

Compliance Risk Areas

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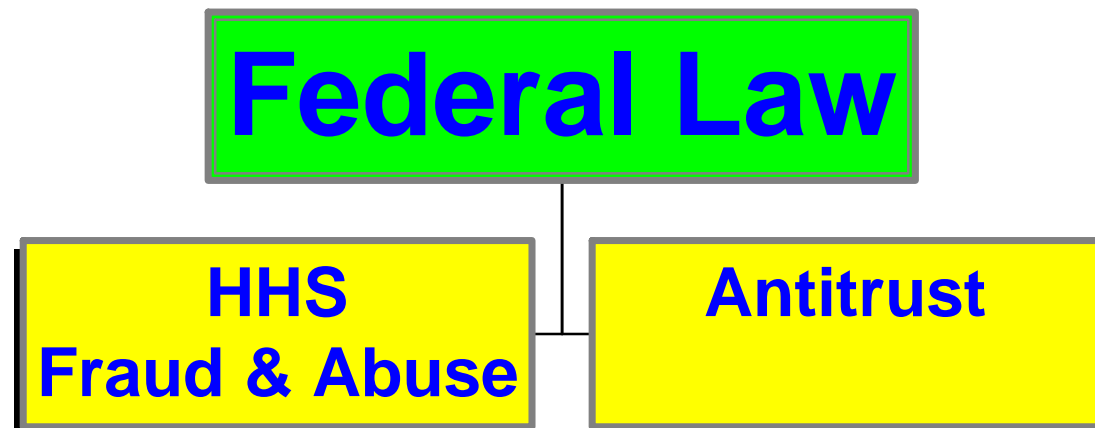
June 11, 2001
Washington, DC

