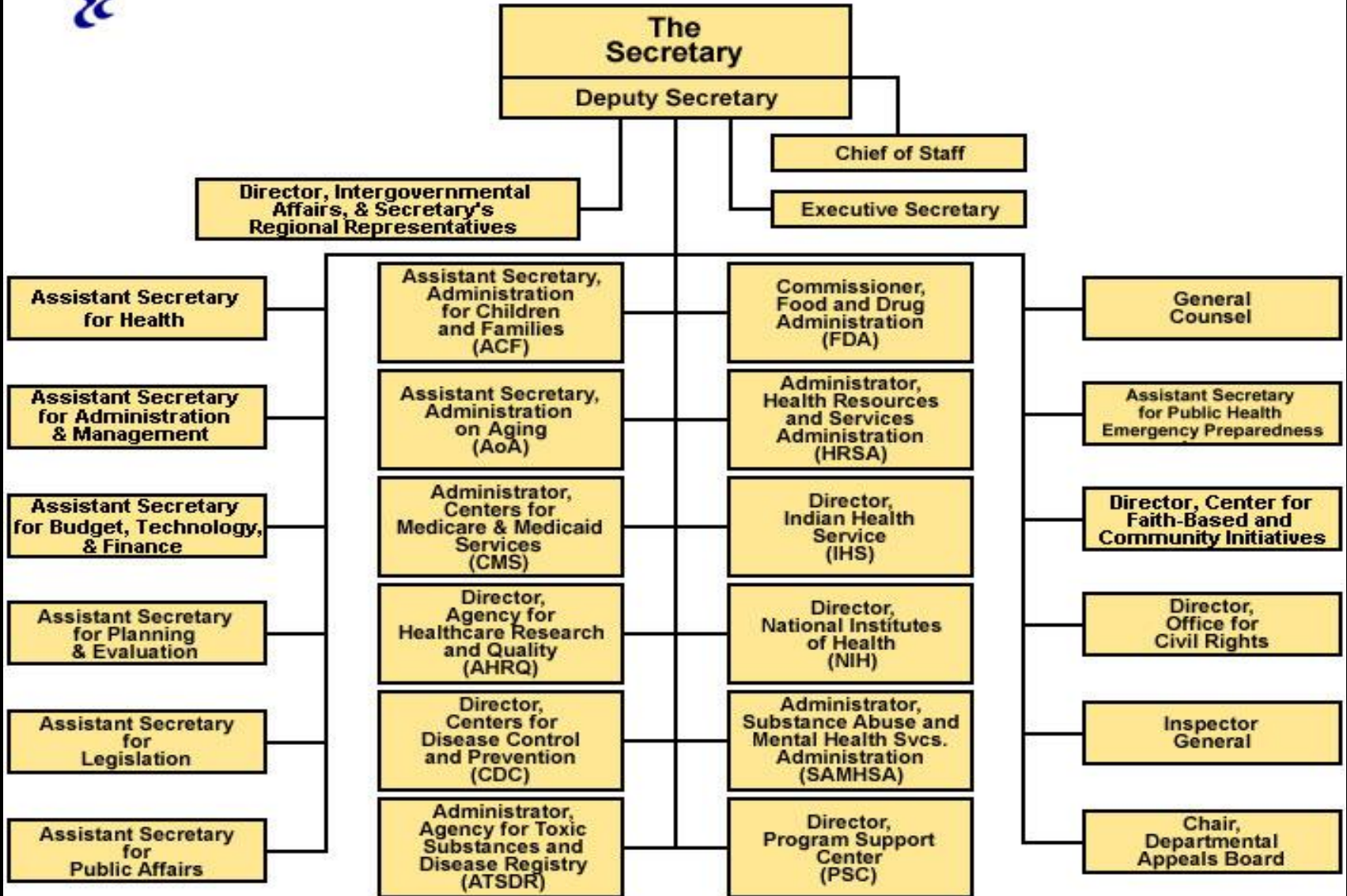


HHS-OIG: Introduction and Essentials

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What is the HHS OIG?

