FRAUD AND ABUSE ISSUES

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(1-21)

HOLLAND&HART LLP

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COMPLIANCE WEBINAR SERIES

Date	Webinar
12/10/20	Provider Relief Fund
12/17/20	New Stark and Anti-Kickback Rules
1/7/21	Telehealth
1/14/21	Vaccinations
1/19/21	Idaho Compliance Issues
1/21/21	**Fraud and Abuse Laws**
1/26/21	Nevada Compliance Issues
1/28/21	Information Blocking Rule

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Upcoming

- HIPAA
- 42 CFR part 2
- Cybersecurity and Data Privacy
- FDA and Medical Device
- Antitrust
- Employment Laws
- Interpreters, Translators and Auxiliary Aids
- Creating and Terminating Patient Relations
- EMTALA
- Others

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AGENDA

- Key Statutes
  - False Claims Act ("FCA")
  - Anti-Kickback Statute ("AKS")
    - New rules effective 1/19/21
  - Eliminating Kickbacks in Recovery Act ("EKRA")
  - Ethics in Patient Referrals Act ("Stark")
    - New rules effective 1/19/21
  - Civil Monetary Penalties Law ("CMPL")
- Common Compliance Traps
- Report and Repayment Obligations
- Provider Relief Fund Issues

CAUTION

- This is a quick overview of most relevant federal laws and regulations.
  - Beware other laws, including state laws
- Application may depend on—
  - Circumstances of your particular case
  - Payer involved (e.g., govt, insurer, patient)
  - Jurisdiction
- Be sure to confirm applicable laws and requirements when applying to your fact situation.
- If you have questions,
  - Use chat feature, or
  - Email me at kcstanger@hollandhart.com

WRITTEN MATERIALS

- Stanger, *Beware Laws Affecting Healthcare Transactions*
- DeVoy and Ellis, *Final Rules for Stark and Anti-Kickback Reforms Issued by CMS and OIG*
- Stanger, *Fraud and Abuse in Private Payor Situations*
- Stanger, *Marketing Traps for Healthcare Providers*
- Dean, *CMS Issues Final Rule on Reporting and Returning Overpayments*
- Redline of New Anti-Kickback Statute Safe Harbors (effective 1/19/21)
- Redline of New Stark Amendments (effective 1/19/21)

➢ If you did not receive them, contact ldsquyres@hollandhart.com.

KEY 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")
- Healthcare criminal statutes

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Thursday, January 14, 2021

Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020

The Department of Justice obtained more than $2.2 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending Sept. 30, 2020, Acting Assistant Attorney General Jeffrey Bossert Clark 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 $64 billion.

"Even in the face of a nationwide pandemic, the department's dedicated employees continued to investigate and litigate cases involving fraud against the government and to ensure that citizens' tax dollars are protected from abuse and are used

