

# Arrangements with Referring Providers: Fraud and Abuse Issues

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Webinar  
(8/19)

# Disclaimer

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# Overview

## Brief review of relevant statutes

- False Claims Act
- Anti-Kickback Statute
- Eliminating Kickbacks in Recovery Act (“EKRA”)
- Ethics in Patient Referrals Act (“Stark”)
- Civil Monetary Penalties Law
  - Inducements to limit services
  - Exclusions
- Common state laws

## Applying statutes to common situations

- Employment contracts
- Independent contractor arrangements
- Group practice compensation
- Recruitment
- Retention
- Leases
- Timeshares
- Ownership
- Gainsharing
- Gifts and perks
- Professional courtesy
- Medical staff incidental benefits
- Non-monetary compensation
- Others?

# Written Materials

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- .Ppt slides
- OIG Compliance Program Guidance
- OIG, *Avoiding Fraud and Abuse*
- Articles on various issues available at <https://www.hhhealthlawblog.com/>.
- If you did not receive the written materials, contact [LDSquyres@hollandhart.com](mailto:LDSquyres@hollandhart.com).

# Questions?

- Please submit questions using the chat feature, or e-mail me at [kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com).



# Beware

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- This is an overview of some laws.
  - I'm focusing on federal laws.
  - Laws have very specific requirements.
  - Check specifics when applying.
- Beware other laws, especially state laws.
  - State laws may vary.
- Application of laws may depend on the circumstances, parties, and nature of relationships.
- *Check with your compliance professionals or attorneys when applying.*

# Fraud and Abuse Laws



- False Claims Act
- Anti-Kickback Statute (“AKS”)
- Eliminating Kickbacks in Recovery Act (2018) (“EKRA”)
- Ethics in Patient Referrals Act (“Stark”)
- Civil Monetary Penalties Law (“CMPL”)
- State Laws

# False Claims Act

- **Cannot knowingly submit a false claim for payment to the federal govt.**
  - Applies to claims that do not comply with laws or regs.  
*(Univ. Health Serv., Inc. v. US ex rel. Escobar, 136 S.Ct. 1989 (2016))*
- **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)

- **Subject to *qui tam* litigation.**

## Penalties

- **Repayment plus interest**
- **Civil monetary penalties of \$11,781 to \$21,563 per claim**
- **3x damages**
- **Exclusion from Medicare/Medicaid**

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



# 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”**

## Penalties

- 10 years in prison
- \$100,000 criminal fine
- \$100,000 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))



# 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))

- Applies to referrals paid by private or public payers.

## Penalties

- \$200,000 criminal fine
- 10 years in prison  
(18 USC 220(a))
- Maybe Anti-Kickback Statute violation

# 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.

(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.
  - \$24,748 per claim submitted
  - \$164,992 per scheme

(42 CFR 411.353, 1003.310; 45 CFR 102.3)

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

# Civil Monetary Penalties Law

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- 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

- \$5,000 per violation.
- Exclusion from Medicare and Medicaid

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

# Excluded Entities

- Excluded person cannot order or prescribe item or service payable by federal healthcare program.
- Cannot submit claim for item or service 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 or services payable by federal programs.

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

## Penalties

- \$20,000 per item or service ordered.
- \$10,000/day prohibited relationship exists.
- 3x amount claimed.
- Repayment of amounts paid.
- Exclusion from Medicare and Medicaid

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

# Common State Statutes

- Anti-kickback statutes
  - E.g., IC 41-348
- Licensing statutes or medical practices acts
  - Paying for referrals
  - Fee splitting
  - E.g., IC 54-1814
- Medicaid statutes, regulations or provider agreements
  - May impose fraud and abuse provisions
  - May incorporate federal statutes or standards
- Consumer protection statutes
- Others?



- May be broader than federal statutes
  - May apply to private payers
  - May not contain safe harbors
- Check state laws.
- And don't forget about payer contracts

# Applying the Rules



# 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



- ✓ Stark
- ✓ Anti-Kickback Statute
- ✓ 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

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- 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

# Group Practice Compensation

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To qualify for Stark's "group practice" safe harbors, group must qualify as a "group practice", including:

- Overhead expenses and income distributed per method that is determined before receipt of payment for services.
- Physician's compensation may not be based on the volume or value of the physician's referrals for DHS, except for special rules re:
  - **Productivity bonuses**
  - **Profit shares**

(42 CFR 411.352)

# Group Practice Compensation

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## Productivity bonuses

- May pay group physician based on:
  - Services physician personally performed, and/or
  - “Incident to” services.
- Productivity formula deemed not to be based on referrals if:
  - Bonus is based on total patient encounters or RVUs.
  - Bonus based on allocation of compensation attributable to services that are not DHS payable by fed program or private payer.
  - Revenues from DHS < 5% of group’s total revenues, and allocated portion of DHS revenues < 5% of physician’s total compensation.

