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Shared Goals: How the HHS Office of Inspector General Supports Health Care Industry Compliance Efforts

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SHARED GOALS: HOW THE HHS OFFICE OF INSPECTOR GENERAL SUPPORTS HEALTH CARE INDUSTRY COMPLIANCE EFFORTS

Gregory E. Demske,[†] Geeta Taylor,^{††} and James Ortmann^{†††}

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I. INTRODUCTION

Health care providers¹ in the United States operate in a complex regulatory and business environment that presents many

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risks. Providers need to manage compliance risks inherent in operating in this environment. The United States Department of Health and Human Services (HHS) Office of Inspector General (OIG) assesses risks across HHS programs, including Medicare and Medicaid, to inform its priorities in audits, evaluations, investigations, administrative enforcement, and other activities.² As a government agency that values transparency, OIG maintains and continually updates information on its website that can inform providers about risk areas for those operating in Federal health care programs.³

OIG uses information gained from audits, evaluations, and enforcement actions to educate providers through guidance that can inform voluntary compliance efforts. OIG's goals in promoting health care industry compliance are for providers to: (1) comply with Federal health care program requirements, (2) self-identify compliance issues as they arise, and (3) appropriately address such issues.

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1. In this article, we use the term provider broadly to include any individual or entity that directly or indirectly furnishes items or services payable by federal health care programs.

2. The OIG's purpose is to "promote economy, efficiency, and effectiveness" and to "prevent and detect fraud and abuse" in HHS programs, including Federal health care programs like Medicare and Medicaid. Inspector General Act of 1978, as amended, § 2(2) (amended 2008) (codified as amended at 5 U.S.C. app. 3 § 2(2)). The Inspector General Act establishes inspectors general at all cabinet-level departments and many other agencies. § 2. HHS OIG is distinguishable from other federal inspector general offices because of the size (over \$1 trillion annual budget) and scope of HHS, as well as the unique enforcement and guidance authorities for which HHS OIG is responsible. See *About Us*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/about-oig/about-us/index.asp> [<https://perma.cc/7Y39-YKDD>] (last visited July 31, 2018) (explaining the structure of the HHS OIG and what the services they provide).

3. Federal health care programs include "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the [Federal Employees Health Benefits Program]), or any State health care program." 42 U.S.C. § 1320a-7b(f) (2012); accord 42 C.F.R. § 1000.10 (2017). OIG's enforcement and guidance responsibilities encompass all Federal health care programs, including programs administered outside of HHS, like those run by the Departments of Defense and Veterans Affairs. See 42 C.F.R. § 1000.10.

OIG and providers share an interest in identifying and mitigating risks, and providers should use OIG's information to guide their own risk analysis, identify compliance issues, and take corrective action when issues arise, including fulfilling report and return obligations under the sixty-day rule and self-disclosing fraud issues. As OIG continues to use all its tools to identify and address risks for HHS programs, health care providers should use the resources OIG shares with the public to guide their own compliance efforts and reduce organizational and individual risks.

II. HOW OIG PROMOTES COMPLIANCE

OIG promotes compliance through a process that identifies fraudulent and abusive practices in Federal health care programs,⁴ educates the industry on risk areas and voluntary compliance measures,⁵ and uses targeted enforcement to prevent and deter providers from defrauding and abusing the programs.⁶

A. *Identify Risk Areas that Could Lead to Fraud, Waste, and Abuse in Medicare & Medicaid*

OIG uses a variety of tools to identify risks to Medicare and Medicaid. Audits and evaluations identify specific practices and nationwide trends that can lead to improper billing or noncompliance.⁷ OIG's in-house data experts use data analytics to identify trends and outliers that focus OIG efforts on higher risk specialties, issues, geographic areas, and providers.⁸ Through OIG's hotline, the public provides tips or information that can lead to an investigation.⁹ Many investigations are initiated by *qui tam* complaints under the False Claims Act (FCA).¹⁰ OIG uses the above

4. See *infra* Section II.A.

5. See *infra* Section II.B.

6. See *infra* Section II.C.

7. See *infra* Sections II.B.2 and II.B.3.

8. See *A Message from the Inspector General*, in OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., SEMI-ANNUAL REPORT TO CONGRESS APR. 1, 2017–SEPT. 30, 2017 (2017).

9. See *Report Fraud*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/fraud/report-fraud> [<https://perma.cc/M6CY-7T5P>] (last visited July 31, 2018).

10. 31 U.S.C. §§ 3730–33 (2012). *Qui tam* complaints are civil actions brought by private persons for FCA violations for both the person and the United States. *Id.* § 3730(b).

methods, tips, and traditional law enforcement techniques to identify and investigate persons who may be defrauding HHS programs or harming program beneficiaries.¹¹ OIG investigations often lead to criminal, civil, or administrative enforcement actions.¹² Identifying risk areas promotes compliance by giving the industry notice of improper conduct, which deters like conduct and highlights areas of focus for a provider's voluntary compliance efforts.¹³

B. Educate Industry on Risks and Compliance

OIG operates with a high degree of transparency, which gives providers insight into the issues OIG subjects to audits or evaluations (either in the past, currently, or as planned for the future), enforcement priorities and outcomes, and OIG's perspective on many compliance issues.¹⁴

1. Work Plan and Semiannual Report

Perhaps the most widely followed tool OIG uses to communicate with the industry is the Work Plan.¹⁵ The Work Plan lists ongoing and upcoming OIG audits, evaluations, and other

11. See *Office of Investigations*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/about-oig/about-us/office-of-investigations.asp> [<https://perma.cc/WB4V-V8XG>] (last visited July 31, 2018).

12. See *Enforcement Actions*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/fraud/enforcement/index.asp> [<https://perma.cc/WUV9-8LCC>] (last visited July 31, 2018) (showing the different enforcement actions OIG takes). While enforcement actions indicate risk areas, these actions often do not become public until years after the conduct occurred, making them a lagging indicator of risk relative to other publicly available information discussed in this article.