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*

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

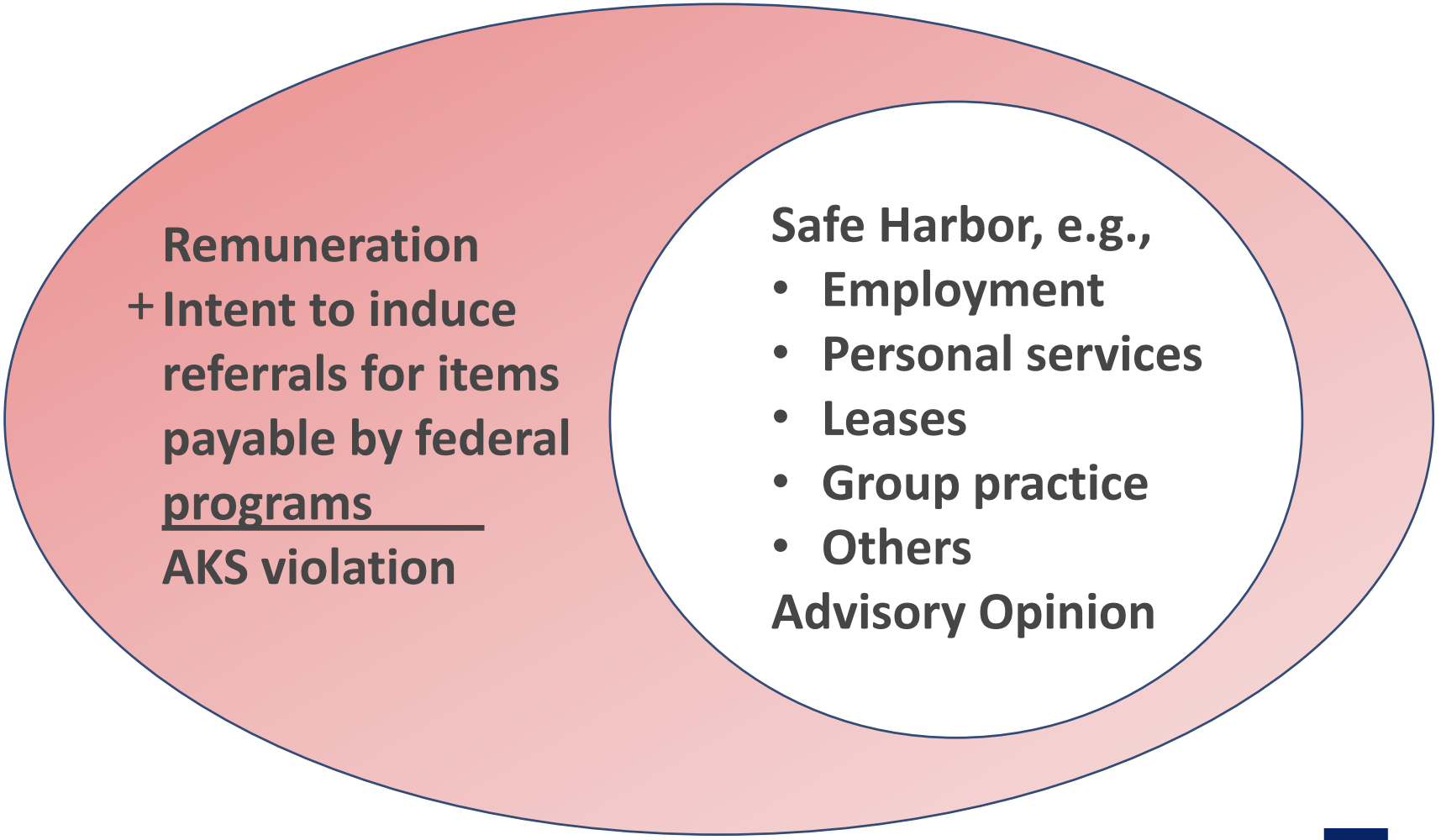
- Felony
- 10 years in prison
- $100,000 criminal fine
- $104,330* civil penalty
- 3x damages
- Exclusion from Medicare/Medicaid

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

➢ *Automatic False Claims Act violation*

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

ANTI-KICKBACK STATUTE



ANTI-KICKBACK STATUTE: SAFE HARBORS

- Bona fide employment
  - Modified terms.
- Personal services contracts
  - Modified terms
- 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)

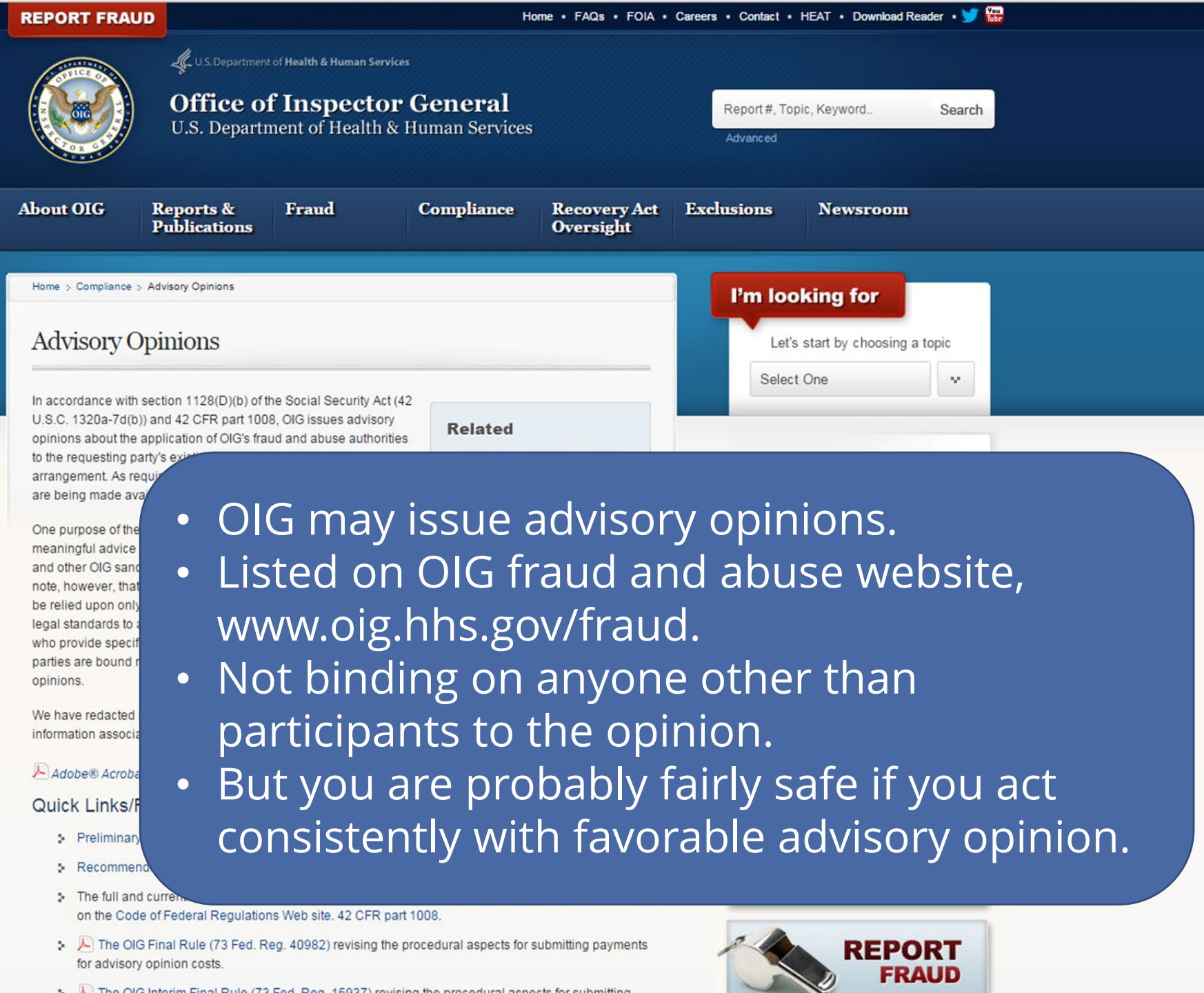
- Transportation programs
  - Modified terms.
- OB malpractice insurance subsidies
- Electronic health record items or services
  - Modified terms.
- Warranties
  - Modified terms
- Discounts
- Others