Risk Areas

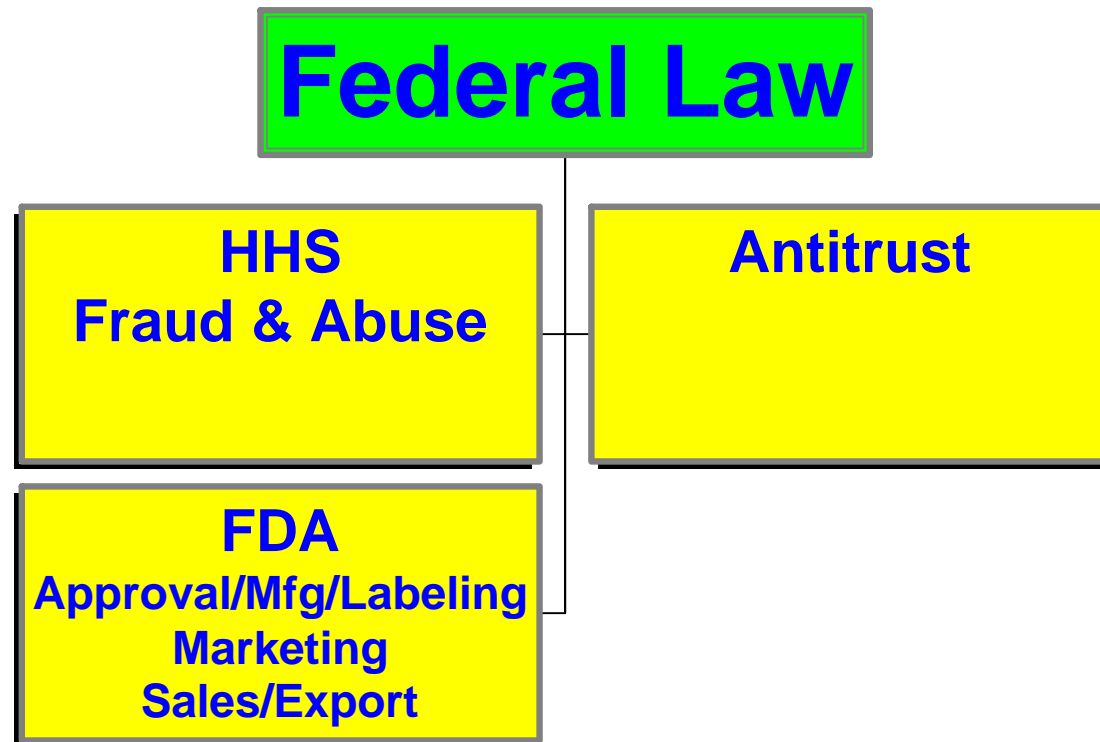
Federal Law

**HHS
Fraud & Abuse**

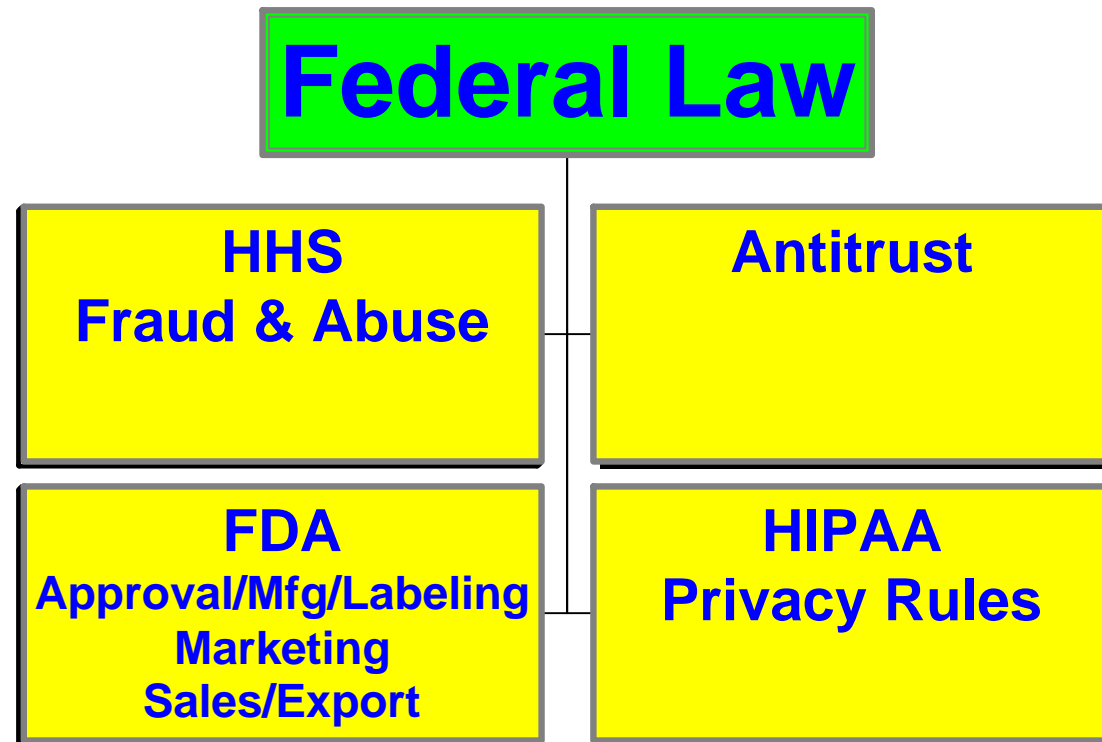
