FRAUD AND ABUSE LAWS

KIM C. STANGER

Compliance Bootcamp

(2/20)

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OVERVIEW

The statutes

- False Claims Act
- Anti-Kickback Statute
- Eliminating Kickbacks in Recovery Act ("EKRA")
- Ethics in Patient Referrals Act ("Stark")
- Civil Monetary Penalties Law
- Healthcare Fraud

Common traps

- Free or discounted items to patients
- Free or discounted items to referral sources
- Provider contracts or financial arrangements
- Excluded entities

Report and repay obligations

- Requirements
- Suggestions for responding

CAUTION

- This is a quick overview of relevant laws.
- Application may change depending on—
  - Circumstances of your particular case
  - Payor involved
  - Jurisdiction
- We are focusing on—
  - Federal law
  - Idaho law
- Be sure to confirm applicable laws and requirements when applying to your fact situation.

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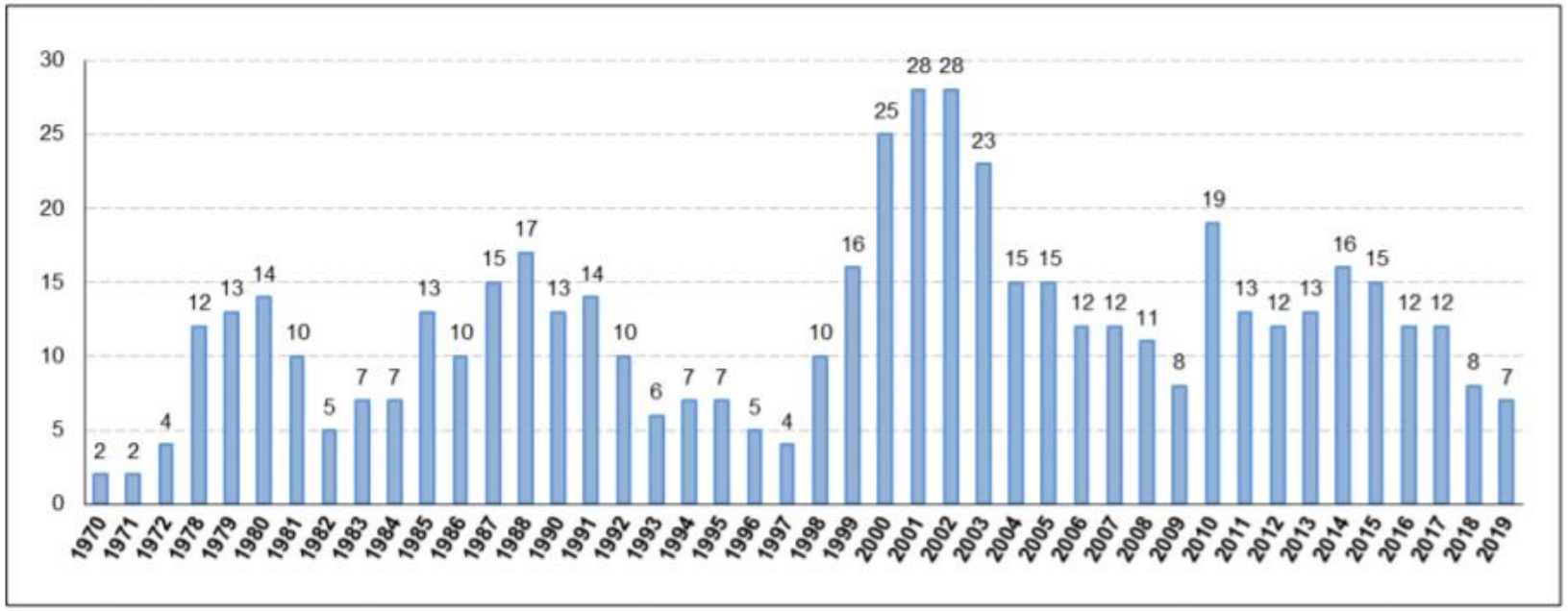
Medicare: Insolvency Projections

Updated July 3, 2019

Figure 1. Projected Number of Years Until Medicare HI Trust Fund Insolvency



Sources: Intermediate projections of various Medicare Trustees Reports, 1970-2019.

Notes: No specific estimates were provided by the Medicare trustees for years 1973-1977 and 1989.

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Thursday, January 9, 2020

Justice Department Recovers over $3 Billion from False Claims Act Cases in Fiscal Year 2019

The Department of Justice obtained more than $3 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending Sept. 30, 2019, Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division announced today. Recoveries since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than $62 billion.

"The significant number of settlements and judgments obtained over the past year demonstrate the high priority this administration places on deterring fraud against the government and ensuring that citizens' tax dollars are well spent," said Assistant Attorney General Hunt. "The continued success of the department's False Claims Act enforcement efforts are a testament to the tireless efforts of the civil servants who investigate, litigate, and try these important cases as well as to the fortitude of whistleblowers who report fraud."

GOVERNMENT ENFORCEMENT

- Government investigations
  - Data analytics
  - Contractors
  - Survey agencies reporting to fraud units
- Qui tam lawsuits
  - Private parties sue on behalf of the govt
  - Receive percentage of recovery
- Must self-report and repay
  - Failure to timely report overpayment = False Claims Act violation
- DOJ focus on holding individuals responsible for corporate actions
  - "Yates memo" and aftermath

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JUSTICE NEV

Of the $3 billion recovered in FY 2019:

- $2.6 billion recovered for healthcare fraud.
- $2.1 billion arose from qui tam lawsuits.
- $295 million paid to qui tam relators.
- "The department continued its commitment to use the False Claims Act and other civil remedies to deter and redress fraud by individuals as well as corporations. "

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INCREASED PENALTIES

	Old Penalty	New Penalty
False Claims Act	$5,500 to $11,000 per claim	$11,781* to $21,563* per claim
• Failure to repay		$20,866* per claim
Anti-Kickback Statute	$25,000 criminal penalty 5 years in prison	$100,000 criminal penalty 10 years in prison
	$50,000	$104,330* civil penalty
Stark Law	$15,000 per claim	$25,820* per claim
• Circumvention scheme	$100,000	$172,137*
Civil Monetary Penalties Law		$20,866* to $104,330*
• Induce beneficiaries	$10,000	$20,866*
• Induce physicians	$2,000	$5,126*
• Excluded Provider	$10,000	$20,866*
(See 45 CFR 102.3; 84 FR 1352)		* Subject to periodic adjustment

FRAUD AND ABUSE LAWS

- False Claims Act
- Anti-Kickback Statute ("AKS")
- Eliminating Kickbacks in Referrals Statute ("EKRA")
- Ethics in Physician Referrals Act ("Stark")
- Civil Monetary Penalties Law ("CMPL")
- State law comparables

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FALSE CLAIMS ACT

- Cannot knowingly submit a false claim for payment to the federal govt, e.g.,
  - Not provided as claimed
  - Substandard care
  - Failure to comply with regulations
- Must report and repay an overpayment within the later of 60 days or date cost report is due.

(31 USC 3729; 42 USC 1320a-7a(a); 42 CFR 1003.200)

Penalties

- Repayment plus interest
- Civil monetary penalties of $11,181* to $22,363* per claim
- Admin penalty $20,866* per claim failed to return
- 3x damages
- Exclusion from Medicare/Medicaid

(42 USC 1320a-7a(a); 42 CFR 1003.210; 45 CFR 102.3)

➢ *Subject to qui tam claims*

FALSE CLAIMS ACT

- *U.S. ex rel. Drakeford v. Tuomey Healthcare System* (4th Cir. 2013)
  - Part-time employment contracts violated Stark.
    - $39,313,065 x 3 damages = $117,939,195
    - 21,730 false claims x $5,500 per claim = $119,515,000

    $237,454,195 judgment

➢ Ultimately settled for $72.4 million.

➢ Relator received $18 million.

ANTI-KICKBACK STATUTE

- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by government program unless transaction fits within a regulatory safe harbor.