13. HHS and the Department of Justice annually publish a report summarizing efforts to combat health care fraud and abuse under the Health Care Fraud and Abuse Control (HCFAC) program. See *Health Care Fraud and Abuse Program Control Report*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/reports-and-publications/hcfac> [<https://perma.cc/UFF5-ZR46>] (last visited July 31, 2018) (collecting the annual reports from 1997 to 2016).

14. See *infra* Section II.B.1.

15. *Work Plan*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/reports-and-publications/workplan/index.asp> [<https://perma.cc/4QWY-VBEY>] (last visited July 31, 2018).

work.¹⁶ It is a living document that is updated monthly¹⁷ and presents OIG's priorities.¹⁸ The Work Plan provides a window into OIG's response to program risk areas or emerging trends, like the opioid crisis.¹⁹ Providers can review the Work Plan to inform their own compliance and internal audit program priorities.²⁰

While the Work Plan is forward looking, OIG's Semiannual Report to Congress²¹ highlights the audits, evaluations, investigations, and administrative actions OIG has completed in the past six months.²² OIG also updates its website daily to include the latest reports, publications, case results, guidance, and other issuances.²³

16. *Id.*

17. Before 2017, the OIG released a work plan once a year with occasional mid-year updates. *Work Plan*, *supra* note 15. In June 2017, the OIG started updating the Work Plan monthly. *Id.*

18. *See id.*; *Active Work Plan Items*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp> [<https://perma.cc/6WKN-E6KC>] (last visited July 31, 2018).

19. *See, e.g., FDA Oversight of Risk Evaluation and Mitigation Strategies to Address Prescription Opioid Abuse*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-000254.asp> [<https://perma.cc/KB4T-RT3C>] (last visited July 31, 2018); *SAMHSA Pre-Award Process for Opioid State Targeted Response Grants*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-000247.asp> [<https://perma.cc/UV6S-T4DT>] (last visited July 31, 2018). *See generally Active Work Plan Items*, *supra* note 18 (listing OIG audits, evaluations, and inspections that are underway or planned).

20. Gregory Demske, Chief Counsel to the Inspector Gen., U.S. Dep't of Health & Human Servs., Keynote Address at the Mitchell Hamline School of Law, Law Review Symposium: OIG Priorities in 2018 (Mar. 16, 2018).

21. The OIG is required to submit semiannual reports to Congress. Inspector General Act of 1978, 5 U.S.C. app. 3 § 5 (2012).

22. *See generally Archives—Semiannual Report*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/reports-and-publications/archives/semiannual/index.asp> [<https://perma.cc/W2E8-U3KU>] (last visited July 31, 2018) (providing accessible archives of OIG's semiannual reports). Similarly, as discussed below, the HHS-DOJ HCFAC report provides a retrospective summary of the federal government's efforts to combat health care fraud and abuse. OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM REPORT FOR FISCAL YEAR 2017 (2018).

23. *See generally What's New*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/newsroom/whats-new/index.asp> [<https://perma.cc/FP8R-J536>] (last visited July 31, 2018) (linking monthly OIG updates for 2017 and 2018).

2. *Audits and Evaluations*

OIG's audit and evaluation reports promote industry compliance efforts. These reports look at nationwide trends in HHS programs and examine individual providers' compliance with applicable statutes, regulations, and other authorities.²⁴ These reports often offer broad-based and practical recommendations for improvement.²⁵ Information in the reports can help identify risk areas and can spur providers to strengthen internal controls to address such risk areas in their own activities.

For example, in 2017, OIG issued a data brief looking at opioid prescribing in Medicare Part D.²⁶ OIG's analysis found about 400 prescribers using questionable prescribing practices, placing beneficiaries at risk for overdose.²⁷ Another example is OIG's skilled nursing facilities work. In 2012 and 2015, OIG issued evaluation reports that found inappropriate payments for skilled nursing facility care.²⁸ Compliance officers can build on OIG's reports and focus their resources by looking for similar risk areas in their own organizations.²⁹ An organization can improve its billing practices by conducting internal reviews related to risks identified in an audit or evaluation report.³⁰ And, if the organization finds improper

24. See *Office of Audit Services*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/about-oig/about-us/office-of-audit-services.asp> [<https://perma.cc/XK5L-J8ZH>] (last visited July 31, 2018).

25. *Id.*; *Office of Evaluation and Inspections (OEI)*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/about-oig/about-us/office-of-evaluation-and-inspections.asp> [<https://perma.cc/U4CJ-P4MC>] (last visited July 31, 2018).

26. OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., DATA BRIEF NO. OEI-02-17-00250, OPIOIDS IN MEDICARE PART D: CONCERNS ABOUT EXTREME USE AND QUESTIONABLE PRESCRIBING (2017).

27. *Id.* at 6.

28. OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., OEI-02-13-00610, THE MEDICARE PAYMENT SYSTEM FOR SKILLED NURSING FACILITIES NEEDS TO BE REVALUATED 2 (2015); OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., OEI-02-09-00200, INAPPROPRIATE PAYMENTS TO SKILLED NURSING FACILITIES COST MEDICARE MORE THAN A BILLION DOLLARS IN 2009, 10 (2012).

29. See HCCA-OIG COMPLIANCE EFFECTIVENESS ROUNDTABLE, MEASURING COMPLIANCE PROGRAM EFFECTIVENESS: A RESOURCE GUIDE 15 (2017) [hereinafter RESOURCE GUIDE] (suggesting that compliance departments review regulations that effect an organization as part of a risk assessment).

30. See *id.* (stating that compliance officers should keep up with any changes in the law as part of their own risk assessment).

conduct, it can correct the problem and self-disclose,³¹ rather than face potential government-initiated³² enforcement action.³³

3. *Federal Anti-Kickback Safe Harbors and OIG Advisory Opinions*

The Federal Anti-Kickback Statute (AKS) makes it a criminal offense for any person to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program.³⁴ The statute is broad and potentially reaches relatively low-risk, innocuous, or even beneficial business practices.³⁵ To address the broad reach of the statute, Congress enacted certain exceptions and authorized OIG to develop and promulgate safe harbor provisions.³⁶

31. See *Provider Self-Disclosure Protocol*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/compliance/self-disclosure-info/protocol.asp> [<https://perma.cc/K9ZQ-5R75>] (last visited July 31, 2018); see also *Provider Self-Disclosure Settlements*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/fraud/enforcement/cmp/psds.asp> [<https://perma.cc/964X-G6SZ>] (last visited July 31, 2018).

