or by particular provider or supplier category.²⁰

Now is the Time for Providers to Structure their Mandatory Compliance Programs

It is inevitable: HHS/OIG will publish the mandated core elements and the implementing timeline regulations, pursuant to § 6401. But until then, rather than procrastinate and be caught off guard, *now* is the time for physician practices and ancillary health care professionals and suppliers, regardless of size, to start structuring their compliance programs if they have not already done so. *The OIG advises providers to make compliance plans a priority now*²¹ and has taken steps to provide compliance training tips for small group providers and suppliers. Specifically, the OIG posts on its website, “The Seven Fundamental Elements of an Effective Compliance Program,” and provides informational materials from one of its compliance training workshops held in May 2011

¹⁴ PPACA, § 6401(a)(7)(B) and (C); (b)(5).

¹⁵ 76 Fed. Reg. 5862, at 5941-43 (Feb. 2, 2011).

¹⁶ U.S. Federal Sentencing Guidelines Manual, Ch. 8, at 31-35, http://www.ussc.gov/2010guid/20100503_Reader_Friendly_Proposed_Amendments.pdf.

¹⁷ 76 Fed. Reg. 5942.

¹⁸ *Id.*

¹⁹ *Id.* at 5942-43.

²⁰ *Id.* at 5942.

²¹ See OIG, Health Care Fraud Prevention and Enforcement Action Team (HEAT) Provider Compliance Training, *Health Care Compliance Program Tips*, “Ten Practical Tips for Creating Culture of Compliance,” <http://oig.hhs.gov/compliance-provider-training/index.asp>.

specifically targeted for providers.²² The “Seven Fundamental Elements” posted on the OIG website track the seven (7) FSG elements and OIG’s previously published series of voluntary guidance materials.

Physicians and small group professional health care providers should think of mandatory compliance programs as analogous to practicing preventive medicine in their respective business practices.²³ It would be well worth their efforts to strategically structure a compliance program *now*, and not wait until HHS/OIG sets the mandated implementing timeline. An effective compliance program would not only help to prevent erroneous and fraudulent claim submissions, but it could strategically result in benefits to any health care business practice by minimizing billing mistakes, optimizing proper payment of claims, reducing chances of audits, and avoiding conflicts with the self-referral and anti-kickback statutes.²⁴ Moreover, it could help enhance the delivery of patient care through increased accuracy in documentation.²⁵

The OIG’s “Seven Fundamental Elements for an Effective Compliance Program”

The OIG’s “Seven Fundamental Elements” as posted on its website, are as follows:

1. Implement written compliance policies, procedures, and standards of conduct.
2. Designate a compliance officer and compliance committee, who will be responsible for monitoring compliance efforts and enforcing practice standards.
3. Conduct effective training and education on the compliance policies, procedures, and standards of conduct.
4. Develop effective lines of communication to facilitate communication with staff (updates and training) and allow anonymous reporting mechanisms.
5. Conduct internal monitoring and auditing by performing periodic self-audits.
6. Enforce standards for employees through well-publicized disciplinary guidelines.

²² See OIG, Health Care Fraud Prevention and Enforcement Action Team (HEAT) Provider Compliance Training, *Health Care Compliance Program Tips, “The Seven Fundamental Elements of an Effective Compliance Program,”* <http://oig.hhs.gov/compliance-provider-training/index.asp>. Between February and May 2011, the OIG provided free training workshops for small providers in six (6) major cities nationwide, and currently posts training materials and a web cast video of one of the workshops.

²³ 65 Fed. Reg. 59435.

²⁴ *Id.*

²⁵ *Id.*

7. Respond promptly to detected offenses and develop corrective action.²⁶

Consequences of Not Implementing a Compliance Program

The consequences for not having a § 6401 compliance program in place could result in the obvious: exclusion from Medicare, Medicaid, and CHIP programs.²⁷ But on an equally ominous level, if providers fail to create a culture of compliance and fail to implement written policies, standards and practices, the greater the chance of submitting erroneous and fraudulent claims, leading to violations of the federal and state fraud and abuse statutes with possible imposition of civil penalties, criminal prosecutions, and/or exclusion from federal health care programs.

Because almost all physicians practicing in the U.S. will treat Medicare and/or Medicaid beneficiaries at some point in their career, they must be knowledgeable about certain fraud and abuse laws that could potentially come into play,²⁸ such as the civil False Claims Act;²⁹ the Anti-Kickback Statute;³⁰ the Stark Physician Self-Referral Law;³¹ the Exclusion Authorities;³² the Civil Monetary Penalties Law;³³ and the Criminal Health Care Fraud Statute.³⁴ Several states have analogous state statutes that may be applicable as well. By way of example, the civil False Claims Act (FCA) protects the government from being overcharged or sold goods or services that are sub-standard.³⁵ The civil FCA makes it illegal to submit claims for payment to Medicare or Medicaid that a health care provider knows, or should know, are false or fraudulent.³⁶ Claims are considered “false” if the service is not actually rendered to the patient, is provided but already covered under another claim, is miscoded, or is not supported by the patient’s medical chart.³⁷ To prove an FCA violation, no specific intent to defraud is required.³⁸ To act “knowingly” means not only having actual knowledge, but also acting in deliberate ignorance or reckless disregard of the truth or falsity of the information.³⁹ In other words, practitioners beware:

[Y]ou do not have to intend to defraud the government to violate the FCA.
You can be punished if you act with deliberate ignorance or reckless

²⁶ *The Seven Fundamental Elements of an Effective Compliance Program*, *supra* note 22.