Risk Areas



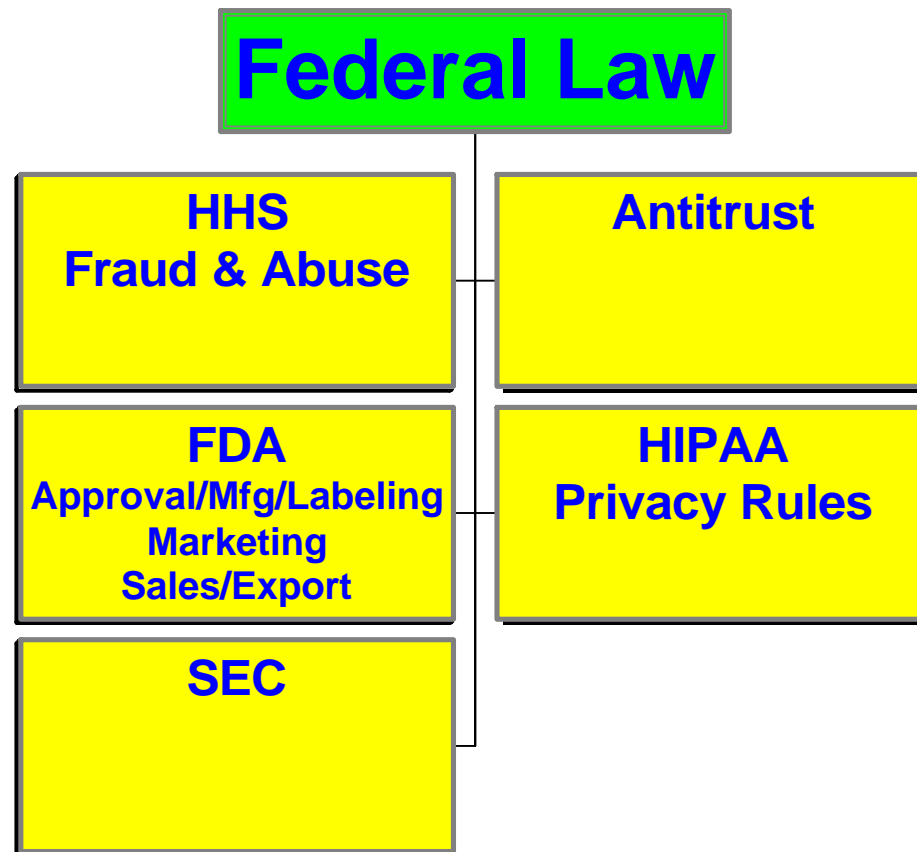
Risk Areas



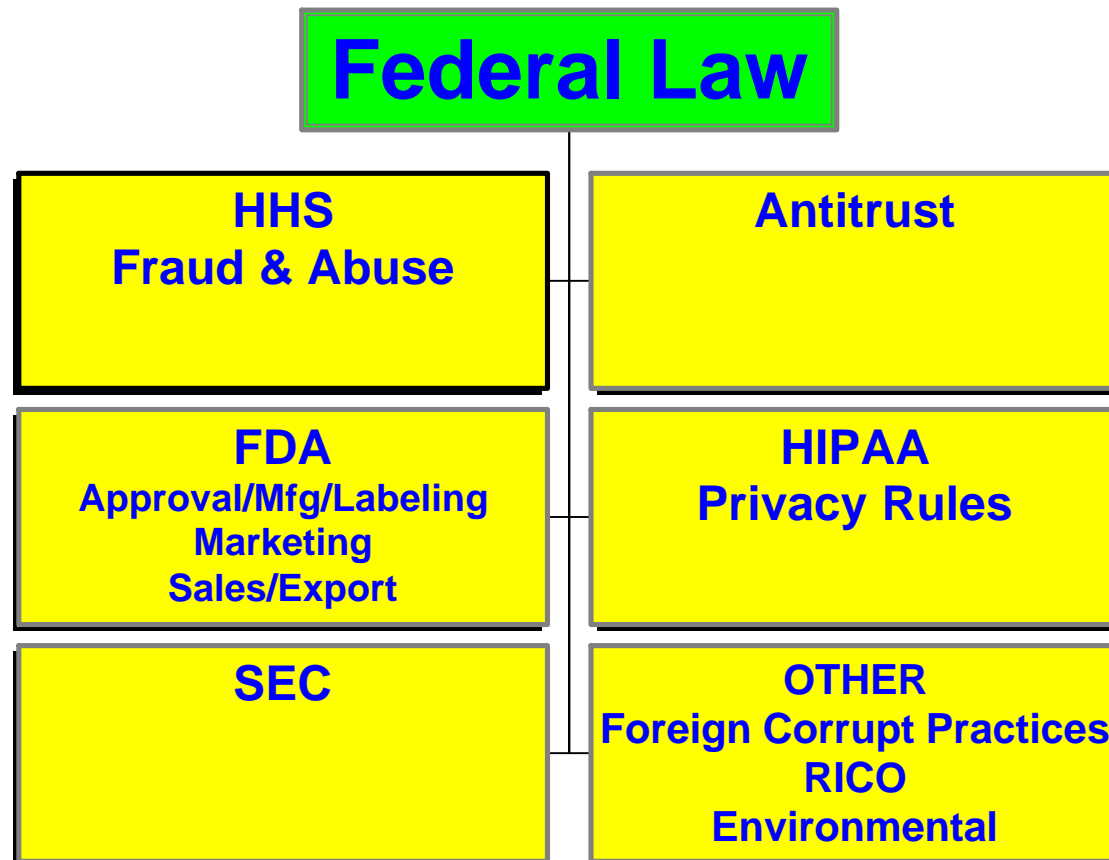