32. In this article, we use the term "government-initiated enforcement actions" to include FCA *qui tam* matters filed by relators.

33. For example, less than a year after OIG's 2015 report on skilled-nursing facilities (SNFs), a California skilled nursing facility entered the OIG self-disclosure protocol and agreed to pay \$8.6 million for submitting claims to Medicare for skilled nursing services without proper certifications and re-certifications for services, establishment and content of therapy plans, and maintenance of clinical records. U.S. DEP'T. JUSTICE & U.S. DEP'T. HEALTH & HUMAN SERVS., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2016, 25 (2017); see ROBERT K. DECONTI ET AL., HOT TOPICS IN FRAUD AND ABUSE: TREACHEROUS TRAILS, PEAKS AND VALLEYS, AND OBSTACLES TO OVERCOME AT THE AMERICAN HEALTH LAWYERS ASSOCIATION, IN-HOUSE COUNSEL PROGRAM AND ANNUAL MEETING (2016). During the presentation, Assistant Inspector General for Legal Affairs Robert DeConti highlighted this settlement and recommended that providers use OIG's evaluations, among other work, to consider whether they should self-disclose improper payments to avoid government-initiated enforcement actions.

34. 42 U.S.C. §§ 1320a-7b(b) (2012).

35. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback, 56 Fed. Reg. 35,952 (July 29, 1991).

36. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14(a), 101 Stat. 680, 697 (1987). Congress delegated authority to the Secretary of the Department of Health and Human Services to create or modify regulatory safe harbors to the Anti-Kickback Statute. Specifically, section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 gives the Secretary authority to develop regulations "specifying payment practices that shall not be treated as a criminal offense under section 1128B(b) of the Social Security Act and shall not serve as the basis for an exclusion under section 1128(b)(7) of

These provisions identify practices that are not subject to prosecution under the AKS; although they are potentially capable of inducing provider referrals of Federal health care program beneficiaries.³⁷

Under this authority, OIG has published twenty-eight safe harbors protecting financial arrangements such as investment interests, personal services and management contracts, space and equipment leases, and free local transportation.³⁸ OIG periodically updates existing safe harbors and establishes new safe harbors to reflect changing health care industry practices.³⁹ Although complying with a safe harbor is voluntary, by structuring or modifying their business practices to comply with safe harbors, “providers can be assured that their arrangements are immune from potential criminal and administrative sanctions under the Anti Kickback Statute.”⁴⁰ The safe harbors and the accompanying regulatory preamble provide significant guidance about OIG’s views of AKS risks on many types of business arrangements.

In addition to safe harbors, Congress requires OIG to issue advisory opinions about the application of OIG’s fraud and abuse authorities to the requesting party’s existing or proposed business arrangement.⁴¹ These opinions, issued in response to a party’s request, explain how OIG would apply its fraud and abuse authorities to the existing or proposed arrangement.⁴² Although advisory opinions protect only the requesting party or parties, health care industry participants, in the OIG’s experience, often find advisory opinions informative. Because they explain how OIG

such Act.” *Id.* § 14(a).

37. The statutory exceptions include discounts, for bona fide employees, and group purchasing organizations and these exceptions are interpreted in the safe harbor regulations. *See* 42 U.S.C. § 1320a-7b(b)(3)(A) (discounts exception); *id.* § 1320a-7b(b)(3)(B) (bona fide employee exception); *id.* § 1320a-7b(b)(3)(C) (group purchasing organizations exception).

38. 42 C.F.R. § 1001.952 (2017).

39. Section 1128D(a) of the Social Security Act, codified at 42 U.S.C. § 1320a-7d(a), requires OIG to issue an annual solicitation for new or modified safe harbors and special fraud alerts. OIG typically issues this solicitation in December of each year. *See, e.g.*, Solicitation of New Safe Harbors and Special Fraud Alerts, 82 Fed. Reg. 61,229 (Dec. 27, 2017).

40. *See* Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Protecting Health Plans, 61 Fed. Reg. 2122, 2124 (Jan. 25, 1996).

41. 42 U.S.C. § 1320a-7d; 42 C.F.R. pt. 1008 (2017).

42. *See, e.g.*, Office Inspector Gen., U.S. Dep’t Health & Human Servs., OIG Advisory Opinion No. 17-09 (Dec. 29, 2017).

applies certain administrative authorities to specific factual situations, advisory opinions provide useful insight into OIG's views on AKS issues. OIG posts all issued advisory opinions on its website.⁴³

4. *Guidance on Specific Risk Areas—Special Fraud Alerts, Special Advisory Bulletins, and Other Publications*

Since 1989, OIG has provided various types of guidance to the health care industry about risk areas—often focused on the AKS and the prohibition on beneficiary inducements.⁴⁴ Special fraud alerts, special advisory bulletins, and similar documents identify practices that present risks of Federal health care program fraud, waste, or abuse.⁴⁵ These documents often discuss factors OIG will consider to determine whether to investigate if an arrangement violates the AKS or another law.⁴⁶ For example, in a 2013 special fraud alert, OIG addressed certain attributes of physician-owned distributorships that raise fraud and abuse risks and which may pose a danger to patient safety.⁴⁷

Other guidance documents explain OIG's legal interpretations or enforcement approaches. For example, in a 2015 Policy Statement, OIG assured hospitals that they will not be subject to OIG administrative sanctions for discounting or waiving amounts Medicare beneficiaries may owe for self-administered drugs they

43. See *Advisory Opinions*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/compliance/advisory-opinions/index.asp> [<https://perma.cc/2KYA-Y3QT>] (last visited July 31, 2018). Posted advisory opinions redact the identity of the requesting party and other named persons.

