

HCCA Healthcare Enforcement Compliance Conference

OIG General Compliance Program Guidance (GCPG)

November 6, 2023 – Washington, DC

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Old CPGs

New GCPG & ICPGs

Published in Federal Register

Published on our website

<https://oig.hhs.gov/compliance/compliance-guidance/>

Covered both general compliance considerations and tailored risk areas specific to industry sectors

GCPG – consolidated, generally applicable compliance considerations and legal overview
ICPGs – focused fraud and abuse risk areas specific to industry sectors and entities involved in health care

Standalone documents

Hub (GCPG) and spoke (ICPGs) approach

Remain good guidance as applicable
No additional FR supplements will be issued

Greater flexibility to update on our website
• GCPG updated as needed
• ICPGs updated more frequently as new risk areas emerge

Sought comments through FR process

Seek feedback and suggestions for new risk areas on an ongoing basis at compliance@oig.hhs.gov

Available as archived material on OIG website

Current information on OIG website

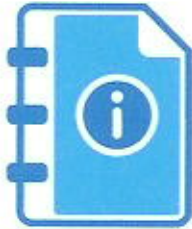


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GCPG User's Guide



- Reference guide
- Table of contents – links to sections
- Accessible on the Internet and downloadable (printer format)
- Defined Terms
 - “should” is used to present voluntary, nonbinding guidance
- Footnotes



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GCPG by Sections

- | | |
|---|---|
| I. Intro | IV. Compliance Program Adaptations for Small and Large Entities |
| II. Health Care Fraud Enforcement and Other Standards: Overview of Certain Federal Laws | V. Other Compliance Considerations |
| III. Compliance Program Infrastructure: The Seven Elements | VI. OIG Resources and Processes |
| | VII. Conclusion |



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II. Legal Overview



A. Federal Anti-kickback Statute (AKS)

- Key questions to help identify problematic arrangements

B. Physician Self-Referral Law (PSL)

- Six elements

C. False Claims Act (FCA)

- Obligation to repay overpayments



**What to Do if You
Identify a Problem**

- OIG Health Care Fraud Self-Disclosure Protocol
- CMS Voluntary Self-Referral Disclosure Protocol



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II. Legal Overview

D. Civil Monetary Penalty Authorities

While False Claims Act cases are pursued by DOJ on behalf of HHS in Federal court, CMP cases are administrative and pursued by OIG before an HHS administrative law judge.

- Presenting a false claim
- Employing an excluded individual
- Medically unnecessary services
- Committing acts described in the AKS
- Emergency Medical Treatment and Labor Act (EMTALA) violations
- Making a false record/statement material to a false claim



**Potential
CMP Liability**



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II. Legal Overview

CMP Highlights

1. Beneficiary Inducements CMP v. AKS: know the similarities and distinctions for compliance training, risk assessments, and policies regarding remuneration to beneficiaries
2. Information Blocking: individuals and entities that meet the definition of health care provider under Office of the National Coordinator for Health Information Technology (ONC) regulations should be mindful that they may be subject to CMPs enforced by OIG
3. CMP Authority Related to HHS Grants, Contracts, and Other Agreements



Tip

- It is important for HHS awardees to understand what conduct leads to liability under OIG's authority, as well as under other fraud and abuse laws, and to put internal controls into place to prevent and identify these issues early.
- Self-disclosure information specific to HHS grants and contracts
<https://oig.hhs.gov/compliance/self-disclosure-info/>



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II. Legal Overview

E. Exclusion Authorities

- List of Excluded Individuals / Entities (LEIE)
- Mandatory v. Permissive
- State Medicaid Exclusion Authorities



Tip

Many providers and their staff employ excluded individuals because they incorrectly believe it is permissible to employ excluded individuals (for example, because an employee obtains a new health care license or has received permission from a State agency to practice, has an administrative role, cannot separately bill).



Tip

If an entity discovers that it has employed or contracted with an excluded individual or entity, the entity should evaluate its overpayment and CMP liability. We recommend that entities in this situation consider whether to submit a self-disclosure through the Health Care Fraud Self-Disclosure Protocol.



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II. Legal Overview

F. Criminal Health Care Fraud Statute



Health care fraud schemes that often involve complex money laundering, tax, and other associated financial criminal offenses

- Fines of up to \$250,000, imprisonment of not more than 10 years, or both



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II. Legal Overview

G. HIPAA Privacy and Security Rules

HHS Office for Civil Rights (OCR) is responsible for administering and enforcing the HIPAA Privacy, Security, and Breach Notification Rules.



Tip

An entity regulated by Privacy Rule requirements should ensure that it is compliant with all applicable provisions of the Privacy Rule, including provisions pertaining to required disclosures (and permitted uses and disclosures), when developing its privacy procedures that are tailored to fit the entity's particular size and needs.