Risk Areas



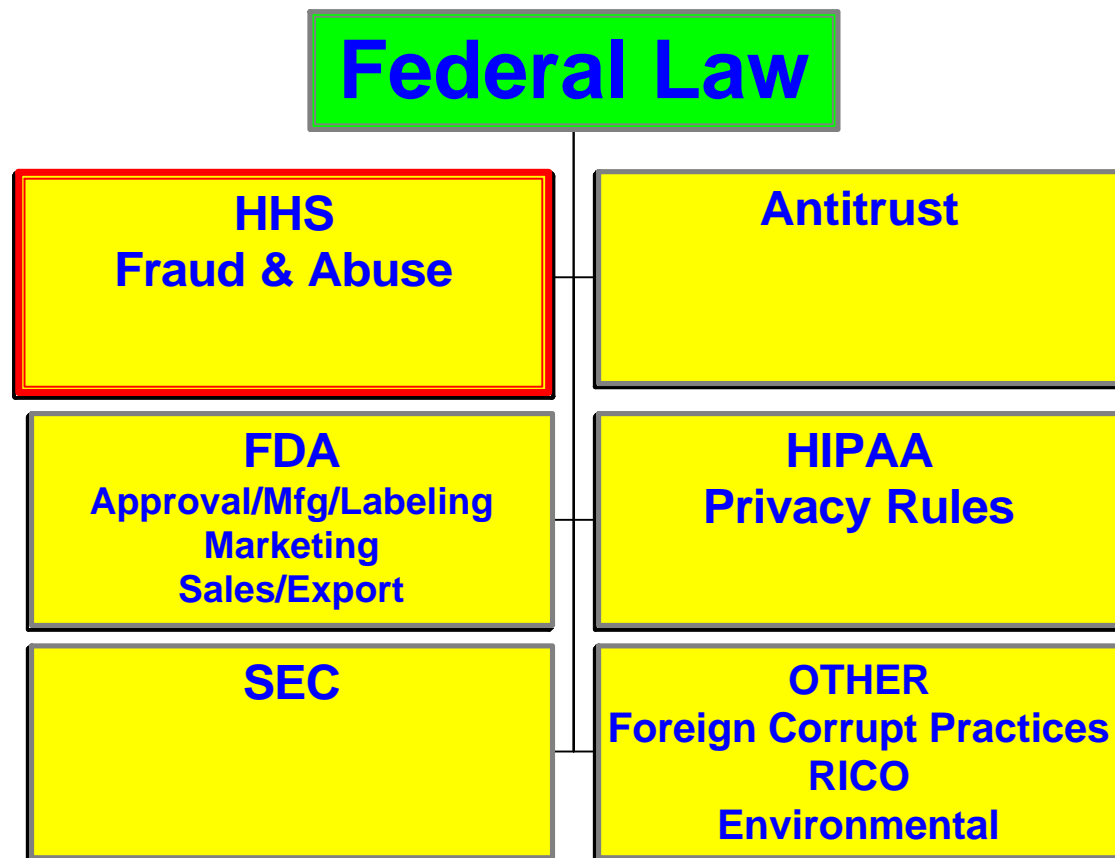
Risk Areas



Risk Areas



Risk Areas



Federal Law