44. See *Bulletins*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/compliance/alerts/bulletins/index.asp> [<https://perma.cc/A6RB-7SPJ>] (last visited July 31, 2018); *Other Guidance*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/compliance/alerts/guidance/index.asp> [<https://perma.cc/8CTU-9C7Z>] (last visited July 31, 2018); *Special Fraud Alerts*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/compliance/alerts/index.asp> [<https://perma.cc/6NS3-AK9R>] (last visited July 31, 2018).

45. See *Other Guidance*, *supra* note 44.

46. *E.g.*, Special Fraud Alert, Office Inspector Gen., U.S. Dep't Health & Human Servs., Laboratory Payments to Referring Physicians (June 15, 2014), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/oig_sfa_laboratory_payments_06252014.pdf [<https://perma.cc/Q3VS-SDBD>].

47. Special Fraud Alert, Office Inspector Gen., U.S. Dep't Health & Human Servs., Physician-Owned Entities (Mar. 26, 2013), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/pod_special_fraud_alert.pdf, [<https://perma.cc/XN9G-26YA>].

receive in outpatient settings when those drugs are not covered by Medicare Part B.⁴⁸ Other information, although not found in the “compliance” section of OIG’s website, provides insight into risk areas in health care. For example, OIG’s “Eye on Oversight” videos provide short summaries of OIG focus areas.⁴⁹ More in-depth discussions of OIG work on priority areas are found in the “Portfolio” section of the website, which brings together OIG audits, evaluations, investigations, enforcement, and guidance work on a subject area such as home health⁵⁰ or Medicare Part D.⁵¹ Together, these guidance documents identify areas of OIG focus and potential risk areas that providers may want to target in their compliance efforts.

5. *Guidance on Compliance Best Practices*

In addition to guidance focused on risk areas, OIG has provided guidance to the health care industry about compliance best practices for decades.⁵² Recently, OIG and the Health Care Compliance

48. Office Inspector Gen., U.S. Dep’t Health & Human Servs., OIG Policy Statement Regarding Hospitals That Discount or Waive Amounts Owed by Medicare Beneficiaries for Self-Administered Drugs Dispensed in Outpatient Settings (Oct. 29, 2015), <https://oig.hhs.gov/compliance/alerts/guidance/policy-10302015.pdf> [<https://perma.cc/6FR2-WTPN>].

49. *Eye on Oversight Video Series*, OFFICE INSPECTOR GEN., U.S. DEP’T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/newsroom/video/2016/eoo/index.asp> [<https://perma.cc/Q6A5-Q2XP>] (last visited July 31, 2018).

50. *OIG Online Portfolio: Home Health*, OFFICE INSPECTOR GEN., U.S. DEP’T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/reports-and-publications/portfolio/home-health/> [<https://perma.cc/PQ5K-8UAT>] (last visited July 31, 2018).

51. OFFICE INSPECTOR GEN., U.S. DEP’T HEALTH & HUMAN SERVS., OEI-03-15-00180, ENSURING THE INTEGRITY OF MEDICARE PART D (2015).

52. See, e.g., OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 56,832, 56,833 (Sept. 30, 2008). See generally *Compliance Guidance*, OFFICE INSPECTOR GEN., U.S. DEP’T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/compliance/compliance-guidance/index.asp> [<https://perma.cc/V56Z-ZSTS>] (last visited July 31, 2018). For example, from 1998 through 2008, OIG issued a series of compliance program guidance (CPG) documents. *Id.* The CPGs, aimed at “various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers,” encourage “the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.” *Id.* Despite not being “model compliance program[s],” the CPGs remain resources for various types of providers in setting up or improving a compliance program, although providers must also be aware of evolving risk areas not reflected in the CPGs. *Id.*

Association (HCCA) collaborated on a compliance officer roundtable that resulted in a Resource Guide listing ideas of “what to measure” and “how to measure” compliance program effectiveness.⁵³ As with other OIG guidance documents, the Resource Guide does not require any action. In fact, OIG and HCCA explicitly explained that the document is not a checklist and that “[a]ny attempt to use this as a standard or a certification is discouraged by those who worked on this project; one size truly does not fit all.”⁵⁴

OIG also issues guidance in a variety of forms to assist a range of people involved in health care. For example, OIG has issued a series of guidance documents for boards of directors of health care entities⁵⁵ and a “Roadmap for New Physicians” brochure that summarizes major fraud and abuse risks that affect physicians.⁵⁶ The OIG website also includes many training videos, webcasts, and written materials on a variety of issues (e.g., the FCA, the AKS, exclusions, self-disclosure) that may interest providers and their compliance officers.⁵⁷

OIG guidance gives providers tools and information to aid their efforts to comply with Federal health care program requirements. Providers are in the best position to determine how to use this information to advance compliance goals within the context of each providers’ industry sector, structure, operations, and resources.

53. RESOURCE GUIDE, *supra* note 29.

54. *Id.* at 2.

55. *Compliance Resource Materials*, OFFICE INSPECTOR GEN., U.S. DEP’T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/compliance/compliance-guidance/compliance-resource-material.asp#hcb> [<https://perma.cc/AB74-PDYY>] (last visited July 31, 2018); see *In re Caremark Int’l, Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. 1996) (recognizing the duty of board members to undertake reasonable efforts to promote compliance).

56. OFFICE INSPECTOR GEN., U.S. DEP’T HEALTH & HUMAN SERVS., A ROADMAP FOR NEW PHYSICIANS: AVOIDING MEDICARE & MEDICAID FRAUD & ABUSE (2017) [hereinafter ROADMAP]; see also *Continuing Medical Education*, OFFICE INSPECTOR GEN., U.S. DEP’T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/compliance/101/cme.asp> [<https://perma.cc/8JHG-B687>] (last visited July 31, 2018).