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

NEW AKS SAFE HARBORS (EFFECTIVE 1/19/21)

- Outcomes-based payments. (42 CFR 1001.952(d)(2))
- Care coordination arrangements to improve quality, health and efficiency. (42 CFR 1001.952(ee)
- Value-based arrangements with substantial downside risk. (42 CFR 1001.952(ff))
- Value-based arrangements with full financial risk. (42 CFR 1001.952(gg))
- Arrangements for patient engagement and support to improve quality, health outcomes and efficiency. (42 CFR 1001.952(hh))
- CMS-sponsored model arrangements and CMS-sponsored model patient incentives (42 CFR 1001.952(ii))
- ACO beneficiary incentive program. (42 CFR 1001.952(kk)

- Cybersecurity technology and related services. (42 CFR 1001.952(jj))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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.
The OIG Final Rule (73 Fed. Reg. 40982) revising the procedural aspects for submitting payments for advisory opinion costs.
REPORT FRAUD
• OIG may issue advisory opinions.
• Listed on OIG fraud and abuse website, www.oig.hhs.gov/fraud.
• 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 statutory or regulatory exception.

(18 USC 220(a))

Penalties

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

(18 USC 220(a))

➢ *Labs: beware, including COVID testing*

➢ *Applies to private or public payors.*

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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 drug 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))

➢ *No implementing regulations yet…*

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 = as defined in 42 USC 1395x(r), i.e.,
    - MDs
    - DOs
    - Oral surgeons
    - Dentists
    - Podiatrists
    - Optometrists
    - Chiropractors
  - Family member =
    - Spouse
    - Parent, child
    - Sibling
    - Stepparent, stepchild, stepsibling
    - Grandparent, grandchild
    - In-law