HHS
Fraud & Abuse

OIG

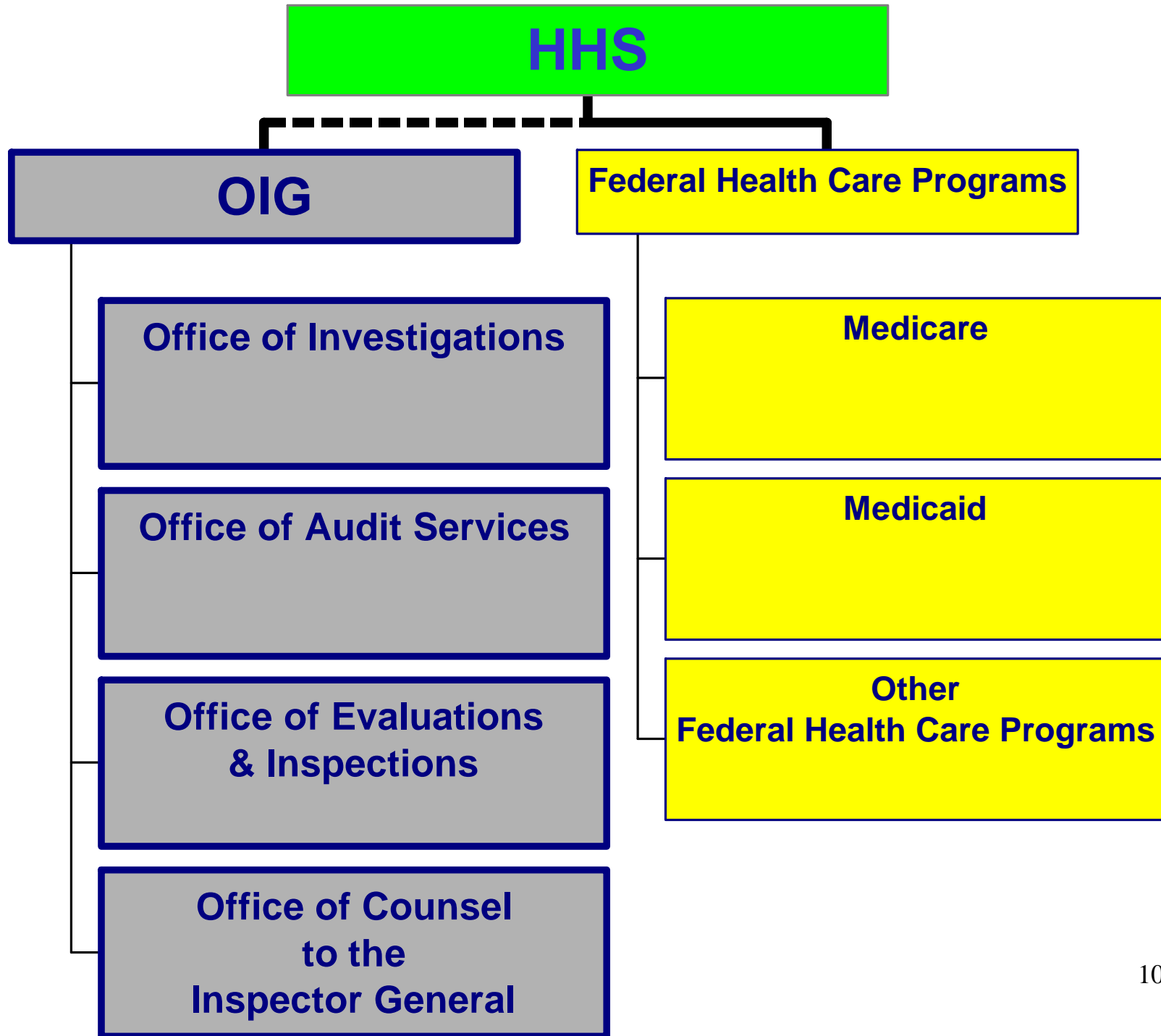
FDA
Approval/Mfg/Labeling
Marketing
Sales/Export