(42 USC 1320a-7b(b); 42 CFR 1003.300(d))

- "One purpose" test

(*US v. Greber* (1985))

Penalties

- 10 years in prison
- $100,000 criminal fine
- $104,330* civil penalty
- 3x damages
- Exclusion from Medicare/Medicaid

(42 USC 1320a-7b(b); 42 CFR 1003.310; 45 CFR 102.3)

➢ *Automatic False Claims Act violation*

(42 USC 1320a-7a(a)(7))

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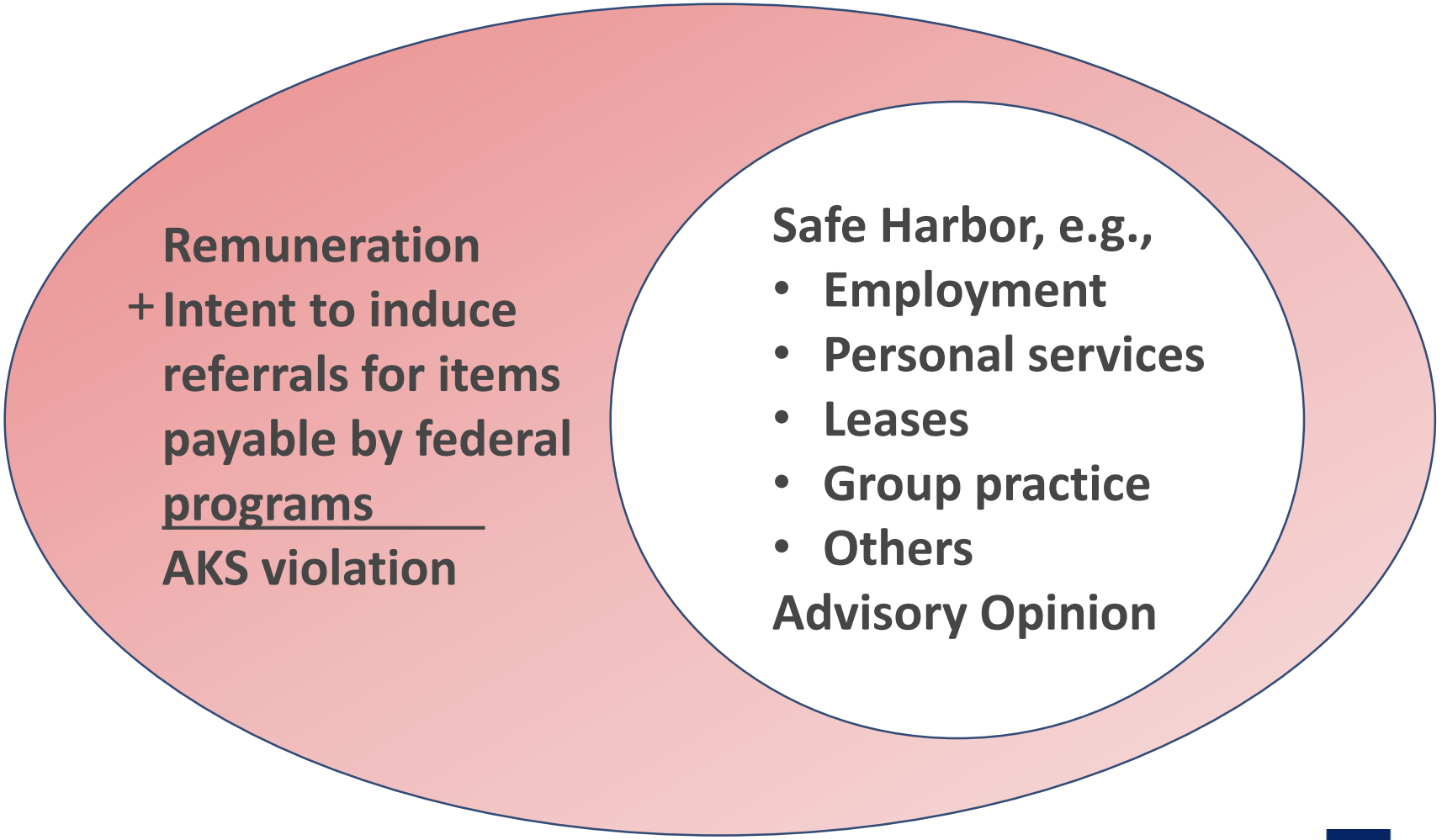
ANTI-KICKBACK STATUTE



ANTI-KICKBACK STATUTE: SAFE HARBORS

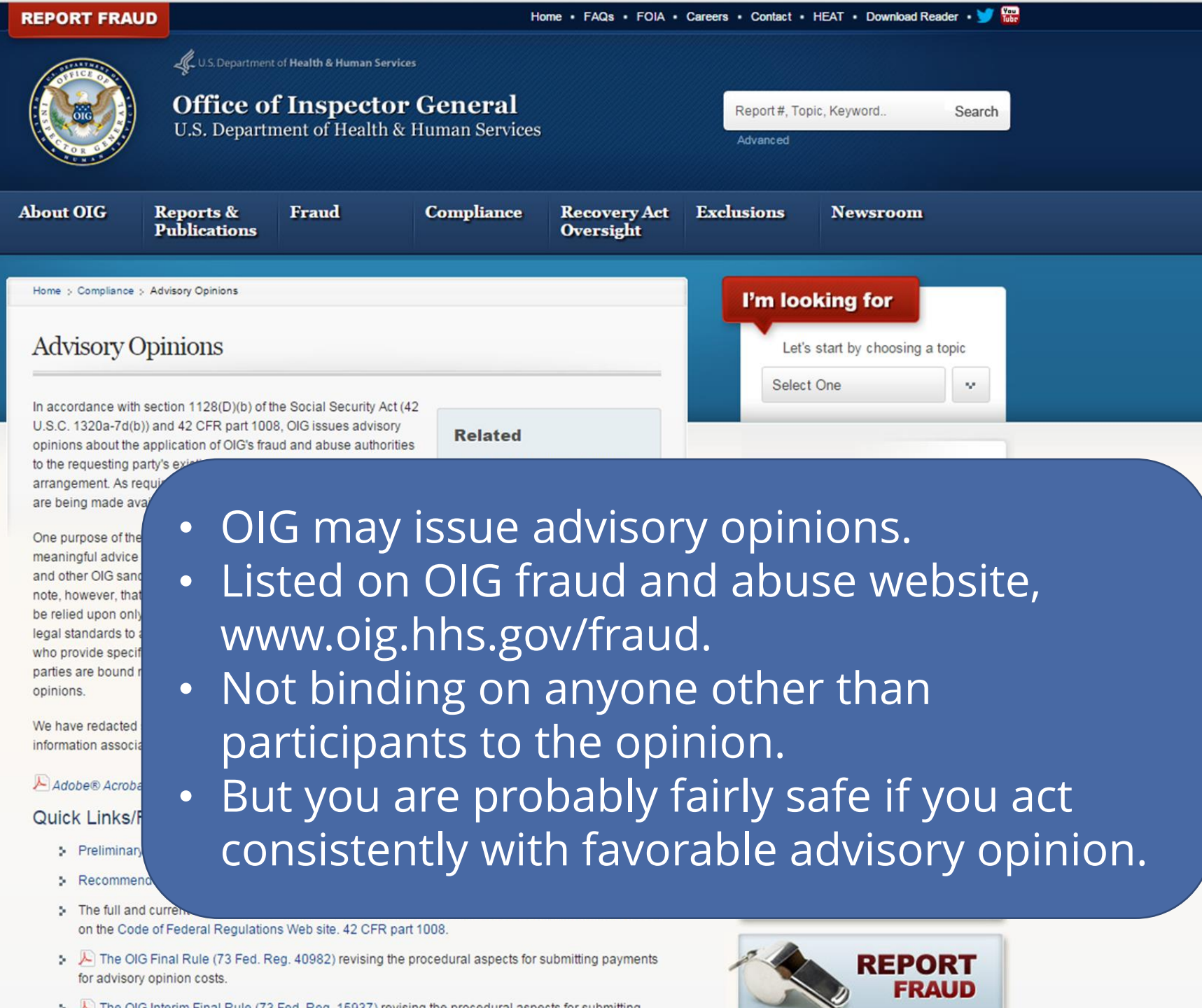
- Bona fide employment
- Personal services contracts
- Leases for space or equipment
- Investments in group practice
- Investments in ASCs
- Sale of practice
- Recruitment
- Certain investment interests
- Waiver of beneficiary coinsurance and deductible amounts.

(42 CFR 1001.952)

- Transportation programs
- OB malpractice insurance subsidies
- Electronic health record items or services
- Referral services
- Referral arrangements for specialty services
- Warranties
- Discounts
- Others

➢ *Not essential to fit safe harbor, but closer you can come the better.*

➢ *OIG has proposed new safe harbors*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Advisory Opinions
In accordance with section 1128(D)(b) of the Social Security Act (42 U.S.C. 1320a-7d(b)) and 42 CFR part 1008, OIG issues advisory opinions about the application of OIG's fraud and abuse authorities
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on the Code of Federal Regulations Web site. 42 CFR part 1008.
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• Not binding on anyone other than participants to the opinion.
• But you are probably fairly safe if you act consistently with favorable advisory opinion.