(42 CFR 411.352(i))

# Group Practice Compensation

## Share of Profits

- May pay group physician based on share of overall profits from DHS of group or component of at least 5 physicians, provided that share is not determined in a manner that directly relates to volume or value of DHS by the physician.
- Share of profits deemed not to be based on referrals if:
  - Profits divided per capita.
  - Revenues from DHS distributed based on distribution of revenues from services that are not DHS payable by fed program or private payer.
  - Revenues from DHS < 5% of group's total revenues, and allocated portion of DHS revenues < 5% of physician's total compensation.

(42 CFR 411.352(i))



# Ownership in Rural Provider

## Stark (Physicians)

- Physician-owned entity furnishes DHS in a “rural area”, i.e., outside a metropolitan statistical area (“MSA”).
- Entity furnishes at least 75% of the DHS that it furnishes to residents of a rural area.
- If entity is a hospital in which physicians or family members have ownership or investment interest, hospital must satisfy additional requirements applicable to physician-owned hospitals in 42 CFR 411.362.

(42 CFR 411.356(c)(1))

# Ownership in Hospital (e.g., Specialty Hospital)

## Stark (Physicians)

- Physician or family member has ownership or investment in the whole hospital, not a department or distinct part.
- Status established as of 12/31/10.
  - Physician had interests as of 12/31/10.
  - No addition of operating rooms, procedure rooms, or beds unless exception granted through reg process.
  - No increase in the percentage of physician ownership.
- Compensation does not depend on referrals.
- Returns based on investment, not referrals.
- Cannot loan money for investment.
- Investment offered on same terms to non-physicians.
- Other conditions, including notices.

(42 CFR 411.356(c)(3) and .362)

# Ownership in Ambulatory Surgery Centers

## Stark (Physicians)

- DHS does not include services that are reimbursed by Medicare as part of composite rate, including ASC services identified in 42 CFR 416.164(a).
- May apply to extent ASC provides services outside the composite rate.

(42 CFR 411.351)

## Anti-Kickback Statute

- Safe harbors for:
  - Surgeon-owned ASCs
  - Single-specialty ASCs
  - Multi-specialty ASCs
  - Hospital/Physician ASCs
- See specific requirements for safe harbor protection.

(42 CFR 1001.952(r))

# 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.
  - 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))



# Isolated Transactions (e.g., Sale of Practice)

## Stark (Physicians)

- Isolated financial transaction such as one-time sale of practice.
- Remuneration is:
  - Consistent with FMV.
  - Does not take into account the volume or value of referrals.
- Commercially reasonable even if physician made no referrals.
- No additional transactions within 6 months except:
  - reasonable post-closing adjustments, and
  - transactions that meet another Stark safe harbor.

(42 CFR 411.357(f))

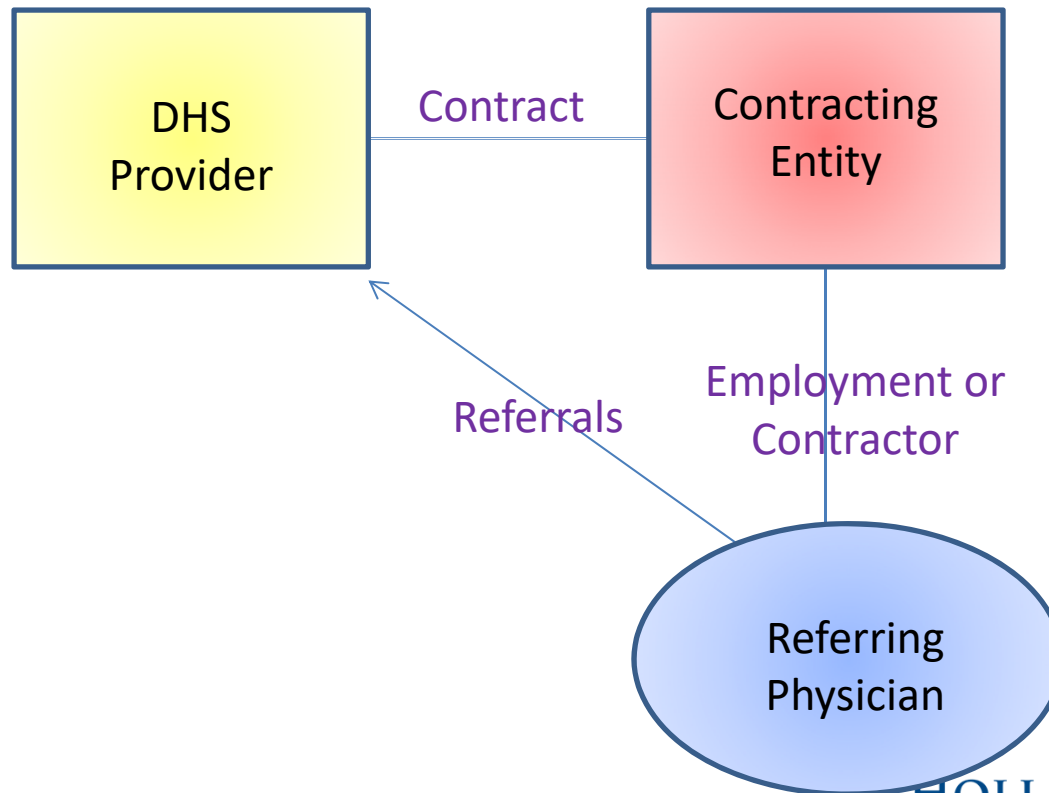
## Anti-Kickback Statute

- Sale of practice to another practitioner
- Completed within 1 year.
- Seller not in a position to make referrals for federal programs after 1 year.
- Special rules for sale to hospital.  
(42 CFR 1001.952(e))