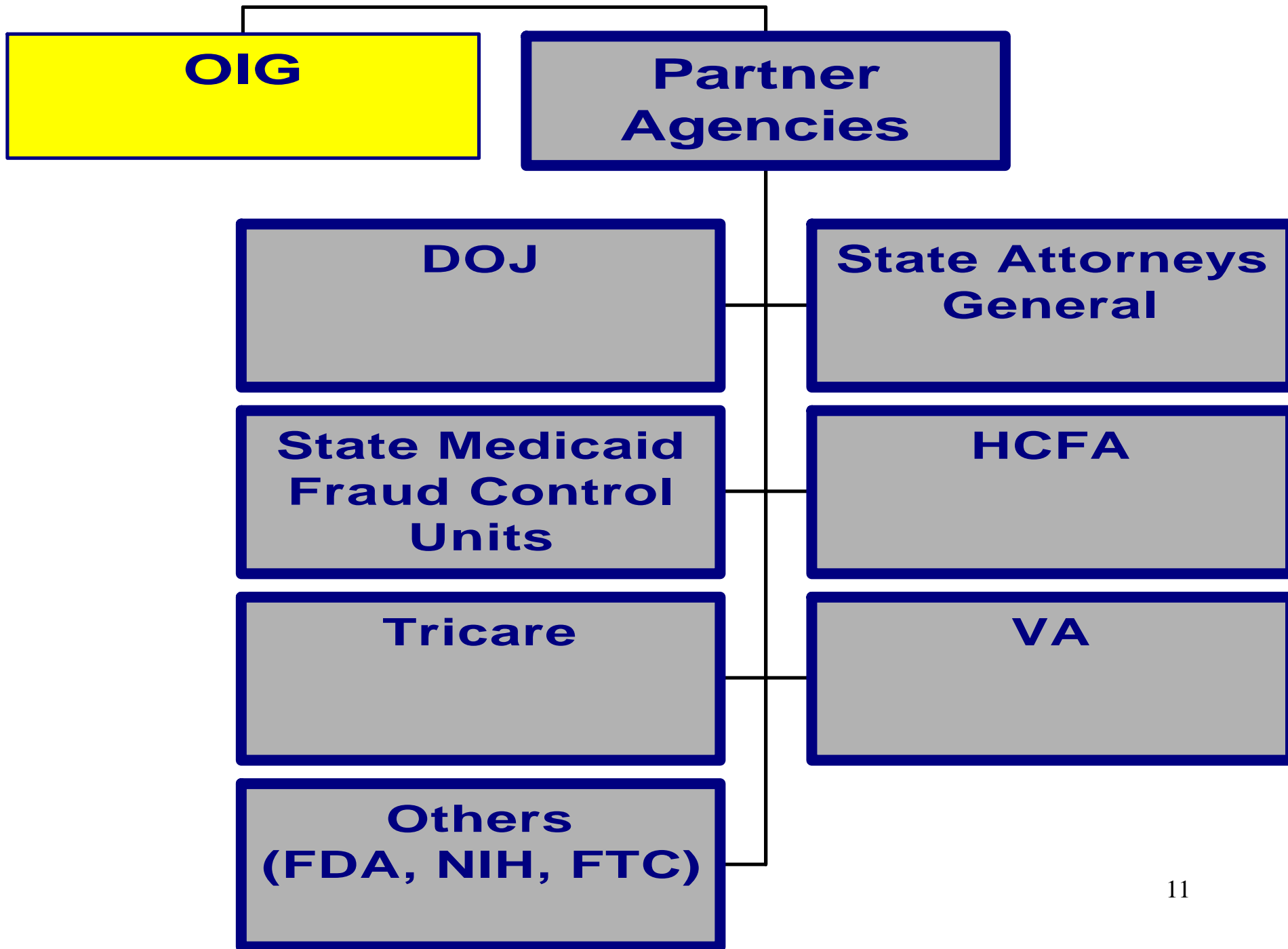
SEC

Antitrust

HIPAA
Privacy Rules

OTHER
Foreign Corrupt Practices
RICO
Environmental





Relevant Authorities

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graph TD; A[Relevant Authorities] --- B[Federal False Claims Act]; A --- C[Federal Anti-Kickback Statute]; A --- D[Analogous State Laws];
```

**Federal
False Claims Act**

**Federal
Anti-Kickback Statute**

**Analogous
State Laws**

Federal False Claims Act

31 U.S.C. § 3729-3733

- **Submitting/causing to submit a claim for payment to the Federal Government**
- **False or fraudulent claim**
- **Acts “knowingly”**
- **Treble damages plus penalties**

Federal Anti-Kickback Statute

42 U.S.C. § 13201-7b(b)

- Remuneration (anything of value)
- Offered, paid, solicited or received
- To induce or reward referrals of Federal health care program business
- Knowingly and willfully
- Imprisonment and/or criminal fines; CMPs; exclusion

Exclusion

- **Meaning/Effect**
- **Types (mandatory and permissive)**
- **Reach of Exclusion**
 - **Direct and indirect providers**

OIG Guidance

www.dhhs.gov/oig

- **OIG Annual Work Plan**
- **Reports by OEI/OAS**
- **Special Fraud Alerts**
- **Advisory Opinions**
- **Compliance Program Guidance**

Advisory Opinions

42 C.F.R. Part 1008

- Does actual/contemplated transaction violate the Federal anti-kickback statute?
- Written opinion
- Binding for HHS and requestor

Compliance Program Guidance

- Voluntary
- OIG suggestions for internal controls, monitoring procedures
- Risk areas identified

Fraud & Abuse Risks

Fraud & Abuse Risks

Sales & Marketing

Fraud & Abuse Risks

Sales & Marketing

Gifts

Fraud & Abuse Risks

Sales & Marketing

Gifts

Monetary

Fraud & Abuse Risks

Sales & Marketing

Gifts

Monetary

Merchandise

Fraud & Abuse Risks

Sales & Marketing

Gifts

Monetary

Merchandise

Travel & Entertainment

Fraud & Abuse Risks

Sales & Marketing

Gifts

Monetary

Merchandise

Travel &
Entertainment

Drug
Products

**Fraud & Abuse
Risks**

Sales & Marketing

Gifts

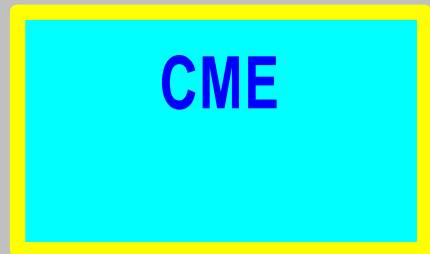
Monetary

Merchandise

**Travel &
Entertainment**

**Drug
Products**

CME



Fraud & Abuse Risks

Sales & Marketing

Gifts

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Educational

**Fraud & Abuse
Risks**

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graph TD; A[Fraud & Abuse Risks] --- B[Sales & Marketing]; B --- C[Gifts]; B --- D[Grants]; D --- E[Educational]; D --- F[Training/Preceptorships];
```