57. *Compliance Education Materials*, OFFICE INSPECTOR GEN., U.S. DEP’T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/compliance/101/index.asp> [<http://perma.cc/XV4Y-GA65>] (last visited July 31, 2018).

C. Amplify OIG Work and Provide Guidance Through Enforcement

OIG uses its administrative enforcement tools of exclusion and Civil Money Penalties (CMP) to support and amplify OIG work, and to protect Federal health care programs and their beneficiaries.

1. Exclusions

OIG has authority to exclude individuals and entities who have engaged in fraud, abuse, or other misconduct from participation in Medicare, Medicaid, and other Federal health care programs.⁵⁸ Exclusion is a remedial measure that prohibits Federal health care program payment for any item or service furnished, directly or indirectly, by an excluded person.⁵⁹

Although most exclusions are derivative,⁶⁰ OIG has broad authority to initiate its own affirmative exclusion of a person if OIG can prove, for example, that the person submitted or caused to be submitted to a Federal health care program claims that the person knows or should know⁶¹ were false or fraudulent.⁶² This false claims exclusion authority parallels the FCA in its substantive elements.⁶³ Because of this, in FCA cases involving Federal health care programs, OIG generally resolves its exclusion actions at the same time the Department of Justice resolves its civil monetary claims.⁶⁴ Consistent

58. 42 U.S.C. § 1320a-7 (2012); 42 C.F.R. pt. 1001 (2017).

59. See generally Office Inspector Gen., U.S. Dep't Health & Human Servs., Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 8, 2013), <https://oig.hhs.gov/exclusions/files/sab-05092013.pdf> [<https://perma.cc/J92V-XE7Q>] (describing exclusion's effect).

60. See 42 U.S.C. §§ 1320a-7(a)–(b). We use the term “derivative” to describe exclusions that are based on a finding by an outside tribunal, e.g., a conviction in state or federal court or a revocation of a license to provide health care. See *id.* The vast majority of OIG exclusions are derivative. See *id.*

61. *Id.* § 1320a-7a(i)(7) (defining the term “should know” in the CMP statute to mean “reckless disregard” or “deliberate ignorance,” so this knowledge standard is the same as that in the False Claims Act).

62. *Id.* § 1320a-7(b)(7) (authorizing OIG to pursue an affirmative exclusion for violations that would form the basis for an OIG CMP *under id.* § 1320a-7a). OIG can also pursue affirmative exclusions for many other offenses, including violations of the AKS and causing the furnishing of services that are medically unnecessary or fail to meet professionally recognized standards of care. *Id.* § 1320a-7(b)(6)(B).

63. *Id.* § 1320a-7(b)(7) (authorizes exclusion for violations of § 1320a-7a). Compare *id.* § 1320a-7a(a)(1)(B), with 31 U.S.C. § 3729(a)(1)(A) (2018).

64. Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authorities, 82 Fed. Reg. 4100, 4102 (Jan. 12, 2017).

with its commitment to transparency, OIG has explained the factors that it will consider to place a person along a risk spectrum that ranges from exclusion to an administrative release with no further action.⁶⁵

2. *Corporate Integrity Agreements*

Corporate Integrity Agreements (CIAs) are a means of reducing the risk a provider poses to the Federal health care programs while allowing the provider to continue furnishing items and services paid for by these programs.⁶⁶ CIAs are process-focused documents that require mechanisms that OIG believes support the goals of compliance.⁶⁷

In the mid-1990s, OIG began requiring defendants in FCA cases to enter into CIAs in exchange for an administrative exclusion release.⁶⁸ Since then, OIG has changed its approach to reflect the maturation of compliance in the health care industry. For example, OIG initially sought CIAs in every FCA case in which it was not seeking exclusion.⁶⁹ Today, in FCA case resolutions, OIG uses its section 1128(b)(7) risk analysis to determine whether a CIA is the best way to achieve a positive outcome.⁷⁰ OIG now requires CIAs in

65. Office Inspector Gen., U.S. Dep't Health & Human Servs., Opinion Letter on Criteria for Implementing Section 1128(b)(7) Exclusion Authority (Apr. 18, 2016) [hereinafter *Criteria*], <https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf> [<https://perma.cc/4K32-QK5H>].

66. *Corporate Integrity Agreements*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp> [<https://perma.cc/68TS-HPLV>] (last visited July 31, 2018).

67. CIAs typically last five years and include requirements to: (1) hire a compliance officer; (2) develop written standards and policies; (3) implement a comprehensive employee training program; (4) retain an independent review organization to conduct annual reviews; (5) establish a confidential disclosure program; (6) screen and restrict employment of excluded persons; (7) report overpayments, reportable events, and ongoing investigations or legal proceedings; and (8) regularly report to OIG on the status of the entity's compliance activities. *Id.* CIA requirements reflect the compliance standards in the Federal Sentencing Guidelines. *See generally* U. S. SENTENCING COMM'N, GUIDELINES MANUAL 389–91 (Nov. 1, 2016).

68. OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., PROTECTING PUBLIC HEALTH AND HUMAN SERVICES PROGRAMS: A 30-YEAR RETROSPECTIVE 38 (2006) [hereinafter *PROTECTING PUBLIC HEALTH*].

69. *Id.* at 39.

70. *Criteria*, *supra* note 65, at 2.

cases involving significant monetary loss, patient harm, or other factors indicating significant ongoing risk from the provider.

Further, CIAs have evolved from focusing on compliance infrastructure and employee training to placing more emphasis on risk assessment.⁷¹ Current CIA requirements encourage providers to implement a proactive compliance program that takes steps to assess and mitigate risks and actively prevent fraud, including the use of risk-based reviews.⁷²

CIAs have also evolved to focus more on the organization's leadership. Operating in a complex regulatory environment such as health care, compliance programs must include systems and controls such as those required in a CIA, but an organization's compliance also depends on commitment and focus from the organization's leaders.⁷³ OIG has increasingly required board members, executives, and senior managers to certify compliance based on their duties and roles in the company.⁷⁴ Providers should consider evolving CIA requirements as they focus on compliance risks and promote accountability for compliance among leadership and management positions and throughout their organizations.