HIPAA Security Risk Assessment Tool

- <https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool>

National Institute of Standards and Technology (NIST) Toolkit

- <https://csrc.nist.gov/projects/security-content-automation-protocol/hipaa>



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III. Compliance: The Seven Elements

7 Elements of a Successful Compliance Program

1. Written Policies and Procedures
2. Compliance Leadership and Oversight
3. Training and Education
4. Effective Lines of Communication with the Compliance Officer and Disclosure Program
5. Enforcing Standards: Consequences and Incentives
6. Risk Assessment, Auditing, and Monitoring
7. Responding to Detected Offenses and Developing Corrective Action Initiatives



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Compliance Officer's Primary Responsibilities

The Compliance Officer's primary responsibilities should include advising the CEO, board, and other senior leaders on compliance risks facing the entity, compliance risks related to strategic and operational decisions of the entity, and the operation of the entity's compliance program.



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Duties of Compliance Committee

Member attendance, active participation, and contributions should be included in each member's performance plan and compensation evaluation.



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Board Role

The board should ensure that the compliance officer has sufficient power, independence, and resources to implement, maintain, and monitor the entity's compliance program and advise the board about the entity's compliance operations and risk.



As OIG has stated in the Practical Guidance for Health Care Boards on Compliance Oversight, "[s]cheduling regular executive sessions creates a continuous expectation of open dialogue, rather than calling such a session only when a problem arises, and is helpful to avoid suspicion among management about why a special executive session is being called."



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Effective Lines of Communication and Disclosure Programs

An open line of communication between the compliance officer and entity personnel (including contractors and agents) is critical to the successful implementation of a compliance program and the reduction of any potential for fraud, waste, and abuse



Tip

Some entities may have compliance departments, any member of whom may receive compliance concerns. Other entities may have facilities in multiple locations, each with their own facility compliance officer. Any of these would be considered designees.



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Compliance Incentives

For a compliance program to be effective, the organization should establish appropriate consequences for instances of noncompliance, as well as incentives for compliance.



Tip

Although an entity may not be able to publicly recognize an individual who raises a substantiated concern that results in the mitigation of harm or risk, the entity should find a way to recognize this in the performance reviews of individuals. This, of course, is not possible for people who wish to remain anonymous. Also, this does not apply to individuals who raise compliance or legal violations for which they themselves committed or were responsible.



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Risk Assessments

...in recent years OIG, the compliance community, and other stakeholders have come to recognize and place increasing emphasis upon the importance of a formal compliance risk assessment process as part of the compliance program.



Tip

Entities that want to conduct compliance risk assessments more often should ensure that they dedicate the necessary time and resources for each compliance risk assessment they perform during the year.



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IV. Compliance Program Adaptations Small Entities



- Compliance Contact
- Open Lines of Communication
- Risk Assessment



Tip

An excluded employee or an employee with a lapsed license can have a significant impact on a small entity.



Tip

A corrective action plan may include policy and process revisions, education of personnel, a revision to the entity's training plan, and consequences for offending individuals.



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IV. Compliance Program Adaptations Large Entities



- Compliance Departments
- Compliance Subcommittees
- Board Role



Tip

To the extent possible, given the facility or location's staffing constraints, the facility compliance officer should not have responsibility for clinical, financial, legal, or operational duties.



Tip

Boards of large organizations operating in the United States but owned or controlled by international organizations should ensure that the parent board is provided with sufficient information about the applicable law, Federal health care program requirements, and the compliance risks presented by the operation of the U.S. organization.



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V. Other Compliance Considerations



- Quality and Patient Safety
- New Entrants in the Health Care Industry
- Financial Incentives: Ownership and Payment—Follow the Money
- Financial Arrangements Tracking



Tip

Forthcoming ICPGs will address industry subsector-specific risk areas for different types of providers, suppliers, and other participants in health care industry subsectors or ancillary industry sectors relating to Federal health care programs. Our existing CPGs and supplemental CPGs will remain available for use as ongoing resources to help identify risk areas in particular industry segments as we develop the ICPGs.



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VI. OIG Resources and Processes

- Compliance Toolkits
- RAT-STATS Statistical Software
- Reports and Publications
- Advisory Opinions, Special Fraud Alerts, Bulletins, and other guidance
- Safe harbor regulations
- Frequently Asked Questions
- Corporate Integrity Agreements
- Enforcement Action Summaries
- OIG Self-Disclosure Information
- OIG Hotline



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VII. Conclusion

Compliance@oig.hhs.gov

- Submit feedback about compliance considerations and risk areas

Our Contact Info

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- Laura.Ellis@oig.hhs.gov

<https://oig.hhs.gov/compliance/compliance-guidance/>



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