ELIMINATING KICKBACK IN RECOVERY ACT ("EKRA")

- Cannot solicit, receive, pay or offer any remuneration in return for referring a patient to a laboratory, recovery homes or clinical treatment facility unless arrangement fits within regulatory exception.

(18 USC 220(a))

Penalties

- $200,000 criminal fine
- 10 years in prison

(18 USC 220(a))

➢ *Applies to private or public payors.*

➢ *Waiting for regulations.*

EKRA SAFE HARBORS

- Discount or other reduction in price under a health care benefit program.
- Payment by employer to employee or independent contractor
- Discounts by dug of a manufacturer under Medicare coverage gap discount program
- Compensation that satisfies AKS personal services and management contract safe harbor so long as compensation does not vary with referrals.
- Waiver or discount of copays that satisfies Stark safe harbor and certain other conditions met
- Subsidies to health centers
- Remuneration under alternative payment models
- Any other payment, remuneration, discount, or reduction as determined by the Attorney General, in consultation with the Secretary of Health and Human Services, by regulation

(18 USC 220(b))

ETHICS IN PATIENT REFERRALS ACT ("STARK")

- If physician (or family member) has financial relationship with entity:
  - Physician may not refer patients to entity for designated health services ("DHS"), and
  - Entity may not bill Medicare or Medicaid for such DHS

  unless arrangement fits within a regulatory exception (safe harbor).

(42 USC 1395nn; 42 CFR 411.353 and 1003.300)

Penalties

- No payment for services provided per improper referral.
- Repayment w/in 60 days.
- Civil penalties.
  - $25,820* per claim
  - $172,137* per scheme

(42 CFR 411.353, 1003.310; 45 CFR 102.3)

- *Likely False Claims Act violation*
- *Likely Anti-Kickback Statute violation*

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STARK

- Applies to referrals by physician to entities with which the physician (or their family member) has financial relationship.
  - Physician =
    - MDs
    - DOs
    - Oral surgeons
    - Dentists
    - Podiatrists
    - Optometrists
    - Chiropractors

  (42 CFR 411.351)

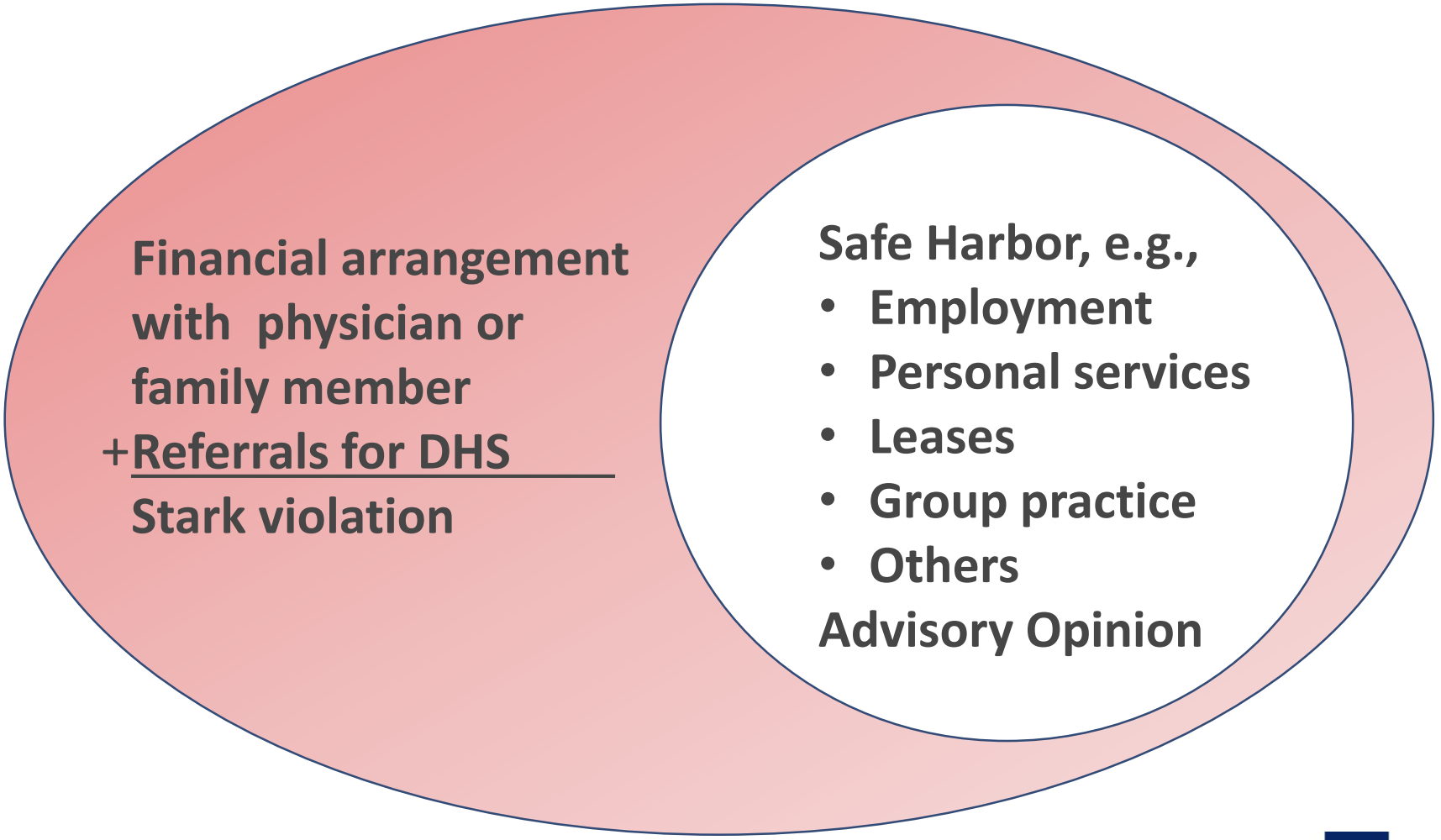
  - Family member =
    - Spouse
    - Parent, child
    - Sibling
    - Stepparent, stepchild, stepsibling
    - Grandparent, grandchild
    - In-law

STARK

- Applies to referrals for designated health services ("DHS") payable in whole or part by Medicare.
  - Inpatient and outpatient hospital services
  - Outpatient prescription drugs
  - Clinical laboratory services
  - Physical, occupational, or speech therapy
  - Home health services
  - Radiology and certain imaging services
  - Radiation therapy and supplies
  - Durable medical equipment and supplies
  - Parenteral and enteral nutrients, equipment, and supplies
  - Prosthetics and orthotics
- CMS website lists some of the affected CPT codes.

(42 CFR 411.351)

STARK


Financial arrangement with physician or family member
+Referrals for DHS
Stark violation
Safe Harbor, e.g.,
• Employment
• Personal services
• Leases
• Group practice
• Others
Advisory Opinion

STARK SAFE HARBORS

Compensation

- Employment
- Personal services contracts
- Fair market value
- Space or equipment leases
- Timeshare arrangements
- Recruitment and retention
- Non-monetary compensation up to $416*
- Medical staff incidental benefits
- Professional courtesy
- Health information technology support
- Others

(42 CFR 411.355 et seq.)

Ownership

- Physician supervision
- In-office ancillary services
- Rural providers
- Whole hospital
- Publicly traded securities
- Intra-family rural referrals
- Others

➢ *Must satisfy all requirements of specific safe harbor.*

➢ *New safe harbors proposed.*

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- Advisory opinions
- FAQs
- DHS by CPT code
- Self-Referral Disclosure Protocol
- Recent settlements

CIVIL MONETARY PENALTIES LAW

Prohibits certain specified conduct, e.g.:

- Submitting false or fraudulent claims, misrepresenting facts relevant to services, or engaging in other fraudulent practices.
- Violating Anti-Kickback Statute or Stark law.
- Violating EMTALA.
- Failing to report and repay an overpayment.
- Failing to grant timely access.
- Misusing "HHS", "CMS", "Medicare", "Medicaid", etc.
- Failing to report adverse action against providers.
- Offering inducements to program beneficiaries.
- Offering inducements to physicians to limit services.
- Submitting claims for services ordered by, or contracting with, an excluded entity.

(42 USC 1320a-7a; 42 CFR 1003.200-1100)

CIVIL MONETARY PENALTIES LAW

- Prohibits offering remuneration to a Medicare/Medicaid beneficiary if know or should know that it is likely to influence such beneficiary to order or receive services from a particular provider or supplier.