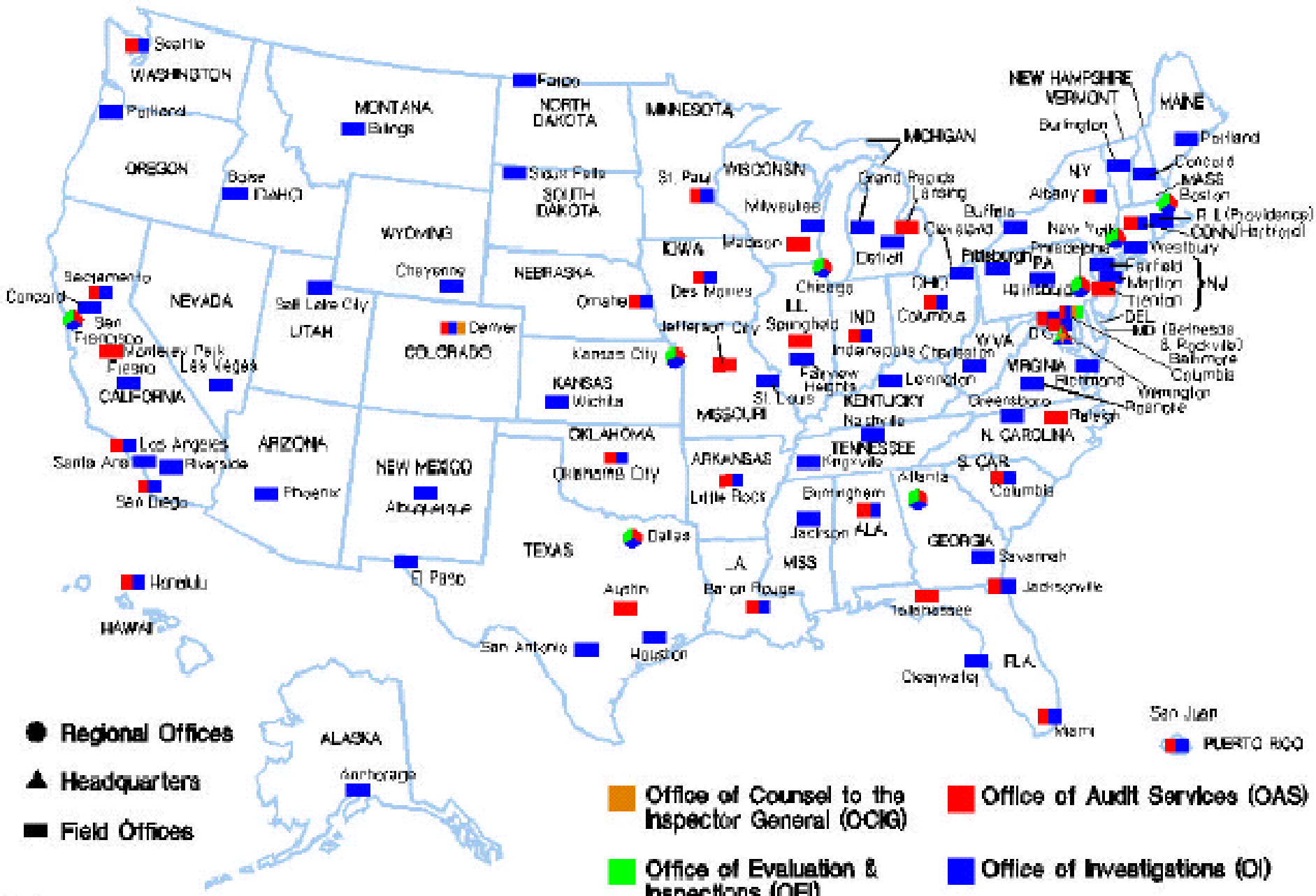
- One of many operating divisions of the U.S. Department of Health and Human Services (HHS)
- Office of Inspector General (OIG) focuses on preventing, detecting fraud and abuse in HHS programs



Relevant components of OIG

- Office of Evaluation and Inspections
- Office of Audit Services
 - Reports of both components are on OIG website: oig.hhs.gov
- Office of Investigations
 - Investigative agents
- Office of Counsel to the Inspector General (OCIG)

OIG Component Locations



OCIG – Administrative and Civil Remedies Branch

- Administrative and Civil Remedies Branch
 - Serves as HHS point of contact for DOJ
 - Represents HHS in False Claims Act cases
 - Handles administrative issues involved in settlements
 - Exclusion
 - Corporate Integrity Agreement (CIA)

OCIG – Administrative and Civil Remedies Branch

- Organized into 4 teams according to OIG geographic region and/or subject matter
 - Team 1: Chicago, KC, and NY regions
 - Team 2: Dallas, SF, Miami, and Boston regions
 - Team 3: Atlanta, LA, and Phila regions
 - Team 4: Compliance Monitoring, Exclusions Policy, and FOIA

What is exclusion?

