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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Modernization of Compliance Program Guidance Documents

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS)

ACTION: Notice

SUMMARY: This *Federal Register* notice sets forth upcoming procedures for issuing compliance program guidance documents from HHS-OIG.

FOR FURTHER INFORMATION CONTACT: Amanda Copsey, (202) 619-0335.

HHS-OIG is modernizing the accessibility and usability of our publicly available resources, including OIG's Compliance Program Guidances (CPGs). OIG developed CPGs as voluntary, nonbinding guidance documents to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. More specifically, beginning in 1998, OIG embarked on a major initiative to engage the private health care community in preventing the submission of erroneous claims and in combating fraud and abuse in Federal health care programs through voluntary compliance efforts. As part of that initiative, OIG developed a series of CPGs directed at the following segments of the health care industry: (1) hospitals;¹ (2) home health agencies;² (3) clinical laboratories;³ (4) third-party medical billing companies;⁴ (5) the durable medical equipment, prosthetics, orthotics, and supply industry;⁵ (6) hospices;⁶ (7) Medicare Advantage (formerly known as Medicare+Choice) organizations;⁷ (8) nursing facilities;⁸ (9) ambulance suppliers;⁹ (10) physicians;¹⁰ and (11) pharmaceutical manufacturers.¹¹

¹ *OIG Compliance Program Guidance for Hospitals*, 63 FR 8987 (Feb. 23, 1998); *Supplemental Compliance Program Guidance for Hospitals*, 70 FR 4858 (Jan. 31, 2005).

² *OIG Compliance Program Guidance for Home Health Agencies*, 63 FR 42410 (Aug. 7, 1998).

³ *OIG Compliance Program Guidance for Clinical Laboratories*, 63 FR 45076 (Aug. 24, 1998).

⁴ *OIG Compliance Program Guidance for Third-Party Medical Billing Companies*, 63 FR 70138 (Dec. 18, 1998).

⁵ *OIG Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry*, 64 FR 36368 (July 6, 1999).

⁶ *OIG Compliance Program Guidance for Hospices*, 64 FR 54031 (Oct. 5, 1999).

⁷ *OIG Compliance Program Guidance for Medicare+Choice Organizations*, 64 FR 61893 (Nov. 15, 1999).

⁸ *OIG Compliance Program Guidance for Nursing Facilities*, 65 FR 14289 (Mar. 16, 2000); *OIG Supplemental Compliance Program Guidance for Nursing Facilities*, 73 FR 56832 (Sept. 30, 2008).

⁹ *OIG Compliance Program Guidance for Ambulance Suppliers*, 68 FR 14245 (Mar. 24, 2003).

¹⁰ *OIG Compliance Program Guidance for Individual and Small Group Physician Practices*, 65 FR 59434 (Oct. 5, 2000).

¹¹ *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 FR 23731 (May 5, 2003).

Based on feedback received as part of OIG’s Modernization Initiative and other input,¹² we understand that CPGs have served as an important and valuable OIG resource for the health care compliance community and industry stakeholders over the last 25 years. OIG has carefully considered ways to improve and update existing CPGs and to deliver new CPGs specific to segments of the health care industry or entities involved in the health care industry that have emerged in the last two decades. In modernizing OIG’s CPGs, our goal is to produce useful, informative resources—as timely as possible—to help advance the industry’s voluntary compliance efforts in preventing fraud, waste, and abuse in the health care system.

Through this Notice, OIG is notifying the public of the following:

- OIG will no longer publish updated or new CPGs in the *Federal Register*. All current, updated, and new CPGs will be available on our website.¹³
- OIG has developed a new format for CPGs:
 - We will publish a General CPG (GCPG) that applies to all individuals and entities involved in the health care industry. The GCPG will address topics such as: federal fraud and abuse laws, compliance program basics, operating effective compliance programs, and OIG processes and resources. We anticipate updating the GCPG as changes in compliance practices or legal requirements warrant. OIG plans to publish the GCPG by the end of calendar year 2023.
 - Second, we will publish industry-specific CPGs (ICPGs) for different types of providers, suppliers, and other participants in health care industry subsectors or ancillary industry sectors relating to Federal health care programs. ICPGs will be tailored to fraud and abuse risk areas for each industry subsector and will address compliance measures that the industry subsector participants can take to reduce these risks. ICPGs are intended to be updated periodically to address newly identified risk areas and compliance measures and to ensure timely and meaningful guidance from OIG. OIG expects to begin publishing ICPGs in calendar year 2024. Currently, OIG anticipates that the first two ICPGs will address Medicare Advantage and nursing facilities.
- When the new GCPG and ICPGs, along with any updates to these documents, are published on OIG’s website, OIG will notify the public using our public listserv¹⁴ and other communications platforms.

Neither OIG’s existing CPGs nor any forthcoming GCPG or ICPG constitutes a model compliance program. Rather, the goal of these documents has been, and will continue to be, to set forth a voluntary set of guidelines and identified risk areas that OIG believes individuals and entities engaged in the health care industry should consider when developing and implementing a new compliance program or evaluating an existing one. Our existing CPGs and supplemental

¹² See, e.g., Department of Health and Human Services, Office of Inspector General, *OIG Modernization Initiative To Improve Its Publicly Available Resources—Request for Information*, 86 FR 53072 (Sept. 24, 2021).

¹³ All CPGs issued to date are currently available on the Compliance Guidance page of our website at <https://oig.hhs.gov/compliance/compliance-guidance/> (last visited Mar. 6, 2023).

¹⁴ To join OIG’s listserv, visit <https://cloud.connect.hhs.gov/OIG/>.

CPGs will remain available for use as an ongoing resource as we develop and publish the GCPG and ICPGs.

DATED: _____

Christi A. Grimm
Inspector General

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