(42 USC 1320a-7a(5); 42 CFR 1003.1000(a))

Penalties

- $20,866* per violation.
- Exclusion from Medicare and Medicaid

(42 CFR 1003.1010(a); 45 CFR 102.3)

INDUCEMENTS TO GOVT PROGRAM PATIENTS

- "Remuneration" = anything of value, including but not limited to:
  - Items or services for free or less than fair market value unless satisfy certain conditions.
  - Waiver of co-pays and deductibles unless satisfy certain conditions.

(42 USC 1320a-7a(i); 42 CFR 1003.110; OIG Bulletin, *Gifts to Beneficiaries*)

INDUCEMENTS TO GOVT PROGRAM PATIENTS

- "Remuneration" does not include:
  - Waivers or co-pays based on financial need or after failed collection efforts if certain conditions met.
  - Items or services if financial need and certain conditions met.
  - Incentives to promote delivery of preventative care if certain conditions met.
  - Payments meeting Anti-Kickback Statute safe harbor.
  - Retailer coupons, rebates or rewards offered to public.
  - Any other remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs.
  - Certain other situations.

(42 USC 1320a-7a(i); 42 CFR 1003.110)

CIVIL MONETARY PENALTIES LAW

- Hospital or CAH cannot knowingly make a payment, directly or indirectly, to a physician as an inducement to reduce or limit medically necessary services provided to Medicare or Medicaid beneficiaries who are under the direct care of the physician.

(42 USC 1320a-7a(b))

Penalties

- $5,216* per violation.
- Exclusion from Medicare and Medicaid

(42 CFR 1003.1010(a); 45 CFR 102.3)

➢ *Beware gainsharing arrangements.*

CIVIL MONETARY PENALTIES LAW

- Excluded person cannot order or prescribe items payable by federal healthcare program.
- Cannot submit claim for item ordered or furnished by an excluded person.
- Excluded owners cannot retain ownership interest in entity that participates in Medicare.
- Cannot hire or contract with excluded entity to provide items payable by federal programs.

(42 USC 1320a-7a(a)(8); 42 CFR 1003.200(a)(3), (b)(3)-(6))

Penalties

- $20,866* per item or service ordered.
- 3x amount claimed.
- Repayment of amounts paid.
- Exclusion from Medicare and Medicaid

(42 USC 1320a-7a(a)(8); 42 CFR 1003.210; 45 CFR 102.3; OIG Bulletin, *Effect of Exclusion*)

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LEIE Downloadable Databases

E-mail me when this page is updated.

Download the LEIE Database

ANNOUNCEMENT: As of the September 2013 update, only the LEIE files containing the NPI, Waiver, and Waiver States fields will be available.

Instructions and information About the LEIE Files.

Below files updated: 05-08-2015

LEIE Database

- 04-2015 Updated LEIE Database: EXE | ZIP

Current Monthly Supplements

- 04-2015 Exclusions: EXE | ZIP
- 04-2015 Reinstatements: EXE | ZIP
- Monthly Supplement Archive

Profile Updates

- 04-2015 Profile Corrections

Current Record Layout

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- Waiver Info
- Search the Online LEIE Database

How To Use These Files

View a video tutorial on using the downloadable files.

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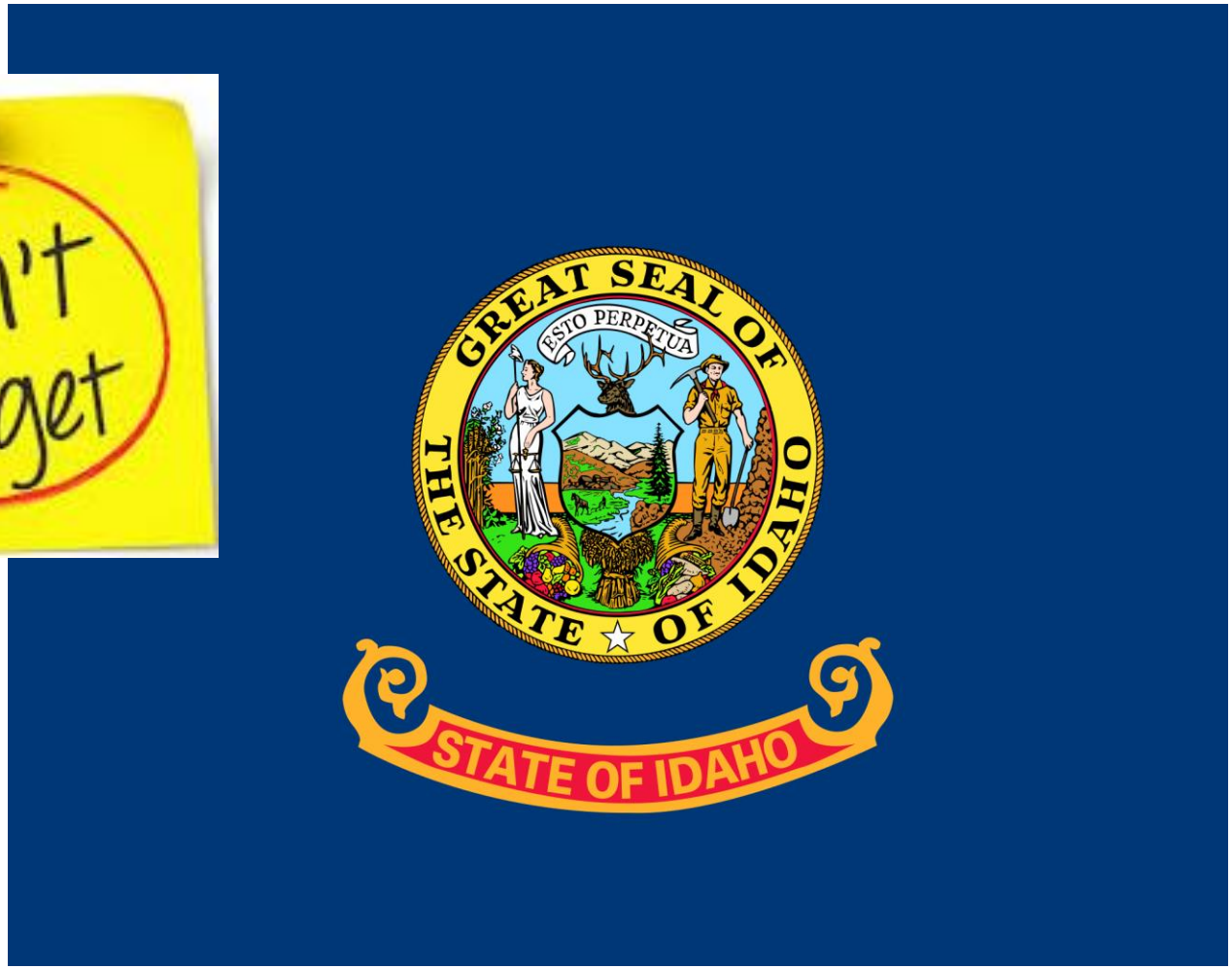
EXCLUSIONS DATABASE

IDAHO FRAUD AND ABUSE LAWS



IDAHO FALSE CLAIMS ACT

Cannot knowingly:

- Submit claim that is incorrect.
- Make false statement in any document to state.
- Submit a claim for medically unnecessary item or service.
- Fail repeatedly or substantially to comply with DHW rules.
- Breach provider agreement.
- Fail to repay amounts improperly received.
- Be managing employee in an entity that engaged in fraud or abusive conduct.

(IC 56-209h(6))

Penalties

- Exclusion from state health programs, e.g., Medicaid.
- Civil penalty of up to $1000 per violation.
- Referral to Medicaid fraud unit.

(IC 56-209h)

IDAHO MEDICAID PROVIDER AGREEMENT

- Current Medicaid provider agreement requires providers to comply with broad range of requirements, including:
  - Compliance with federal and state statutes, regs and rules.
  - Provide accurate information in applications.
  - Be properly licensed, certified and registered, and properly supervise others.
  - Document services and maintain records for 5 years.
  - Certify that items or services claimed were:
    - Actually provided;
    - Medically necessary; and
    - Provided per applicable professional standards and DHW rules.
  - Repay amounts improperly received.
  - Do not balance bill services payable by Medicaid.

(Medicaid Provider Agreement (06/11))

- Failure to comply with provider agreement may result in civil penalties.

(IC 56-209h))

IDAHO ANTI-KICKBACK STATUTE

- Healthcare providers cannot:
- Pay another person, and other person may not accept payment, for a referral.
- Provide services knowing the claimant was referred in exchange for payment.
- Engage in a regular practice of waiving, rebating, giving or paying claimant's deductible for health insurance.

(IC 41-348)

Penalties

- $5,000 fine by Dept of Insurance

➢ Violation of Medicaid provider agreement?