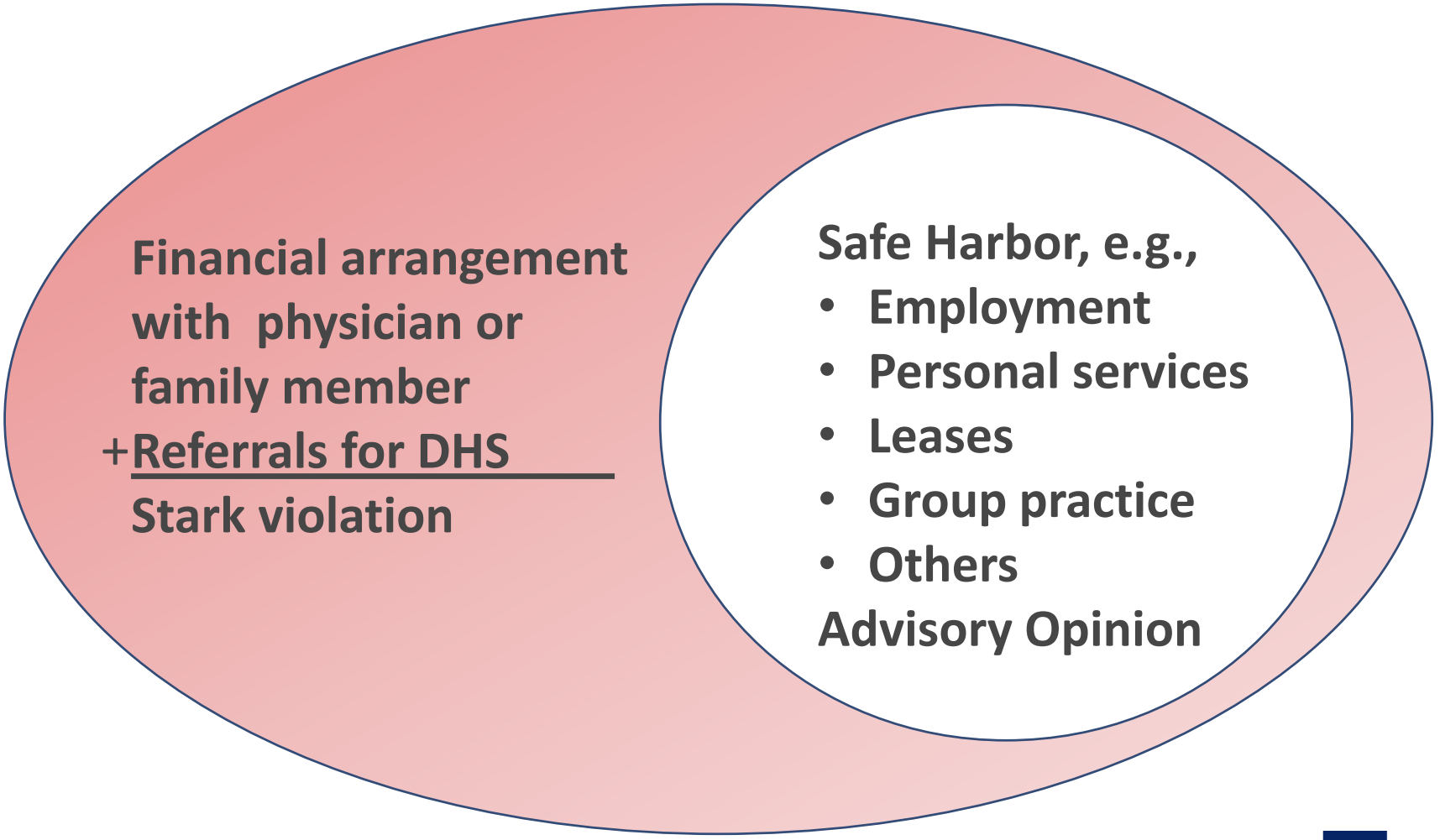
(42 CFR 411.351)

STARK

- Applies to referrals for designated health services ("DHS") payable in whole or part by Medicare.
  - Inpatient and outpatient hospital services
    - New: not inpatient services if furnishing service does not increase hospital's reimbursement under PPS.
  - 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, e.g., radiology.

(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: OWNERSHIP

Ownership + Compensation Arrangements

- Physician services
- In-office ancillary services
- Prepaid health plans
- Academic medical centers
- Implants by an ASC
- EPO and dialysis drugs
- Preventive screening tests, immunizations and vaccines
- Eyeglasses and contact lenses following surgery

(42 CFR 411.355)

Ownership Arrangements

- Publicly traded securities
- Mutual funds
- Rural providers
- Whole hospital
- Publicly traded securities
- Intra-family rural referrals
- Others

(42 CFR 411.356)

➢ *Must satisfy all the requirements to receive safe harbor protection*

STARK SAFE HARBORS COMPENSATION

Compensation

- Employment*
- Personal services contracts*
- Fair market value*
- Space or equipment leases
- Timeshare arrangements
- Recruitment and retention
- Non-monetary compensation up to $429
- Medical staff incidental benefits
- Professional courtesy
- OB malpractice subsidies
- Isolated transactions
  - Now includes settlements and forgiveness of debts.
- Payments by a physician
- Charitable donations by a physician
- Risk sharing arrangements
- Compliance training
- Indirect compensation arrangements*
- Referral services
- Health information technology and support

(42 CFR 411.357)

** Check new requirements when applying, including directed referral requirements.*

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NEW STARK SAFE HARBORS (EFFECTIVE 1/19/21)

- Value based compensation arrangements. (42 CFR 411.357(aa))
  - Full financial risk.
  - Meaningful downside risk.
  - Value-based arrangements.
- Remuneration to physician < $5000 per calendar year for service rendered if:
  - Not based on volume or value of referrals.
  - Does not exceed fair market value.
  - Arrangement is commercially reasonable even if no referrals
  - Compensation for leases satisfy certain conditions.
  - If directed referrals, satisfy 42 CFR 411.354(d)(4).