3. *Civil Money Penalties*

Civil money penalties (CMPs) are another means of addressing fraud.⁷⁵ OIG uses CMPs to recover dollars, penalize wrongdoers, and

71. This assertion comes from the authors' own knowledge and experience in creating CIAs.

72. *See, e.g.*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND DIGNITY HEALTH (2014); OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND ANMED HEALTH (2017).

73. *Id.* *See generally* OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., PRACTICAL GUIDANCE FOR HEALTH CARE GOVERNING BOARDS ON COMPLIANCE OVERSIGHT (2015) [hereinafter PRACTICAL GUIDANCE].

74. PRACTICAL GUIDANCE, *supra* note 73, at 14. In contrast, older CIAs required only the compliance officer to certify compliance with the CIA. Through dialogue with the industry, OIG determined that this process placed an undue burden on the compliance officer, who was not necessarily in control of the resources needed to implement the CIA successfully.

75. 42 U.S.C. § 1320a-7a (2012); 42 C.F.R. pt. 1003 (2017). The Civil Monetary Penalties Law allows OIG to impose penalties on individuals and entities that, among other things, submit false or fraudulent claims to the Federal health care programs, violate the AKS, or employ excluded individuals. Office Inspector Gen.,

deter improper conduct.⁷⁶ While the FCA is the federal government's primary civil tool to address health care fraud, the CMP is a powerful supplement that allows OIG to fill enforcement gaps and bring cases that support OIG priorities.⁷⁷ By coordinating CMP enforcement and compliance guidance efforts, OIG is able to amplify and reinforce messages to the public. For example, while DOJ successfully pursued an FCA case against a physician and an entity that had paid kickbacks to physicians through sham medical directorships and improper office staff arrangements,⁷⁸ OIG pursued CMP cases against twelve physicians who received these kickbacks.⁷⁹ After settling with the physicians, OIG issued an alert on suspect physician compensation arrangements that reward physicians for referrals.⁸⁰ In another example, OIG issued an alert notifying the industry of improper arrangements between home health agencies and physicians after several FCA settlements and OIG reports identified home health as an area vulnerable to fraud.⁸¹

U.S. Dep't Health & Human Servs., Special Advisory Bulletin, The Effect of Exclusion from Participation in Federal Health Care Programs (2013), <https://oig.hhs.gov/exclusions/files/sab-05092013.pdf> [<https://perma.cc/FM7X-4VNK>].

76. OFFICE INSPECTOR GEN., SEMI-ANNUAL REPORT TO CONGRESS: APRIL 1–SEPTEMBER 30, 2010, III-4, 5 (2010) (identifying specific examples of CMPs imposed in various states); see *Background*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/fraud/enforcement/cmp/background.asp> [<https://perma.cc/7L8J-VUWS>] (last visited July 31, 2018) (describing instances where CMPs are commonly imposed).

77. See Press Release, U.S. Dep't of Justice, Justice Department Recovers Over \$3.7 Billion From False Claims Act Cases in Fiscal Year 2017 (Dec. 21, 2017), <https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017> [<https://perma.cc/2CX9-YUU9>].

78. Press Release, U.S. Attorney's Office for the Southern District of Texas, Prominent Houston Radiologist Settles False Claims Act Allegations (Aug. 14, 2012), <https://www.justice.gov/archive/usao/txs/1News/Releases/2012%20Aug%20120814%20Baker.html> [<https://perma.cc/N6F7-9MPP>].

79. Fraud Alert, Office Inspector Gen., U.S. Dep't Health & Human Servs., Physician Compensation Arrangement May Result in Significant Liability (June 9, 2015), https://oig.hhs.gov/compliance/alerts/guidance/Fraud_Alert_Physician_Compensation_06092015.pdf [<https://perma.cc/Z6LB-VLK8>].

80. *Id.*

81. OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., NATIONWIDE ANALYSIS OF COMMON CHARACTERISTICS IN OIG HOME HEALTH FRAUD CASES (June 2016); Alert, Office Inspector Gen., U.S. Dep't Health & Human Servs., Improper Arrangement and Conduct Involving Home Health Agencies and Physicians (June 22, 2016), https://oig.hhs.gov/compliance/alerts/guidance/HHA_%20Alert20

4. *Self-Disclosure and the Sixty-Day Rule*

Even well-intentioned providers operating strong compliance programs may engage in conduct triggering potential fraud liability.⁸² Since 1998, OIG has successfully operated a self-disclosure protocol allowing providers to resolve fraud claims.⁸³ If a provider identifies an issue for which it faces potential fraud liability, it can disclose to OIG under the protocol,⁸⁴ which has enabled OIG to resolve over 1,200 cases for \$615 million.⁸⁵ Relative to a potential government-initiated enforcement action, disclosure has several benefits: (1) faster resolution, (2) less disruption to operations, (3) lower payment, and (4) exclusion release with no CIA.⁸⁶

Providers that self-disclose compliance issues demonstrate their commitment to compliance through their actions.⁸⁷ OIG therefore provides an exclusion release in self-disclosure settlements without reviewing any other information about the provider's compliance program.⁸⁸ OIG's approach reflects its views on the goals of compliance. A provider's compliance program infrastructure (e.g., policies and procedures, training, hotlines) is a critical process that advances compliance goals. This infrastructure is a means to achieve,

16.pdf [https://perma.cc/4T53-EGV9].

82. OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4859 (Jan. 31, 2005) ("The OIG recognizes that implementation of a compliance program may not entirely eliminate improper or unethical conduct from the operations of health care providers.").

83. Notice, Office Inspector Gen., U.S. Dep't Health & Human Servs., OIG's Provider Self-Disclosure Protocol 1-2 (Apr. 17, 2013) [hereinafter Self-Disclosure Protocol], <https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf> [https://perma.cc/B35N-ZT5B].