IDAHO FEE-SPLITTING STATUTE

Physician and PAs my not:

- Divide fees or gifts or agree to split or divide fees or gifts received for professional services with any person, institution or corporation, in exchange for a referral.
- Give or receive rebates.

(IC 54-1814(8)-(9))

Penalties

- Adverse licensure action.

➢ Violation of Medicaid provider agreement?

IDAHO STARK IMPLICATIONS

- Idaho does not have a state law that mirrors Stark.

But…

- Idaho Medicaid regulations allow DHW to "deny payment for any and all claims it determines are for items or services … provided as a result of a prohibited physician referral under [Stark,] 42 CFR Part 411, Subpart J."

(IDAPA 16.05.07.200.01)

OTHER STATUTES

- Health Care Fraud, 18 USC 1347
- False Statements Relating to Health Care Matters, 18 USC 1035
- Mail and Wire Fraud, 18 USC 1341 and 1343
- Theft or Embezzlement in Connection with Health Care, 18 USC 669
- Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 USC 1961-1968
- Travel Act, 18 USC 1952
- Idaho Insurance Fraud, IC 41-293
- Others?

(*See* OIG Compliance Program for Individual and Small Group Physician Practices, 65 FR 49448 et seq.)

PRIVATE PAYORS

Statutes

- Federal or state healthcare fraud statutes
- Stark
- Consumer protection
- Others?

➢ *Beware laws from other states*

Private lawsuit

- Breach of contract
  - Conditions of payment
  - Repayment
- Common law fraud or misrepresentation
- Unjust enrichment
- Restitution
- Interference with contract
- Others?

APPLYING THE RULES

FREE OR DISCOUNTED ITEMS OR SERVICES TO PATIENTS

- Gifts to patients (e.g., gift basket, gift card, basket of products for new mothers, etc.)
- "Refer a friend" incentive
- Free exam or service
- Free equipment, supplies or drugs
- Free meals
- Free transportation
- Parking reimbursement
- Waiver of copay or deductible
- Write offs
- "Refer a friend" incentive
- Paying premiums
- Anything else of value that does not reflect fair market value ("FMV")

May create problems if it would induce patient to order or receive additional items or services

FREE OR DISCOUNTED ITEMS OR SERVICES TO PATIENTS

Consider:

- Does payor contract prohibit actions?
- Is patient a govt beneficiary?
- Purpose of free or discounted item or service?
  - Intended to induce patient to order item or service from a particular provider?
  - "One purpose" to induce govt program business?
  - Poses a risk of program fraud and abuse? e.g.,
    - Induces patient to order more items than necessary
    - Induces patient to order more expensive items
    - Affects clinical decisionmaking
    - Promotes low quality
- Is there an applicable safe harbor?

FREE OR DISCOUNTED ITEMS OR SERVICES TO PATIENTS

May offer free or discounted items to govt beneficiaries if:

- Remuneration is not likely to influence the beneficiary to order or receive items or services payable by federal or state health care program.

  (42 USC 1320a-7a(a)(5))

- Item or service is of low value, i.e.,
  - Each item or service is less than $15, and
  - Aggregate is less than $75 per patient per year.

  (OIG Bulletin, *Offering Gifts and Inducements to Beneficiaries* (8/02); 66 FR 24410-11; OIG Policy Statement Regarding Gifts of Nominal Value (12/7/16))

FREE OR DISCOUNTED ITEMS OR SERVICES TO PATIENTS

May offer free or discounted services to govt beneficiaries if:

- Financial need
  - Good faith determination that beneficiary has financial need or after reasonable collection efforts have failed;
  - Not offered as part of any advertisement or solicitation;
  - Not tied to provision of other federal program business; and
  - Reasonable connection between item or service and medical care of beneficiary.

(42 CFR 1320a-7a(i); 42 CFR 1003.110; *see also* OIG Bulletin, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills*)

FREE OR DISCOUNTED ITEMS OR SERVICES TO PATIENTS

May offer free or discounted items to govt beneficiaries if:

- Fit within Anti-Kickback Statute safe harbor.
- Promotes delivery of preventative care, i.e.,
  - Pre-natal or post-natal well-baby service, or listed in *Guide to Clinical Preventive Services;*
  - No cash or instruments convertible to cash; and
  - Not tied to other Medicare services.
- Promotes access to items or services payable by Medicare and Medicaid and does not:
  - Interfere with clinical decision making;
  - Increase costs to federal program or beneficiary; or
  - Raise patient care concerns.
- Certain other situations.

(42 USC 1320a-7a(i); 42 CFR 1003.110)

FREE TESTS OR SCREENING

- OIG has approved free screening services (e.g., free blood pressure check by hospital) where:
  - Not conditioned on the use of any items or services from any particular provider;
  - Patient not directed to any particular provider;
  - Patient not offered any special discounts on follow-up services; and
  - If test shows abnormal results, visitor is advised to see his or her own health care professional.

  (Adv. Op. 09-11, but note that *Advisory Opinions are not binding)*
- Some services may fit within CMPL exception for:
  - Certain preventative services.
  - Services that promote care and pose low risk of fraud or abuse.
- Independent foundation or entity may be able to provide such services but be careful.

FREE TRANSPORTATION

Local Transportation

- Set forth in policy applied uniformly
- Not determined based on volume or value of referrals
- Not air, luxury, or ambulance-level transport
- Not publicly marketed or advertised
- Drivers not paid per beneficiary
- Only for established patients within 25 miles or, in rural area, 50 miles
- Costs not shifted to payors or individuals

Shuttle on Set Schedule

- Not air, luxury, or ambulance-level transport
- Not publicly marketed or advertised
- Drivers not paid per beneficiary
- Only within provider's local area, i.e., within 25 miles or, in rural area, 50 miles
- Costs not shifted to payors or individuals

(42 CFR 1001.952(bb))

WAIVING COPAYS OR DEDUCTIBLES

May waive or discount govt copays or deductibles if:

- Good faith determination that beneficiary is in financial need or you are unable to collect after reasonable collection efforts.
- Not offered as part of any advertisement or solicitation; and
- Not offered routinely.

(42 USC 1320a-7a(i)(6); 42 CFR 1003.110; IC 41-348; *see also* Adv. Op. 12-16)

- Document factors such as local cost of living; patient's income, assets and expenses; patient's family size; scope and extent of bills; etc.

WAIVING COPAYS OR DEDUCTIBLES

May waive or discount govt copays if satisfy AKS safe harbor.

- Hospital inpatient stay paid under PPS, and
  - Waived amounts cannot be claimed as bad debt or shifted to any other payors;
  - Offered without regard to the reason for admission, length of stay, or DRG; and
  - Waiver may not be made as part of any agreement with third party payor with limited exceptions.
- FQHC or other health care facility under any Public Health Services Grant.
- Pharmacy if certain conditions satisfied.
- Ambulance service if certain conditions satisfied.

(42 CFR 1001.952(k))

WAIVING COPAYS OR DEDUCTIBLES

Beware waiving copays and deductibles required by private payors.

- Likely violates private payor contracts.
  - Breach of contract
  - Maybe insurance fraud
- May violate Idaho Anti-Kickback Statute if offered routinely. (IC 41-348)

➢ *Check your payor contract or contact your private payors.*

WRITING OFF ENTIRE BILL

- Writing off entire bill for service is safer than waiving copays.
  - No payor is billed so payor is happy.
  - Not an inducement for services related to the bill.
- Document legitimate purpose, i.e., not intended to generate referrals, e.g.,
  - Unable to properly bill, e.g., not medically necessary, substandard care, no documentation, failure to satisfy conditions for payment.
  - Resolution of legitimate dispute or claim.
  - Financial need or unsuccessful attempts to collect. (*See* 42 CFR 1320a-7a(i); 42 CFR 1003.110; OIG Bulletin, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills*)

WRITING OFF BILLS

- OIG suggests that hospitals (and presumably other providers) should:
  - Have a reasonable set of financial guidelines based on objective criteria that documents real financial need;
  - Recheck patient's eligibility at reasonable intervals to ensure they still have financial need; and
  - Document determination of financial need.

(OIG Bulletin, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills*)

PROFESSIONAL COURTESY

- Beware professional courtesies to govt beneficiaries.
  - No AKS or CMPL safe harbor.
  - Consider whether intent is to induce referrals.
  - $15/$75 aggregate may apply.
  - Don't waive copays or deductibles.
- Stark contains safe harbor for courtesies to physicians or their family members if:
  - Practice has formal medical staff.
  - Written policy approved in advance.
  - Offered to all physicians in service area regardless of referrals.
  - Not offered to govt beneficiaries unless showing of financial need.
  - Does not violate AKS.