²⁷ See PPACA, *supra* note 1, §§ 6401(a)(7)(A) and 6401(b)(5).

²⁸ HHS/OIG, *A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse*, PowerPoint presentation, at 1, <http://oig.hhs.gov/compliance/physician-education/index.asp>.

²⁹ 31 U.S.C. §§ 3729-3733.

³⁰ 42 U.S.C. § 1320a-7b(b) with the safe harbor regulations found in 42 C.F.R. § 1001.952.

³¹ 42 U.S.C. § 1395nn with safe harbor regulations found in 43 C.F.R. § 411.350-.389.

³² 42 U.S.C. § 1320a-7; 42 U.S.C. § 1329c-5; 42 C.F.R. Pt. 1001 (Medicare) and Pt. 1002 (Medicaid).

³³ 42 U.S.C. § 1320a-7a; 42 C.F.R. Pt. 1003.

³⁴ 18 U.S.C. §§ 1347 and 1349.

³⁵ HHS/OIG, *A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse*, Booklet, at 3, <http://oig.hhs.gov/compliance/physician-education/index.asp>.

³⁶ *A Roadmap for New Physicians*, Booklet, *supra* note 35, at 3.

³⁷ *A Roadmap for New Physicians*, PowerPoint presentation, *supra* note 28, at 5.

³⁸ *A Roadmap for New Physicians*, Booklet, *supra* note 35, at 3.

³⁹ *Id.*

disregard of the truth. This means you cannot hide your head in the sand to avoid liability.⁴⁰

Filing false claims may result in fines of up to three (3) times the programs' loss plus \$11,000 per claim filed.⁴¹ Because each item or service billed to Medicare or Medicaid counts as a claim, the fines could add up significantly.⁴²

The OIG offers some practical suggestions for creating a culture of compliance, including such practical tips as “know your risk areas,” “educate your employees,” “manage your financial relationships,” “conduct audits,” and most importantly, “when in doubt, ask for help.”⁴³ The OIG encourages small group providers to use additional resources for assistance in preparing their programs, such as (1) obtaining advice from legal counsel knowledgeable about the various fraud and abuse statutes, (2) seeking outside billing and coding consultation, and (3) reviewing the numerous informative resource materials and guidance documents from OIG’s website,⁴⁴ specifically, OIG’s 2000 Physician CPG geared for physician practices.⁴⁵ Obtaining advice from knowledgeable legal counsel up front may be particularly important for navigating through the maze of fraud and abuse statutes when evaluating new or existing billing arrangements, business ventures, or employment and personal services relationships for potential compliance problems⁴⁶ and for establishing the written standards for a compliance practice. Seeking consultation from outside billing companies may help troubleshoot and pinpoint regularly occurring billing and coding mistakes within the practice that could or have in the past adversely affected profits. Correcting the billing and coding problems may not only help reduce the risk of filing erroneous or fraudulent claims, but also improve bottom-line margins of profit.

The OIG, CMS, and the Department of Justice (DOJ) are charged with enforcing the fraud and abuse laws.⁴⁷ Providers need only review the OIG’s recent civil and criminal enforcement actions⁴⁸ taken against physicians and other licensed health care providers, who violated one or more of these laws and fined to the tune of millions of dollars and/or sentenced to imprisonment, to realize the significance of an effective compliance program.

Conclusion

⁴⁰ *A Roadmap for New Physicians*, PowerPoint presentation, *supra* note 28, at 6.

⁴¹ *A Roadmap for New Physicians*, Booklet, *supra* note 35, at 3.

⁴² *Id.*

⁴³ *Ten Practical Tips for Creating Culture of Compliance*, *supra* note 21.

⁴⁴ See OIG, Health Care Fraud Prevention and Enforcement Action Team (HEAT) Provider Compliance Training, *Recommended Compliance Resources*, <http://oig.hhs.gov/compliance-provider-training/index.asp>; see also OIG organization homepage, <http://oig.hhs.gov>.

⁴⁵ 65 Fed. Reg. 59434 - 59452.

⁴⁶ *A Roadmap for New Physicians*, Booklet, *supra* note 35, at 26-27.

⁴⁷ *Id.* at 3.

⁴⁸ OIG, *Fraud, Civil and Criminal Enforcement*, June 2011, <http://oig.hhs.gov/fraud/enforcement/criminal/index.asp>.

All health care providers and suppliers, regardless of size, are under the mandate to implement a compliance program if they want to continue to participate in Medicare, Medicaid and/or CHIP. Given HHS/OIG's notice of its proposed approach for compliance programs, OIG's posted "Seven Fundamental Elements" on its website, and OIG's previous guidance documents, providers and suppliers have the tools to start building an effective compliance program now. By strategically developing a program before the designated timeline for implementation, providers will be not only taking the steps to comply with the mandate, but also would reap benefits by minimizing billing and coding mistakes, optimizing the proper payment of claims, streamlining their business practices, and improving the quality of their delivery of patient care.

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