  (42 CFR 411.357(z))
- Cybersecurity technology and services. (42 CFR 411.357(bb))
- Isolated transactions include settlements. (42 CFR 411.357(f))

ADDITIONAL STARK CHANGES (EFFECTIVE 1/19/21)

- Modified definitions of "fair market value" and "commercially reasonable". (42 CFR 411.351)
- Clarifies meaning of "set in advance." (42 CFR 411.354(d))
- Clarifies meaning of varying with the "volume or value of referrals." (42 CFR 411.354(c), (d))
- Eliminates "period of noncompliance". (42 CFR 411.353)
- May correct inadvertent overpayment/underpayment within 90 days of termination of arrangement. (42 CFR 411.353(g))
- Gives 90-day grace period to obtain necessary signatures. (42 CFR 411.354(e)).
- Modifies rules for indirect compensation arrangements. (42 CFR 411.354(c)(4)).
- Mandates compliance with 42 CFR 411.354(d)(4) if arrangement directs referrals.
- Removes requirements that safe harbors also comply with the Anti-Kickback Statute.

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

CIVIL MONETARY PENALTIES

- 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)

➢ *Likely also an Anti-Kickback Statute violation*

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; and
  - 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

Check the LEIE on regular basis!

I'm looking for

Let's start by choosing a topic

Select One

- Online Searchable Database
- LEIE Downloadable Databases
- Monthly Supplement Archive
- Waivers
- Quick Tips
- Background Information
- Applying for Reinstatement
- Contact the Exclusions Program
- Frequently Asked Questions
- Special Advisory Bulletin and Other Guidance

EXCLUSIONS DATABASE

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
- Others?

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

PRIVATE PAYORS

Statutes

- Federal
  - Healthcare fraud
  - EKRA
- State statutes
  - Anti-kickbacks
  - Self-referrals
  - Fee-splitting
  - Insurance fraud
  - Consumer protection
- Others?

Private lawsuit

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

APPLYING THE LAWS TO COMMON SITUATIONS

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")

Potential violations of

- Anti-Kickback Statute
- Civil Monetary Penalties Law
- State Laws
- Others?

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, 75 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, 75 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 insurer 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 payer contract language.
  - Does not apply where state law requires the disclosure, e.g., Medicaid or private payers.

(78 FR 5628)

REMUNERATION TO REFERRING PROVIDERS

- Employment
- Independent contractor or other services agreement
- Group compensation arrangement
- Use of space or equipment
- Use of personnel
- Recruitment agreement
- Management or support services
- Joint ventures
- Gifts or perks
- More/less than fair market value
- Anything else of value

- ✓Stark
- ✓Anti-Kickback
- ✓EKRA
- ✓Civil Monetary Penalties Law
- ✓State laws?
  - ✓Mini-Stark
  - ✓AKS
  - ✓Fee-splitting
  - ✓Others?

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PHYSICIANS

Stark

- Employment
- Independent contractor
- Compensation < $5000
- Group practice compensation
- Recruitment
- Leases
- Ownership
- Non-monetary compensation up to $429
- Medical staff incidental benefits
- Professional courtesy
- EHR support
- Isolated transactions
- Value-based care
- Others

(42 CFR 411.355-.357)

Anti-Kickback Statute

- Employment
- Independent contractor
- Group practice
- Recruitment
- Leases
- Sale of practice
- Investments in other entities
- EHR support
- Others

(42 CFR 1001.952)

- One purpose to induce referrals?
- Favorable advisory opinion?

NON-PHYSICIAN PROVIDERS

Stark does not apply to providers who are not:

- MDs
- DOs
- Oral surgeons
- Dentists
- Podiatrists
- Optometrists
- Chiropractors

➢ *Beware state laws*

Anti-Kickback Statute

- Employment
- Independent contractor
- Group practice
- Recruitment
- Leases
- Sale of practice
- Investments in other entities
- EHR support
- Others

(42 CFR 1001.952)

REPAYING OVERPAYMENTS

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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))

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, etc.
- 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