  (42 CFR 411.357(s); 72 FR 51064)

FREE OR DISCOUNTED ITEMS TO EMPLOYEES

- Beware waiving copays or other cost-sharing amounts if adversely affects payors.
  - See prior discussion.
- Offering free items or services to employees may implicate tax or employee benefit laws.
  - Benefits to employees are usually taxable.
  - May be structured to fit within employee benefit plan but ensure compliance with ERISA or similar laws.

PROMPT PAY DISCOUNTS

- OIG has approved prompt pay discounts for govt beneficiaries if:
  - Amount of discount relates to avoided collection costs.
  - Offered to all patients for all services without regard to patient's reason for admission, length of stay, or DRG.
  - Not advertised so as to solicit business.
  - Notified private payors of program.
  - Costs not passed to Medicare, Medicaid or other payors.

(56 FR 35952; Adv. Op. 08-3)

PROMPT PAY DISCOUNTS

- Private payor issues
  - Generally cannot discount copays and deductibles without violating managed care contracts unless payor agrees.
  - May adversely affect "usual and customary charges" and payor's reimbursement under contract.
  - payors may claim the benefit of the discount if the insurer pays within the relevant time.
- *Check your payor contract or contact your private payors.*

SELF-PAY DISCOUNTS

- In most states, providers may generally charge different patients or payors different amounts.
  - Payment is a matter of contract between provider and patient or payor.
  - Negotiated rates for payors.
  - Negotiated rates or discounts for self-pay patients.
- But beware limitations….

SELF-PAY DISCOUNTS

Limits on ability to offer self-pay discounts:

- Some states limit ability to charge different rates.
  - Charging insurers more than self-pay patients.
  - Charging self-pay patients more than insurers.
- Maybe facilities that submit cost reports.
  - *See* Provider Reimbursement Manual 15.1 at § 2203 (charge structure should be "applied uniformly").
  - Check with entity that prepares cost reports.
- FQHCs.
  - *See* MLN, *Federally Qualified Health Centers* , ICN 006397 (1/18) ("Charges must be uniform for all patients").
- In some states, payor contracts may contain "most favored nation" clauses requiring providers to give their best rates.
  - Self-pay or other discounts may affect "usual and customary" charges.

MEDICARE "SUBSTANTIALLY IN EXCESS" RULE

- OIG may exclude provider who charges Medicare "substantially in excess" of the provider's usual charges.

(42 USC 1320a-7(b)(6); 42 CFR 1001.701(a)(1)).

  - Test: whether the provider charges more than half of its non-Medicare/Medicaid patients a rate that is lower than the rate it charges Medicare.
    - Presumably applies to specific charge or service.
  - OIG has stated that it would not use the rule to exclude or attempt to exclude any provider or supplier that provides discounts or free services to uninsured or underinsured patients.

(*See* OIG Adv. Op. 15-04; OIG Letter dated 4/26/00, available at http://oig.hhs.gov/fraud/docs/safeharborregulations/lab.html)

CASH INSTEAD OF BILLING PAYORS

- Medicare, maybe Medicaid, and private payors generally prohibit billing patients for covered services except for copays or deductibles.

But…

- HITECH Act prohibits provider from using or disclosing PHI if the patient (or other person) pays for the episode of care and instructs provider not to submit to payor unless law requires disclosure.

(42 CFR 164.522(a)(1)(vi))

  - Exception to Medicare payment rule.
  - Overrules contrary contract language.
  - Does not apply where state law requires the disclosure, e.g., Medicaid or private payors.

(78 FR 5628)

PAYING PATIENT'S PREMIUMS

- If paying Medicare Part B, C or D premiums:
  - OIG approved payment of Part B premiums for ESRD patients where:
    - Patients are already receiving the services, so unlikely to induce services that might not otherwise be received.
    - No inappropriate patient steering to particular providers.
    - Patients are not coerced into enrolling in Part B.
    - Certain protections built in to protect Medicare program from additional costs.
  - OIG cautioned that it might reach different result in other circumstances.

(Adv. Op. 13-16; *see also* Adv. Op. 01-15 and Adv. Op. 13-16))

PAYING PATIENT'S PREMIUMS

- If paying premiums for health insurance exchange:
  - "HHS has significant concerns with this practice because it could skew the insurance risk pool and create an unlevel playing field in the Marketplaces. HHS discourages this practice and encourages issuers to reject such third party payments. HHS intends to monitor this practice and to take appropriate action, if necessary." (HHS Letter dated 11/4/13).
  - Letter does not apply to:
    - Indian tribes and govt grant programs.
    - Payments made by private non-profit foundation based on defined criteria based on financial status that does not consider health status and payment covers entire year.

  (HHS Letter dated 2/7/14; 79 FR 15240)

PAYING PATIENT'S PREMIUMS

- If paying private insurance premiums (e.g., COBRA or other coverage):
  - Probably does not implicate AKS or CMPL unless it is tied to or induces referrals for services payable by govt programs.
  - May implicate state laws.
  - COBRA regulations contemplate that COBRA premiums may be paid by third party.
  - Check payor contracts.
- *But stay tuned—this is a developing area of the law.*

CONTRACTS WITH REFERRING PROVIDERS

- Employment
- Independent contractor or other services agreement
- Group compensation arrangement
- Lease for space or equipment
- Recruitment agreement
- Management or support services
- Joint ventures

✓Stark
✓AKS
✓CMPL
✓State laws

EMPLOYMENT

Stark (Physicians)

- Compensation must be:
  - Consistent with fair market value ("FMV") of services.
  - Does not take into account the volume or value of referrals for DHS
    - Does not apply to services personally performed by referring physician.
  - Commercially reasonable even if no referrals made.

(42 CFR 411.357(c))

Anti-Kickback Statute

- Compensation paid to bona fide employees for furnishing items or services payable by Medicare/Medicaid.

(42 CFR 1001.952(i))

- Safe harbor may not apply to excess payments for referrals instead of "furnishing items or services".

(OIG Letter dated 12/22/92 fn.2)

INDEPENDENT CONTRACTORS

- Professional services agreements
- Call coverage agreements
- Medical directorships
- Medical staff leadership
- Provider supervision
- Management services
- Administrative services
- Other situations in which entity contracts with or pays referring non-employee provider for services

INDEPENDENT CONTRACTORS

Stark (Physicians)

- Writing specifies compensation.
- Compensation formula is:
  - Set in advance.
  - Consistent with FMV.
  - Does not take into account the volume or value of services or other business generated by the physician.
- Arrangement is commercially reasonable and furthers legitimate business purpose.
- Compensation may not be changed within 1 year.

(42 CFR 411.357(d) or (l))

Anti-Kickback Statute

- Writing signed by parties.
- Aggregate compensation is:
  - Set in advance.
  - Consistent with FMV.
  - Does not take into account the volume or value of referrals for federal program business.
- Aggregate services do not exceed reasonably necessary to accomplish commercially reasonable business purpose.

(42 CFR 1001.952(d))

REQUIRING REFERRALS

Under Stark, may require employees and contractors to make referrals if.

- Contract contains requirement to make referrals;
- Compensation is FMV and does not take into account volume or value of referrals; and
- Referrals relate solely to physician's services under the contract and are necessary to effectuate intent of contract.

Cannot require referrals if:

- Patient prefers to go to a different provider;
- Insurer determines the provider; or
- Physician determines referral to the required provider is not in patient's best medical interests.

(42 CFR 411.354(d)(4))

➢ No similar AKS provision.

GROUP PRACTICE COMPENSATION

- Stark applies to referrals within physician group; thus, must structure group compensation to comply with Stark if group is providing DHS.
  - Owners:
    - "Group practice" exceptions
      - Physician services
      - In-office ancillary services
    - Rural provider exception
    - Whole hospital exception
  - Non-owners:
    - "Group practice" exceptions
    - Employment or personal services exceptions

RECRUITING PROVIDERS

- May compensate recruited provider under:
  - Employee safe harbor
  - Independent contractor safe harbor
  - Group practice safe harbor
  - Recruitment safe harbor
    - Allows hospital or FQHC to pay physician or midlevel to relocate to service area.
    - Compensation not limited to FMV.
    - Subject to many conditions.

    (42 CFR 411.357(e) and (x); 1001.952(n))

Limited to FMV

RECRUITMENT AGREEMENT

Stark (Physicians)

- Payments by hospital to recruit.
- Written agreement signed by parties.
- Physician relocates from at least 25 miles into hospital's service area.
- Not conditioned on referrals.
- If recruit into existing group:
  - Cannot subsidize group.
  - Hospital payments must be:
  - Directly passed on to recruited physician.
  - Reimburse group for recruitment expenses.
  - Income guaranty limited to additional incremental expenses attributable to adding physician.
- See other conditions

(42 CFR 411.357(e))

➢ See separate safe harbor for APPs.