Sales & Marketing

Gifts

Grants

Educational

**Training/
Preceptorships**

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Educational

Training/
Preceptorships

Research



Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Educational

Training/
Preceptorships

Research

Phase IV
Clinical Trials

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional Activities

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional
Activities

Off-Label
Product Promotion

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional Activities

Off-Label Product Promotion

Direct-to-Consumer Marketing

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional Activities

Off-Label
Product Promotion

Direct-to-Consumer
Marketing

Programs
(Rebates and Discounts)

**Fraud & Abuse
Risks**

Sales & Marketing

Gifts

Grants

**Promotional
Activities**

**Off-Label
Product Promotion**

**Direct-to-Consumer
Marketing**

**Programs
(Rebates and Discounts)**

**Services
(Cognitive,
Disease Management,
Reimbursement)**

**Fraud & Abuse
Risks**

Sales & Marketing

Gifts

Grants

**Promotional
Activities**

**Off-Label
Product Promotion**

**Direct-to-Consumer
Marketing**

**Programs
(Rebates, Discounts)**

**Cooperative
Sales & Marketing
Agreements**

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional
Activities

Fraud & Abuse Risks

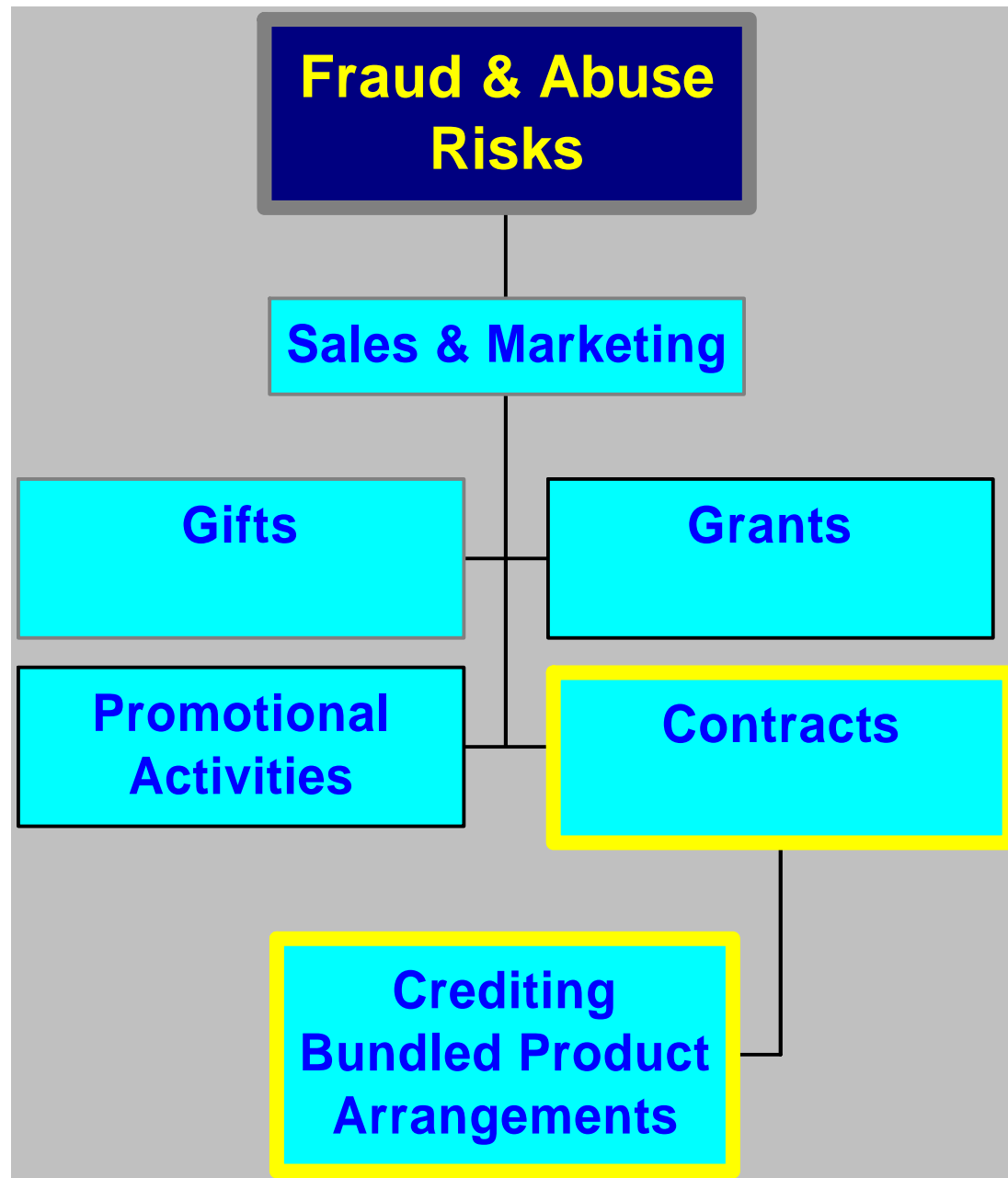
Sales & Marketing

Gifts

Grants

Promotional Activities

Contracts



Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional Activities

Contracts

Crediting
Bundled Product
Arrangements

GPOs, Wholesalers
Pharmacies, PBMCs

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional
Activities

Contracts

Crediting
Bundled Product
Arrangements

GPOs, Wholesalers
Pharmacies, PBMCs

Federal Health
Care Programs
(Medicaid Drug Rebates
State PBMs)

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional Activities

Contracts

Crediting
Bundled Product
Arrangements

GPOs, Wholesalers
Pharmacies, PBMCs

Federal Health
Care Programs
(Medicaid Drug Rebates)
State PBMs

Pricing
(Tricare, VA)

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional
Activities

Contracts

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional
Activities

Contracts

Compensation
Arrangements

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional Activities

Contracts

Compensation Arrangements

Sales/Marketing Staff

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional
Activities

Contracts

Compensation
Arrangements

Sales/Marketing
Staff

Independent
Contractors



Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional Activities