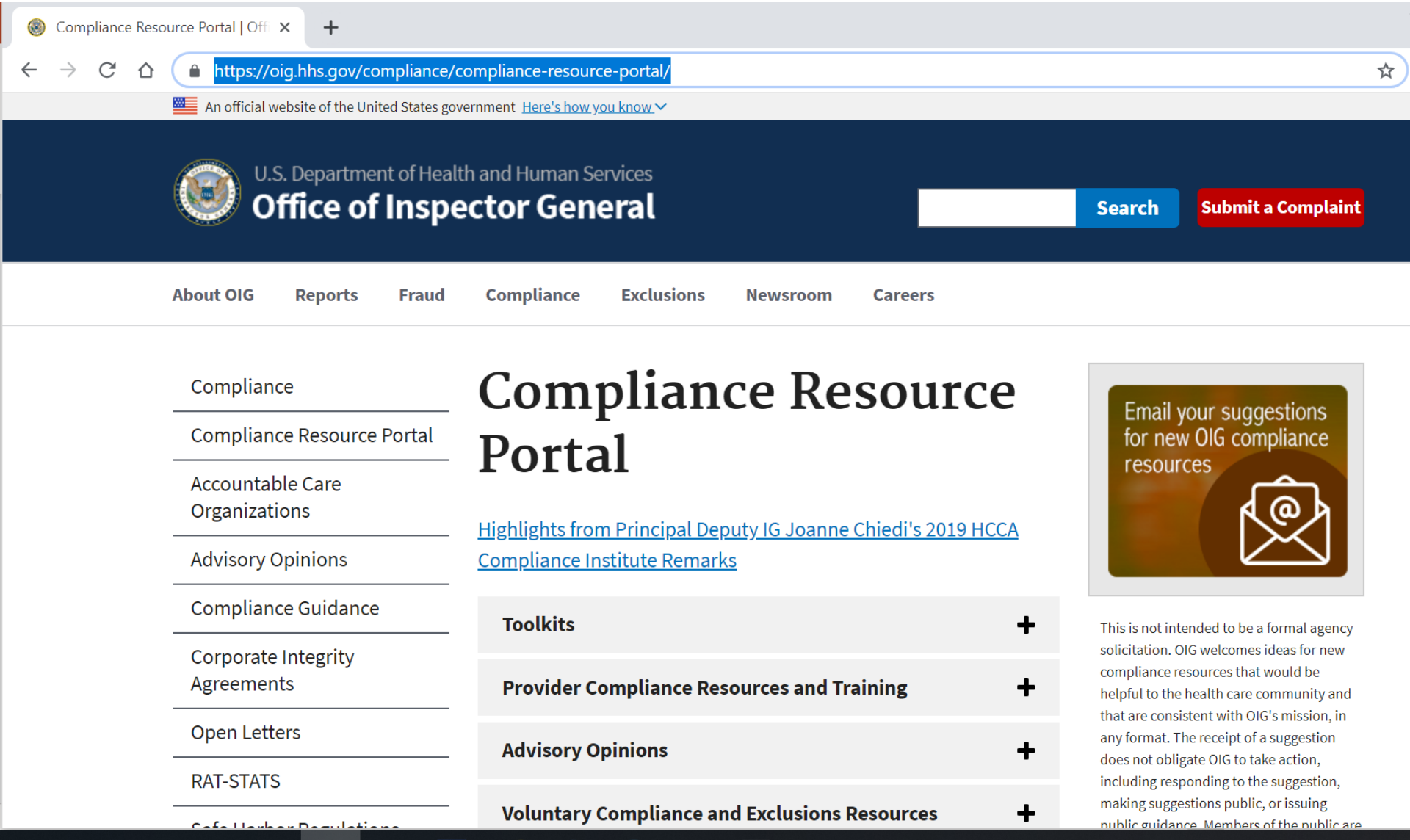
- Repayment per Repayment Rule does not resolve violations or penalties under other laws, e.g.,
  - Anti-Kickback Statute, Civil Monetary Penalties Law, or False Claims Act, which are resolved by OIG or DOJ.
  - Stark, which is resolved by CMS.
- If Medicare contractor believes repayment involves violation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