Anti-Kickback Statute

- Payment to induce practitioner to relocate to HPSA.
- Written agreement signed by parties.
- 75% of revenues from new practice.
- Benefits provided < 3 years.
- Terms not renegotiated during the 3 years.
- No required referrals.
- Amount of benefits not based on referrals.
- No restriction on staff privileges elsewhere.
- Cannot discriminate against federal program beneficiaries.
- Cannot benefit any entity in a position to generate referrals.

(42 CFR 1001.952(n))

RETENTION AGREEMENT

Stark (Physicians)

- Hospital or FQHC payments to retain physician in HPSA or MUA.
- Physician has either:
  - Bona fide offer elsewhere, or
  - Certifies in writing s/he has bona fide opportunity elsewhere.
- Retention payment submit to limits.
- 75% of patients in MUA or MUP.
- Only one retention agreement per 5 years.
- Terms not altered based on referrals.
- Arrangement does not violate Anti-Kickback Statute.
- See additional requirements.

(42 CFR 411.357(t))

LEASE SPACE OR EQUIPMENT

Stark (Physicians)

- Written lease signed by parties.
- Specifies space, equipment, etc.
- No changes within 1 year.
- Legitimate need, no more than necessary, and commercially reasonable.
- Exclusive use by lessee.
- Rent is
  - Fair market value.*
  - Not based on referrals.
  - Not % of revenue.
  - Not per unit of service referred by lessor.
- Holdover okay if based on same terms.

(42 CFR 411.357(a)-(b))

Anti-Kickback Statute

- Written lease signed by parties.
- Specifies space, equipment, etc.
- Specifies schedule of use.
- Term < 1 year.
- Aggregate rent is:
  - Fair market value.*
  - Not based on referrals.
- Reasonably necessary to accomplish commercially reasonable business purpose.

(42 CFR 1001.952(b))

TIMESHARE

Stark (Physicians)

- Between physician/group and hospital or physician organization of which physician is not a member.
- Written agreement signed by parties specifying space, equipment, personnel, supplies, etc.
- Used predominantly for evaluation and management ("E&M")
- Not conditioned on referrals.
- Compensation is
  - Set in advance
  - Fair market value
  - Not based on:
    - % of revenue
    - Per unit of service referred by licensor
- Commercially reasonable.
- Does not violate Anti-Kickback Statute.
- Does not convey leasehold.
- See other conditions.

(42 CFR 411.357(y))

USE OF SPACE/EQUIPMENT

- CMS indicates no "remuneration" if:
  - Physician bills professional fees.
  - Hospital/clinic bill technical/facility fees.
  - Neither bill globally.

(80 FR 71321-22)

- Make sure physician is using appropriate site of service modifier.
- May potentially be AKS issues.

GIFTS OR PERKS TO PROVIDERS OR OTHER REFERRAL SOURCES

E.g., soliciting, giving or receiving:

- Gifts, e.g., "thank you" or appreciation gifts.
- Free items or services, e.g., meals, CME, travel, space, equipment, perks, insurance, etc.
- Discounted items or services, i.e., less than fair market value, professional courtesies, etc.
- Payments for services not performed.
- Payments for unnecessary services.
- Overpayments for items or services.
- Practice or expense subsidies.
- Business opportunities without investment.
- Failure to recoup money owed.

GIFTS OR PERKS TO PROVIDERS

- Lower risk if entity receiving gift does not refer items or services payable by federal healthcare programs.
  - Stark, AKS and CMPL generally apply to referrals for items or services payable by govt programs.
- But no guarantee…
  - OIG has cautioned that carving out federal programs from specific transaction may not protect the parties if there are other referrals for federal programs between parties.
  - May still violate Idaho Anti-Kickback Statute.
  - Private payors have sued based on various statutory and common law theories.

PROFESSIONAL COURTESY

Stark (Physicians)

- Practice has formal medical staff.
- Written policy approved in advance.
- Offered to all physicians in service area regardless of referrals.
- Not offered to govt beneficiaries unless showing of financial need.
- Does not violate AKS.

(42 CFR 411.357(s); 72 FR 51064)

- But beware AKS, CMPL, state laws, and private payor contracts, especially if waive copays or engage in "insurance only billing."

NON-MONETARY COMPENSATION LESS THAN $423*/YEAR

Stark (Physicians)

- Items or services (not cash or cash equivalents) that do not exceed $423/year, as adjusted per CPI.
- Not based on volume or value of referrals or other business generated between the parties.
- Not solicited by physician or physician's practice.
- If there is violation, physician may repay excess if certain conditions met.
- Entity with formal staff may provide one medical staff appreciation event annually.

(42 CFR 411.357(k))

MEDICAL STAFF INCIDENTAL BENEFITS

Stark (Physicians)

- Items or services (not cash or cash equivalents) by hospital to medical staff .
- Used on hospital campus.
- Offered to all medical staff members in same specialty.
- Not based on the volume or value of referrals or other business generated between the parties.
- Provided while physician is making rounds or engaged in services benefiting hospital or patients.
- Reasonably related to patient care at hospital.
- Low value, i.e., less than $35 as adjusted for CPI.

(42 CFR 411.357(m))

GAINSHARING PROGRAMS

- Gainsharing programs likely violate Stark, AKS, and maybe CMPL.
  - CMPL only applies to inducements to limit "medically necessary" services.
- OIG has periodically approved gainsharing in advisory opinions if certain safeguards included, e.g.,
  - Proposed plan does not adversely affect patient care.
  - Quality evaluated by third party.
  - Low risk that incentive will lead physicians to provide medically inappropriate care.
  - Payments limited in duration and amount.
  - Payments not tied to referrals or other suspect actions.

  (*See, e.g.,* Adv. Op. 12-22)
- OIG advisory opinions do not apply to Stark.
- CMS/OIG have issued rules waiving CMPL and Stark for ACOs.
- Proposed value-based safe harbors may offer further protection.

ADDITIONAL SAFE HARBORS

Stark and/or Anti-Kickback Statute:

- Group practice compensation.
- Ownership of rural provider, whole hospital, ASC.
- Compliance training.
- Obstetrical malpractice insurance.
- Community-wide health information systems.
- Electronic prescribing items and services.
- Electronic health records items and services.
- Charitable donations by physician.
- Certain arrangements with physician groups that don't fit within other safe harbors.

(42 CFR 411.357)

REPAY OVERPAYMENTS

REPAYING OVERPAYMENTS

- If provider has received an "overpayment", provider must:
  - Return the overpayment to federal agency, state, intermediary, or carrier, and
  - Notify the entity of the reason for the overpayment.
- Must report and repay within the later of:
  - 60 days after overpayment is identified.
  - date corresponding cost report is due.

(42 USC 1320a-7k(d); 42 CFR 401.305).

OVERPAYMENTS: PENALTY

- "Knowing" failure to report and repay by deadline =
  - False Claims Act violation
    - $11,181* to $22,363* per violation
    - *Qui tam* lawsuit

    (31 USC 3729)
  - Civil Monetary Penalty Law violation
    - $20,866* penalty
    - 3x damages
    - Exclusion from Medicare or Medicaid

    (42 USC 1320a-7a(a)(10))

Department of Justice

U.S. Attorney's Office

Southern District of New York

SHARE

FOR IMMEDIATE RELEASE

Wednesday, August 24, 2016

Manhattan U.S. Attorney Announces $2.95 Million Settlement With Hospital Group For Improperly Delaying Repayment Of Medicaid Funds

Continuum Admits That It Did Not Fully Reimburse Medicaid For Erroneously Billed Claims For Over Two Years

Preet Bharara, the United States Attorney for the Southern District of New York, Scott J. Lampert, Special Agent in Charge of the New York Field Office of the U.S. Department of Health and Human Services,

OVERPAYMENTS

- "Overpayment" = funds a person receives or retains to which the person, after applicable reconciliation, is not entitled, e.g.,
  - Payments for non-covered services
  - Payments in excess of the allowable amount
  - Errors and non-reimbursable expenses in cost reports
  - Duplicate payments
  - Receipt of Medicare payment when another payor is primary
  - Payments received in violation of Stark, Anti-Kickback Statute, Exclusion Statute.
- 6 year lookback period. (42 CFR 401.305(f))

OVERPAYMENTS: IDENTIFIED

- Identify overpayment = person has or should have, through exercise of reasonable diligence, determined that they received overpayment.
  - Actual knowledge
  - Reckless disregard or intentional ignorance
- Have duty to investigate if receive info re potential overpayment, e.g.,
  - Significant and unexplained increase in Medicare revenue
  - Review of bills shows incorrect codes
  - Discover services rendered by unlicensed provider
  - Internal or external audit discloses overpayments
  - Discover AKS, Stark or CMPL violation
- "Reasonable diligence" =
  - Proactive monitoring
  - Reactive investigations

(81 FR 7659-61)

OVERPAYMENTS: DEADLINE

- 60-day deadline begins to run when either:
  - Person completes reasonably diligent investigation which confirms:
    - Received overpayment, and
    - Quantified amount of overpayment.
  - If no investigation, the day the person received credible information that should have triggered reasonable investigation.
- "Reasonable diligence" = timely, good faith investigation
  - At most 6 months to conclude diligence
  - 2 months to report and repay
- Deadline suspended by:
  - OIG Self-Disclosure Protocol
  - CMS Stark Self-Referral Disclosure Protocol ("SRDP")
  - Person requests extended repayment schedule

(42 CFR 401.305(a); 81 FR 7661-63)

OVERPAYMENTS: REPORTING

May either:

- Use Medicare contractor process for reporting overpayments, e.g.,
  - claims adjustment
  - credit balance
  - self-reported refund
- Use OIG or CMS self-disclosure protocol that results in settlement.