- Prospective administrative remedy
- Exclusion means no payment for items/services furnished by excluded provider
- OIG has sole authority for federal exclusion

What is the authority for exclusion?

- 42 U.S.C. § 1320a-7
- 42 C.F.R. Part 1001
- Exclusion applies to direct providers (*e.g.*, doctors, hospitals) and indirect providers (*e.g.*, drug manufacturers, device manufacturers)
- Exclusion applies to individuals and entities

What is the basis for exclusion?

- 20 statutory bases for exclusion
- 4 bases for mandatory exclusion
 - Based on convictions for specified crimes
- 16 bases for permissive exclusion, including:
 - 42 U.S.C. § 1320a-7(b)(7) - affirmative
 - 42 U.S.C. § 1320a-7(b)(1) - derivative

Why is exclusion relevant to False Claims Act (FCA) cases?

- In civil cases, conduct that results in FCA liability also forms a basis for affirmative permissive exclusion.
- In criminal cases, pleas/convictions for many criminal violations implicate derivative exclusion, including mandatory exclusion.
- Coordination with OIG is critical.

Does OIG release exclusion as part of resolving cases?

- The exclusion decision depends on the nature of the case.
- Mandatory exclusion
- Derivative permissive exclusion
 - Presumption in favor of exclusion
- In many FCA civil cases, OIG will release exclusion in exchange for defendant's agreement to enter a CIA.

OCIG Role in FCA Settlements

- Recognize DOJ lead responsibility for FCA
- OCIG is a signatory to settlement agreements
- Exclusion Release/Agreement/Reservation
- Represent HHS Interests
 - Consistency (*e.g.*, DOJ model settlement terms)
 - CMS interests

What are some key aspects of civil settlements from OIG's perspective?

■ Settlement Amount

- Single damages calculation
- Multiplier and rationale
- Low settlement multipliers – greater scrutiny

■ Definition of Covered Conduct

- Should be narrowly tailored
 - time period
 - conduct
- No broader than conduct investigated

What are some key aspects of civil settlements from OIG's perspective?

- Monetary Releases
 - DOJ model settlement agreement
 - Cannot release CMS authorities
 - Cannot release criminal conduct

What are some key aspects of civil settlements from OIG's perspective?

- **OIG Exclusion Authorities**
 - Within the sole jurisdiction of OIG
 - OIG will usually not release individuals or entities not entering into CIA
 - Even if they get FCA release
 - Release of exclusion is usually conditioned on defendant executing a CIA

What is a Corporate Integrity Agreement (CIA)?

- 5-year contract between OIG and provider
- Alternative to exclusion
- Negotiated and monitored by OIG
- Posted on OIG's website

What is a Corporate Integrity Agreement (CIA)?

- CIA requires compliance elements including:
 - Compliance Officer/Committee
 - Training – general and specialized
 - Written policies
 - Audits
 - Reports to OIG

Holding Individuals Accountable

- Identifying Responsible Individuals
 - Collect evidence during the investigation
- Prosecution of Responsible Individuals
 - Criminal cases against Responsible Corporate Officers (RCOs)
 - Exclusion of convicted RCOs

Holding Individuals Accountable

- Exclusion of individuals under 42 U.S.C. § 1320a-7(b)(15)
- This provision authorizes exclusion of certain individual owners and of officers and managing employees of a “sanctioned entity”.

Exclusion of Individuals under 42 U.S.C. § 1320a-7(b)(15)

- Individuals with **ownership or control interest** in sanctioned entity may be excluded if they *knew or should have known* of conduct that led to the sanction.
- **Officers and managing employees** may be excluded solely based on their *position* with the sanctioned entity.