OVERPAYMENT: REPORTING

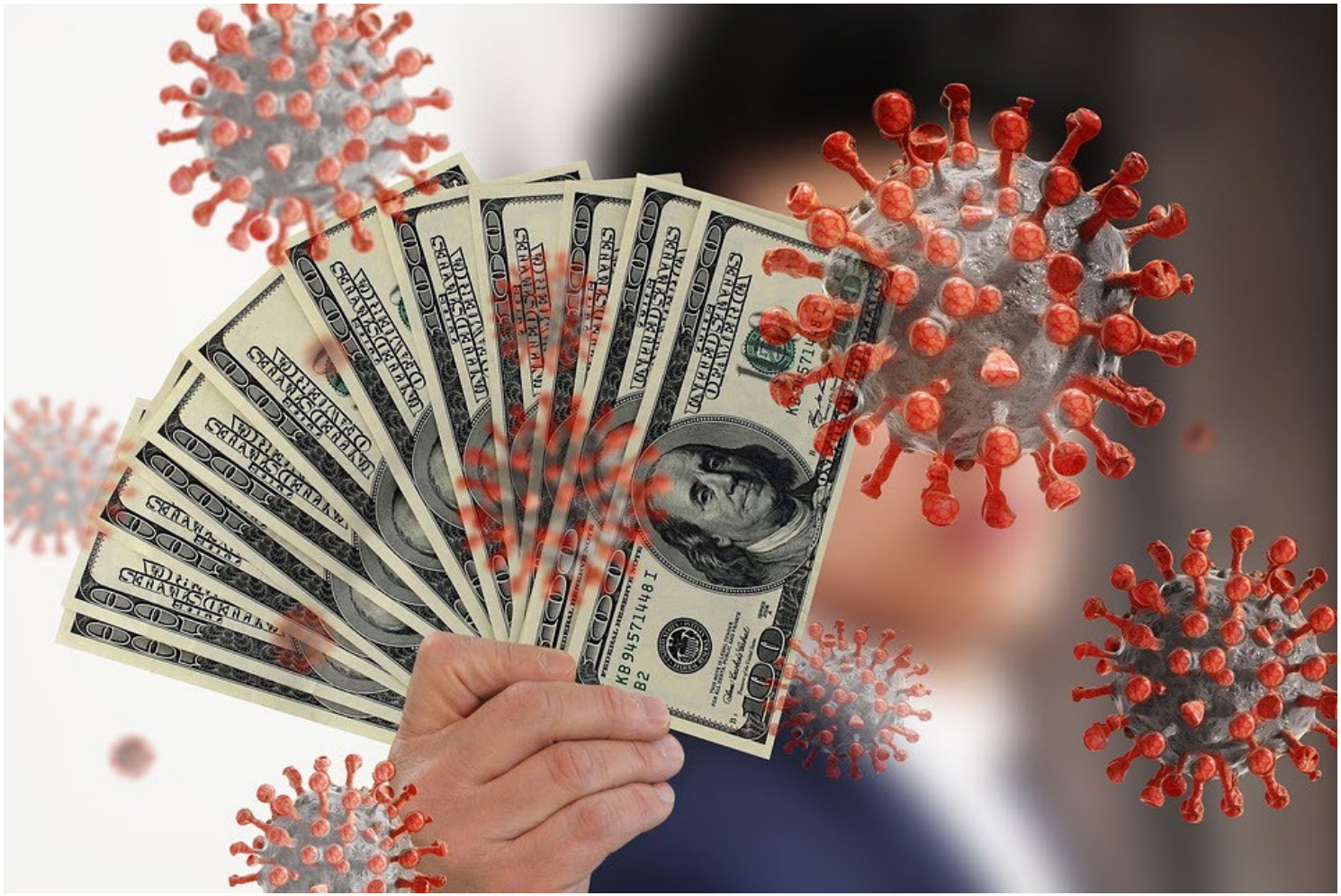
May want to consider other disclosure protocols.

- 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

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



COVID PROVIDER RELIEF FUND



PROVIDER RELIEF FUND

Rules change frequently.

- Coronavirus Response and Relief Supplemental Appropriations Act, 2021 ("CRRSA") (12/27/20)
  - Greater flexibility to claim "lost revenues"
  - Allocate payments among subsidiaries
  - Additional funding
- Post-Payment Notice of Reporting Requirements (1/15/21), https://www.hhs.gov/sites/default/files/provider-post-payment-notice-of-reporting-requirements-january-2021.pdf
- PRF Guidance Update (1/15/21), https://www.hhs.gov/sites/default/files/provider-relief-fund-general-distribution-faqs.pdf

➢Check updated guidance regularly…

HTTPS://WWW.HHS.GOV/CORONAVIRUS/CARES-ACT-PROVIDER-RELIEF-FUND/INDEX.HTML

https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html

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CARES Act Provider Relief Fund

The Provider Relief Funds supports American families, workers, and the heroic healthcare providers in the battle against the COVID-19 outbreak. HHS is distributing $175 billion to hospitals and healthcare providers on the front lines of the coronavirus response.

https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/general-information/index.html

HTTPS://WWW.HHS.GOV/CORONAVIRUS/CARES-ACT-PROVIDER-RELIEF-FUND/FOR-PROVIDERS/INDEX.HTML

CARES Act Provider Relief Fund: F

hhs.gov/coronavirus/cares-act-provider-relief-fund/for-providers/index.html

Recipients must comply with:

- Relevant Terms & Conditions associated with distribution.
- "Any other relevant statutes and regulations."

➢ *Watch for additional guidance.*

CARES Act Provider Relief Fund Terms and Conditions

Terms and Conditions	Description
Relief Fund Payment from $30 Billion General Distribution - PDF	The recipient automatically received payment from the initial $30 billion general distribution.
Relief Fund Payment $20 Billion General Distribution - PDF	The recipient has received payment from the additional $20 billion general distribution.
FFCRA Relief Fund Payment Terms and Conditions - PDF	The recipient plans to submit claims for reimbursement for COVID-19 testing and/or testing related items and services provided to FFCRA (Families First Coronavirus Response Act) Uninsured Individuals.
Uninsured Relief Fund Payment Terms and Conditions - PDF	The recipient plans to submit claims for reimbursement for care or treatment related to positive diagnoses of COVID-19 provided to individuals who do not have any health care coverage at the time the services were provided.
High Impact Relief Fund Payment Terms and Conditions - PDF	The recipient has received a payment from the COVID-19 High Impact Area Distribution, part of the targeted allocations.
Rural Provider Relief Fund Payment Terms and Conditions - PDF	The recipient has received a payment from the Rural Distribution, part of the targeted allocations.
Rural Health Clinic (RHC) Testing Payment Terms and Conditions - PDF	The recipient has received payment from funds appropriated in the Public Health and Social Services Emergency Fund for COVID-19 testing and related expenses.