84. Providers disclosing conduct that violates the Stark Law (section 1877 of the Social Security Act) may use the CMS Voluntary Self-Referral Disclosure Protocol (SRDP). *Self-Referral Disclosure Protocol*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html [https://perma.cc/6HY4-SPYC] (last visited July 31, 2018). Providers should refund other self-identified overpayments to the appropriate CMS or state contractor. *See Medicare Reporting and Returning of Self-Identified Overpayments*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 11, 2016), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-11.html> [https://perma.cc/87SV-94CH].

85. Office of Inspector Gen., U.S. Dep't Health & Human Servs., Office of Investigations, *Self-Disclosure Resolutions 1998-2016*.

86. Self-Disclosure Protocol, *supra* note 83, at 2-3.

87. *Id.* at 2.

88. *Id.* at 13.

among other things, the goal or outcome of the provider identifying, disclosing, and resolving compliance issues. In these circumstances, OIG believes a self-disclosure is a good outcome that eliminates the need to examine the provider's compliance infrastructure.

In addition to the existing reasons supporting self-disclosure, providers must now comply with the sixty-day rule.⁸⁹ Under the sixty-day rule, upon receiving credible information of a potential overpayment, providers must: (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify the overpayment amount over a six-year lookback period, and (3) report and return any overpayments within sixty days of identifying those overpayments.⁹⁰ Providers face significant FCA and CMP liability for failure to comply with the sixty-day rule.⁹¹

This rule has other significant impacts. For example, OIG audits can trigger sixty-day rule obligations.⁹² Recently published OIG provider audits recommend that providers "exercise reasonable diligence to identify and return any additional similar overpayments

89. 42 U.S.C. §§ 1320a-7k(d) (2012); *see also* Requirements for Reporting and Returning of Overpayments, 42 C.F.R. § 401.305 (2017).

90. 42 U.S.C. § 1320a-7k(d); 42 C.F.R. §§ 401.305(a)-(f), 422.326, 423.360 (2017).

91. 42 U.S.C. § 1320a-7a(a)(10) (2012); 42 C.F.R. § 401.305(e); *see, e.g.*, Kane *ex rel.* United States v. Healthfirst, Inc., 120 F. Supp. 3d 370 (S.D.N.Y. 2015) (providing an example of enforcement of the 60-day rule); Press Release, U.S. Attorney's Office, Southern District of New York, Manhattan U.S. Attorney Announces \$2.95 Million Settlement With Hospital Group For Improperly Delaying Repayment Of Medicaid Funds (Aug. 24, 2016), <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-295-million-settlement-hospital-group-improperly> [<https://perma.cc/BFE5-YDUT>]; Press Release, U.S. Attorney's Office, Southern District of Georgia, Pediatric Services of America and Related Entities to Pay \$6.88 Million to Resolve False Claims Act Allegations (Aug. 4, 2015), <https://www.justice.gov/usao-sdga/pr/pediatric-services-america-and-related-entities-pay-688-million-resolve-false-claims> [<https://perma.cc/67YG-MG75>]. OIG entered into a CIA with Pediatric Services of America that included specific requirements and an independent review organization claims review addressing the identification, quantification and repayment of overpayments. *See* OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND PEDIATRIC SERVICES OF AMERICA, INC., 13-14, App. C (2015).

92. *See, e.g.*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., MEDICARE COMPLIANCE REVIEW OF RUSH UNIVERSITY MEDICAL CENTER (2017) [hereinafter RUSH UNIVERSITY]; OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., MEDICARE COMPLIANCE REVIEW OF NORTHSORE UNIVERSITY HEALTHSYSTEM FOR 2013 AND 2014 (2016) [hereinafter NORTHSORE UNIVERSITY].

received outside of [the] audit period, in accordance with the sixty-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.”⁹³ OIG believes that the findings of provider-specific audit reports constitute credible information of a potential overpayment to that provider, requiring the provider to take action pursuant to the sixty-day rule.⁹⁴ In this context, the findings in an audit report place a responsibility on the provider not only to respond directly to the report findings, but also to undertake an internal review that examines the full six-year lookback period and which exceeds the time period covered by the audit.⁹⁵ This internal review may result in a self-disclosure, or the return of an overpayment.⁹⁶ In addition, a provider subject to an audit should consider whether the credible information of a potential overpayment compels it to undertake an internal review that includes similar overpayments in similarly situated facilities or service lines.⁹⁷ For example, in 2017, following a recommendation included in an OIG audit,⁹⁸ a hospital system conducted an internal review with a broader timeframe than the audit, and ultimately reported and returned an overpayment to Medicare.⁹⁹

5. *The Future of OIG Administrative Enforcement*

Over the past few years, OIG has increased its focus and resources on CMP and affirmative exclusion cases. OIG established a unit of attorneys focused on pursuing these cases and has pursued more and different types of CMP and affirmative exclusion cases.¹⁰⁰

93. See, e.g., RUSH UNIVERSITY, *supra* note 92, at 7.

94. See, e.g., OFFICE INSPECTOR GEN., U.S. DEP’T HEALTH & HUMAN SERVS., MEDICARE COMPLIANCE REVIEW OF NEW YORK-PRESBYTERIAN HOSPITAL FOR 2011 & 2012, ii (2016) [hereafter NEW YORK-PRESBYTERIAN HOSPITAL]; NORTSHORE UNIVERSITY, *supra* note 92.

95. See, e.g., NEW YORK-PRESBYTERIAN HOSPITAL, *supra* note 94; NORTSHORE UNIVERSITY, *supra* note 92.

96. See, e.g., NEW YORK-PRESBYTERIAN HOSPITAL, *supra* note 94; NORTSHORE UNIVERSITY, *supra* note 92.

97. As discussed throughout this article, even if a provider is not audited, it should consider audit or evaluation findings related to its industry sector as it plans its proactive compliance activities.

98. NEW YORK-PRESBYTERIAN HOSPITAL, *supra* note 94, at ii.

99. OIG at HHS (@OIGatHHS), TWITTER (Jun. 30, 2017, 7:21 AM), <https://twitter.com/OIGatHHS/status/880793507287453696> [<https://perma.cc/CT8Z-MDYL>].