Contracts

Compensation Arrangements

Sales/Marketing Staff

Independent Contractors

External Advisors

Speakers/ Writers

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

**Promotional
Activities**

Contracts

**Compensation
Arrangements**

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional
Activities

Contracts

Compensation
Arrangements

Excluded,
Sanctioned and Debarred
Individuals and
Entities

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional Activities

Contracts

Compensation Arrangements

Excluded, Sanctioned and Debarred Individuals and Entities

OIG List

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional
Activities

Contracts

Compensation
Arrangements

Excluded,
Sanctioned and Debarred
Individuals and
Entities

OIG List

GSA List

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional
Activities

Contracts

Compensation
Arrangements

Excluded,
Sanctioned and Debarred
Individuals and
Entities

Pricing

**Fraud & Abuse
Risks**

Sales & Marketing

Gifts

Grants

**Promotional
Activities**

Contracts

**Compensation
Arrangements**

**Excluded,
Sanctioned and Debarred
Individuals and
Entities**

Pricing

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional Activities

Contracts

Compensation Arrangements

Excluded, Sanctioned and Debarred Individuals and Entities

Pricing

Reporting
First Data Bank
Medicaid
Private Payors

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

Promotional Activities

Contracts

Compensation Arrangements

Excluded, Sanctioned and Debarred Individuals and Entities

Pricing

Reporting to First Data Bank and Red Book

Reporting to Medicaid Agencies

Fraud & Abuse Risks

Sales & Marketing

Gifts

Grants

**Promotional
Activities**

Contracts

**Compensation
Arrangements**

**Excluded,
Sanctioned and Debarred
Individuals and
Entities**

Pricing

Fraud & Abuse Risks

Sales & Marketing

Monitoring

Gifts

Grants

Promotional
Activities

Contracts

Compensation
Arrangements

Excluded,
Sanctioned and Debarred
Individuals and
Entities

Pricing

Fraud & Abuse Risks

Sales & Marketing

Monitoring

Gifts

Grants

Continuous Testing

Promotional
Activities

Contracts

Compensation
Arrangements

Excluded,
Sanctioned and Debarred
Individuals and
Entities

Pricing

Fraud & Abuse Risks

Sales & Marketing

Gifts

Promotional Activities

Compensation Arrangements

Pricing

Grants

Contracts

Excluded,
Sanctioned and Debarred
Individuals and
Entities

Monitoring

Continuous Testing

Corrective Action

Compliance Risk Areas

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