ELIGIBILITY

- Recipient must certify that on or after 1/31/20, provided diagnoses, testing or care for individuals with possible or actual cases of COVID-19.
  - "Care does not have to be specific to treating COVID-19."
  - "HHS broadly views every patient as a possible case of COVID-19."
  - Compare "presumptive" cases for purposes of balance billing.

(PRF FAQs; Terms & Conditions)

USE OF PRF PAYMENTS

- Recipient certifies that
  - Payment will only be used to prevent, prepare for, and respond to coronavirus, and
  - Payment shall reimburse the Recipient only for
    - health care related expenses or
    - lost revenues that are attributable to coronavirus.

(Terms & Conditions)

- *Post-Payment Notice of Reporting Requirements* (1/15/21), available at https://www.hhs.gov/sites/default/files/provider-post-payment-notice-of-reporting-requirements-january-2021.pdf
- *PRF Guidance Update* (1/15/21), https://www.hhs.gov/sites/default/files/provider-relief-fund-general-distribution-faqs.pdf

TERMS & CONDITIONS: IMPERMISSIBLE USES

- Cannot use PRF payments to cover expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse.

(Terms & Conditions)

➢ Beware using funds for expenses covered by other sources:

  – Other state or federal payment programs, e.g., Medicare, Medicaid, CHIP, Paycheck Protection Program; other PRF distributions; increased reimbursement under state programs, etc.
  – Private obligations.

TERMS & CONDITIONS: IMPERMISSIBLE USES

- Cannot use PRF payments to pay salary of an individual in excess of Executive Level II, i.e., $197,300.
  - Salary cap is exclusive of fringe benefits and indirect costs.
  - May use non-federal funds to pay salary in excess of the salary cap.

(Terms & Conditions; PRF FAQs)

TERMS & CONDITIONS: IMPERMISSIBLE USES

- Cannot use PRF payments for other specified purposes, e.g., To entity that uses confidentiality agreements to prohibit reporting of fraud and abuse.
  - To entity with unpaid federal tax liability.
  - To entity that was convicted of felony in prior 24 months.
  - Abortion except in limited circumstances.
  - Human embryo research.
  - Lobbying.
  - Legalization of controlled substances.
  - Needle exchange programs except in limited circumstances.
  - Dissemination of deliberately false info.
  - Promote gun control.
  - Pornography.
  - Human trafficking.
  - Capture of chimpanzees.
  - Association of Community Organizations for Reform Now ("ACORN").
  - Violations of the Privacy Act.

(Terms & Conditions)

USE OF PRF PAYMENTS

- Providers may generally claim expenses incurred between January 1, 2020 and June 30, 2021.
  - "HHS expects that it would be highly unusual for providers to have incurred eligible expenses prior to January 1, 2020."
  - Providers must expend funds by June 30, 2021.
- If on June 30, 2021, providers have leftover PRF money that they cannot expend on permissible expenses or losses, they must return the money to HHS.

(PRF FAQs)

DOCUMENTATION

- Must maintain appropriate records, cost documentation, and other info required by HHS to substantiate the costs and expenses for 3 years from date of last expenditure.
- Must promptly submit copies of such records upon request by HHS.
- Must fully cooperate in all audits that HHS conducts to ensure compliance with the Terms & Conditions.

(Terms & Conditions)

TRUTH OF INFO

- Recipient certifies that all info it provides is true, accurate and complete, to the best of its knowledge.
- Any deliberate omission, misrepresentation, or falsification of any info may be punishable by:
  - criminal,
  - civil, or
  - administrative penalties

- Revocation of Medicare billing privileges,
- Exclusion from federal health care programs,
- Fines,
- Civil damages, and/or
- Imprisonment.

(Terms & Conditions)

ENFORCEMENT

- HHS may recoup funds.
  - *Note change from prior guidance.*
- Recipients must demonstrate proper use.
  - Document and maintain documentation.
- HHS will have significant anti-fraud monitoring of PRF payments.
  - Reporting requirements
  - Audits
  - Risk assessment and data analytics
  - Whistleblowers
  - Others

(PRF FAQs)

ENFORCEMENT

- HHS has already warned about:
  - Civil, criminal, and administrative penalties.
  - Revocation of Medicare billing privileges
  - Exclusion from federal healthcare programs
  - Fines, civil damages, and imprisonment.

(Terms & Conditions)

- False Claims Act
  - Repayment plus interest
  - Civil penalty of up to $23,300 per false claim
  - $20,866 for failure to repay
  - Treble damages
  - Exclusion from federal programs
  - Qui tam litigation
- Federal fraud laws
  - Prison
  - Criminal fines

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QUESTIONS?

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