100. In 2017, OIG recovered \$44.1 million through CMP settlements, an

Congress has continued to grant OIG additional CMP and exclusion authority.¹⁰¹ In addition to its traditional sources of investigative referrals, OIG now initiates many CMP and affirmative exclusion cases based on OIG audits, evaluations, and data analytics.¹⁰² For example, OIG work reports identifying vulnerabilities related to pediatric dentistry,¹⁰³ urine drug tests,¹⁰⁴ home health,¹⁰⁵ and clinical

increase from \$17.1 million in 2011. Office of Inspector Gen., U.S. Dep't Health & Human Servs., Office of Counsel to the Inspector General, Analysis of Civil Monetary Penalty Recoveries. This figure includes CMP recoveries from OIG initiated CMP matters as well as matters self-disclosed through the Self-Disclosure Protocol.

101. For example, Congress recently granted OIG authority to investigate and pursue penalties against parties engaged in health care information blocking and parties engaged in grant or contract fraud against HHS. 42 U.S.C. § 300jj-52(b) (2016); *id.* § 1320a-7a(o)-(s) (2012).

102. OFFICE INSPECTOR GEN., U.S. DEP'T. OF HEALTH & HUMAN SERVS., SEMI-ANNUAL REPORT TO CONGRESS 1, 5 (2017).

103. OFFICE INSPECTOR GEN., U.S. DEP'T. HEALTH & HUMAN SERVS., OEI 02-14-00480, QUESTIONABLE BILLING FOR MEDICAID PEDIATRIC DENTAL SERVICES IN CALIFORNIA (2015) (evaluating a pediatric dentistry OEI report); OFFICE INSPECTOR GEN., U.S. DEP'T. HEALTH & HUMAN SERVS., OEI 02-14-00120, QUESTIONABLE BILLING FOR MEDICAID PEDIATRIC DENTAL SERVICES IN LOUISIANA (2014) (evaluating a pediatric dentistry OEI report); OFFICE INSPECTOR GEN., U.S. DEP'T. HEALTH & HUMAN SERVS., OEI-02-12-00330, QUESTIONABLE BILLING FOR MEDICAID PEDIATRIC DENTAL SERVICES IN NEW YORK (2014) (evaluating a pediatric dentistry OEI report); *California Dentist Settles Case Involving Medically Unnecessary Claims, on Civil Monetary Penalties and Affirmative Exclusions*, OFFICE INSPECTOR GEN., U.S. DEP'T. HEALTH & HUMAN SERVS. (May 15, 2017), <https://oig.hhs.gov/fraud/enforcement/cmp/cmp-ae.asp> [<https://perma.cc/XRS4-EFCG>]; *Colorado Dentist Agrees to Voluntary Exclusion, on Civil Monetary Penalties and Affirmative Exclusions*, OFFICE INSPECTOR GEN., U.S. DEP'T. HEALTH & HUMAN SERVS. (Aug. 12, 2015) (pediatric dentistry enforcement).

104. Press Release, Office Inspector Gen., U.S. Dep't Health & Human Servs., Drug Testing Company to Pay \$5 Million Civil Money Penalty Settlement (Feb. 20, 2014) <https://oig.hhs.gov/newsroom/news-releases/2014/drug-cmp.asp> [<https://perma.cc/H4WN-K3E9>] (explaining urine drug testing enforcement); *ALJ Upholds OIG Civil Monetary Penalty and Exclusion Determination, on Civil Monetary Penalties and Affirmative Exclusions*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., (Aug. 29, 2016); *Utah Pain Doctor and Medical Practice Settle False and Fraudulent Medicare Claims Case, on Civil Monetary Penalties and Affirmative Exclusions*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., (July 21, 2017)

105. OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., NATIONWIDE ANALYSIS OF COMMON CHARACTERISTICS IN OIG HOME HEALTH FRAUD CASES (2016); *OIG Online Portfolio: Home Health*, OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/reports-and-publications/portfolio/home-health/enforcement.asp#mainBody> [<https://perma.cc/282Q-LTGP>] (last visited July 31, 2018) (summarizing home-health-fraud enforcement actions).

laboratories¹⁰⁶ generated CMP cases. Assessing risk in areas that have undergone review by OIG's auditors and evaluators complements traditional investigative referrals and allows OIG to use enforcement actions to directly target risk areas and amplify OIG's compliance message. We expect OIG to continue to build capacity and capability, and to increase the number and range of these cases. OIG will use its CMP and exclusion authorities to reinforce OIG priorities, fill enforcement gaps, deter misconduct, and protect the Federal health care programs and their beneficiaries.

III. CONCLUSION

In promoting compliance, OIG's goals are for providers to: (1) comply with requirements of Federal health care programs and provide high quality care to patients, (2) self-identify compliance issues when they arise, and (3) appropriately remediate and take corrective action in response to compliance issues.¹⁰⁷ Because OIG and providers share an interest in identifying and mitigating risks, OIG's work should inform providers' compliance efforts. OIG targets risk areas for HHS and Federal health care programs in its audits, evaluations, investigations, and enforcement actions. In addition, OIG publishes guidance on risk areas and compliance best practices designed to help providers in their voluntary compliance efforts. Through all this work, OIG provides information that providers should use to address compliance risks, maintain a strong compliance program, identify compliance problems, and take corrective and remedial action when compliance issues arise.

106. OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., MEDICARE PAYMENT FOR CLINICAL DIAGNOSTIC LABORATORY TESTS IN 2016: YEAR 3 OF BASELINE DATA (2017); OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., MEDICARE PAYMENTS FOR CLINICAL DIAGNOSTIC LABORATORY TESTS IN 2015: YEAR 2 OF BASELINE DATA (2016); OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., MEDICARE PAYMENTS FOR CLINICAL LABORATORY TESTS IN 2014: BASELINE DATA (2015).

107. ROADMAP, *supra* note 56.

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