(42 CFR 401.305(d))

OVERPAYMENT: REPORTING

- Repayment per Repayment Rule does not resolve violations or penalties under other laws, e.g.,
  - Anti-Kickback Statute, Civil Monetary Penalties Law, or False Claims Act, which are resolved by OIG or DOJ.
  - Stark, which is resolved by CMS.
- If Medicare contractor believes repayment involves violation of federal law, contractor may report repayment to the OIG, CMS, or other federal agency.

OVERPAYMENT: REPORTING

May want to consider other disclosure protocols.

- OIG Self-Disclosure Protocol, https://oig.hhs.gov/compliance/self-disclosure-info/index.asp
- Stark Self-Referral Disclosure Protocol, https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/self_referral_disclosure_protocol.html

ACTION ITEMS

HOLLAND&HART LLP

CHECK YOUR ARRANGEMENTS

Patients

- Billing policies
  - Waiving copays
  - Write offs
  - Prompt pay or self-pay discounts
  - Free or discounted items
- Marketing /advertising
  - Thank you gifts
  - Loss leaders
  - Free screening programs
  - “Refer a friend” programs
  - Others?

Providers

- Employees
- Contractors
  - Professional Services Agreements
  - Medical directorships
  - Call coverage
  - Others
- Leases
- Use of space/equipment
- Medical staff benefits
- Practice support
- Professional courtesies

TRAIN KEY PERSONNEL

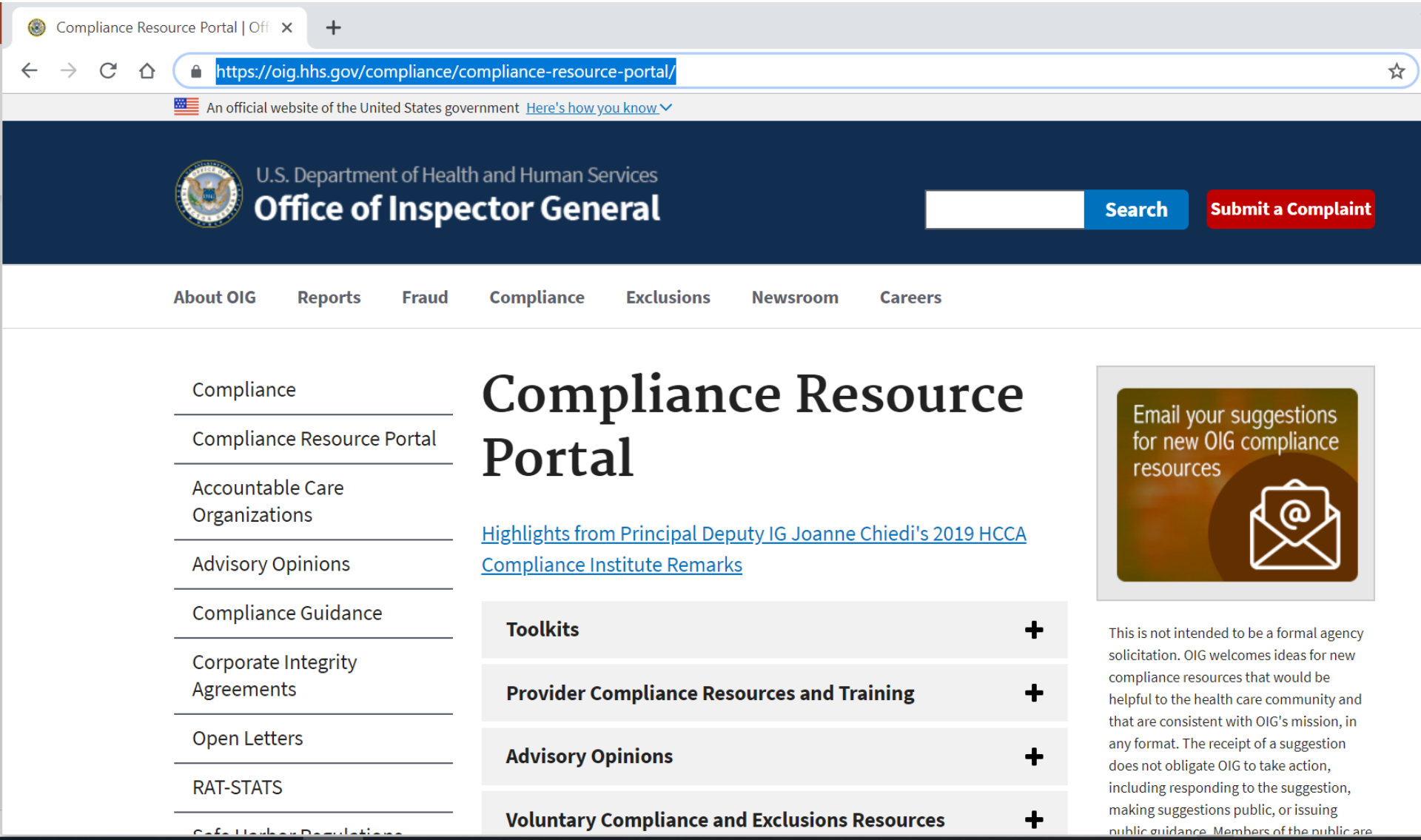
- Include following people:
  - Administration.
  - Compliance officers and committees.
  - Human resources.
  - Physician relations and medical staff officers.
  - Marketing / public relations.
  - Governing board members.
  - Purchasing.
  - Accounts payable.
- Document training.
- Review and repeat.

IF YOU THINK YOU HAVE A PROBLEM

- Suspend claims until resolved.
- Investigate problem per compliance plan.
  - Consider involving attorney to maintain privilege.
- Implement appropriate corrective action.
  - But remember that prospective compliance may not be enough.
- If repayment is due:
  - Report and repayment per applicable law.
  - Self-disclosure program.
    - To OIG, if there was knowing violation of False Claims Act, Anti-Kickback Statute or Civil Monetary Penalties Law.
    - To CMS, if there was violation of Stark.

ADDITIONAL RESOURCES

HTTPS://OIG.HHS.GOV/COMPLIANCE/COMPLIANCE-RESOURCE-PORTAL/



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CONTACTS

Kim Stanger
Partner
Boise

Blaine Benard
Partner
Salt Lake City

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Access to previous webinar recordings, publications, and more.

The Healthcare Industry is poised to continue its rapid evolution. W this sector now making up close to 20 percent of GDP, our lawyers stand ready to help as changes unfold.

Issues such as rising healthcare costs, healthcare reform, data and privacy security, and innovations in healthcare delivery, device and pharmaceutical designs are forefront in t minds of many of our clients. We are here to guide our clients through the challenges a opportunities that arise in this dynamic industry.

Clients We Serve

- Hospitals
- Individual medical providers
- Medical groups
- Managed care organizations (MCOs)
- Third-party administrators (TPAs)
- Health information exchanges (HIEs)
- Practice managers and administrators
- Veterinary service providers and facilities
- ons (IPAs)
- Imaging centers
- Ambulatory surgery centers
- Medical device and life science companies

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Blue Cross of Idaho is changing its network product. They are have removed the prefe prov organization p

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Kim C. Stanger
Office: (208) 383-3913
Cell: (208) 409-7907
kcstanger@hollandhart.com

Lisa M. Carlson
Office: (208) 383-3910
Cell: (208) 949-0845
lcarlson@hollandhart.com