# Indirect Financial Relationships

- Under Stark, no “financial relationship” exists if closest compensation relationship with physician does not vary with volume or value of referrals.
- Beware physician owners who “stand in the shoes” of their group.

(42 CFR 411.354(c))



# Indirect Financial Relationship

## Stark (Physicians)

- Indirect compensation arrangement.
- Compensation is
  - Fair market value for services provided, and
  - Not determined based on referrals.
  - Additional rules for leases.
- Compensation arrangement:
  - Set out in written agreement signed by parties (except employment agreement);
  - For identifiable services; and
  - Commercially reasonable.
  - Does not violate Anti-Kickback Statute or other law governing billing submissions.

(42 CFR 411.357(p))

# 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

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- 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 state laws.

# Professional Courtesy

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## 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 payer contracts, especially if waive copays or engage in “insurance only billing.”**

# Non-Monetary Compensation Less than \$416/Year

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## Stark (Physicians)

- Items or services (not cash or cash equivalents) that do not exceed \$416/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

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## 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 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.

# Additional Safe Harbors

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## **Stark and/or Anti-Kickback Statute:**

- 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)

# If you think you have a problem

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- 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.

# Upcoming Webinar

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Thursday, September 19 at noon Mountain Time:

- **Responding to Non-Compliance: Self-Reporting and Repaying Overpayments**
  - False Claims Statute
  - Report and Repayment Rule
  - OIG Self-Disclosure Protocol
  - CMS Self-Referral Disclosure Protocol (Stark)
  - Contractor Reports

# Check your state law!

- State law may differ...



# Additional Resources

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<https://oig.hhs.gov/compliance/compliance-resource-portal/>

The screenshot shows a web browser window displaying the Compliance Resource Portal. The browser's address bar shows the URL <https://oig.hhs.gov/compliance/compliance-resource-portal/>. The page header includes the U.S. Department of Health and Human Services logo and the text "Office of Inspector General". A search bar and a "Submit a Complaint" button are visible. The main navigation menu includes "About OIG", "Reports", "Fraud", "Compliance", "Exclusions", "Newsroom", and "Careers". The main content area features a large heading "Compliance Resource Portal" and a sub-heading "Highlights from Principal Deputy IG Joanne Chiedi's 2019 HCCA Compliance Institute Remarks". A sidebar on the left lists various resources such as "Compliance", "Compliance Resource Portal", "Accountable Care Organizations", "Advisory Opinions", "Compliance Guidance", "Corporate Integrity Agreements", "Open Letters", and "RAT-STATS". A right-hand sidebar contains a call to action: "Email your suggestions for new OIG compliance resources" with an envelope icon. Below this, a paragraph explains that the portal is not a formal agency solicitation and that suggestions are welcome. The Windows taskbar at the bottom shows the date and time as 10:07 AM on 6/22/2019.

Compliance Resource Portal | Off x +

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# Compliance Resource Portal

[Highlights from Principal Deputy IG Joanne Chiedi's 2019 HCCA Compliance Institute Remarks](#)

**Toolkits** +

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**Advisory Opinions** +

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This is not intended to be a formal agency solicitation. OIG welcomes ideas for new compliance resources that would be helpful to the health care community and that are consistent with OIG's mission, in any format. The receipt of a suggestion does not obligate OIG to take action, including responding to the suggestion, making suggestions public, or issuing public guidance. Members of the public are

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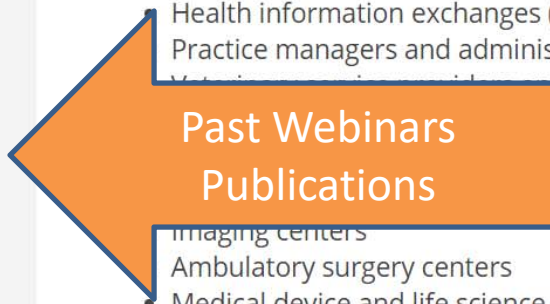
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**The Healthcare Industry is poised to continue its rapid evolution. With this sector now making up close to 20 percent of GDP, our lawyers stand ready to help as changes unfold.**

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

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- Practice managers and administrators
- Veterinary hospitals and facilities
- Independent Practice Associations (IPAs)
- Imaging centers
- Ambulatory surgery centers
- Medical device and life science companies





# Questions?

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