

# Arrangements with Patients: Fraud and Abuse Issues



Kim C.  
Stanger

Webinar  
(7/19)

# Disclaimer

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# Overview

## Brief review of relevant statutes

- False Claims Act
- Anti-Kickback Statute
- Eliminating Kickbacks in Recovery Act
- Civil Monetary Penalties Law



## Applying statutes to common patient situations

- Free or discounted items
- Free screening or similar services
- Free transportation
- Waiving copays
- Writing off bills
- Prompt pay discounts
- Self-pay or cash discounts
- Professional courtesies
- Paying patient premiums

# 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



- This is an overview of some laws.
    - I'm focusing on federal laws.
    - 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”)
- 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 regulations.  
(*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

# Civil Monetary Penalties Law

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- 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

- \$20,000 per violation.
- Exclusion from Medicare and Medicaid

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

# 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





# 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 or discounted service (e.g., free screening)
- 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

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- Beware any inducements for:
  - Laboratory services
  - Recovery home
  - Clinical treatment facility
- Check for EKRA safe harbors
- Watch for implementing regulations

# Free or Discounted Items or Services to Patients

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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

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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

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May offer free or discounted items to **govt beneficiaries** if:

- Incentives to promote delivery of preventative care as determined by HHS in regulations.
- Payments meeting AKS safe harbor.
- Any other remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs.
- Retailer coupons, rebates or rewards offered to public.
- Certain other situations.

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



# Free Tests or Screening

- OIG has approved free screening services or tests (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 or follow-up services.
  - 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



- AKS safe harbor: 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 payers or individuals

(42 CFR 1001.952(bb))

# Free Transportation

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- AKS safe harbor: shuttle service that operates 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 payers or individuals

(42 CFR 1001.952(bb))

# Waiving Copays or Deductibles



May waive or discount **govt** copays or deductibles if:

- Waive or discount after
    - good faith determination that the beneficiary is in financial need, or
    - unable to collect after reasonable collection efforts.
  - Not offered as part of any advertisement or solicitation;
  - Do not routinely waive copays or deductibles; and
- (42 USC 1320a-7a(i)(6); 42 CFR 1003.110; *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.

# Waiving Copays or Deductibles

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

- **Hospital inpatient stay paid under PPS.**
  - Waived amounts cannot be claimed as bad debt or shifted to any other payers.
  - Offered without regard to the reason for admission, length of stay, or DRG.
  - Waiver may not be made as part of any agreement with third party payer with limited exceptions.
- **FQHC or other health care facility under any Public Health Services Grant.**

(42 CFR 1001.952(k))

# Writing Off Bills



- Writing off entire debt safer than waiving copays.
  - No one gets billed.
- The key: document legitimate purpose, i.e., not intent to generate referrals!
  - Resolution of legitimate dispute or settlement of claim.
  - Unsuccessful attempts to collect.
  - Financial need.
  - Other

# Writing Off Bills

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- Under CMPL, may waive or discount beneficiary's bills if:
  - 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*)

# Writing Off Bills

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- 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.
  - Document determination of financial need.

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

# Professional Courtesy



- Offering free or discounted items to referral sources (e.g., referring providers, their family members, their staff, etc.) may implicate Anti-Kickback Statute, Ethics in Patient Referrals Act (“Stark”), CMPL.
  - **Stark contains safe harbor for courtesies offered 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.
  - 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 payers of program.
  - Costs not passed to Medicare, Medicaid or other payers.

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

# Prompt Pay Discounts

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

# Self-Pay Discounts



- Providers may generally charge different patients or payers different amounts.
  - Negotiated rates for payers.
  - Negotiated rates or discounts for self-pay patients.
- Limitations:
  - Some states limit ability to charge different rates.
    - Charging insurers more than self-pay patients.
    - Charging self-pay patients more than insurers.
  - Perhaps 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, payer 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

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- 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.
- 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 Payers

- Medicare and private payers 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 payer unless law requires disclosure.

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

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

(78 FR 5628)



# Paying Patient's Premiums

- If paying Medicare Part B, C or D premiums:
  - **OLG approved plan's 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.
  - **OLG 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

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- 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 payer contracts.
- *But stay tuned—this is a developing area of the law.*

# Action Items



# Check your arrangements with patients

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- 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?

# Review and Update Compliance Plan

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- Ensure it has required elements
  - Policies, procedures and standards of conduct
  - Designated compliance officer and committee
  - Conduct effective training and education
  - Develop effective lines of communication, e.g., complaint hotline
  - Conduct internal monitoring and auditing
  - Enforce through publicized disciplinary guidelines
  - Respond promptly to offenses and implement corrective action.

*See* OIG Supplemental Compliance Program Guidance for Hospitals, 70 FR 4858, available at

<https://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf>

# Train Key Personnel

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- 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

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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.

# Check your state law!

- State law may differ...

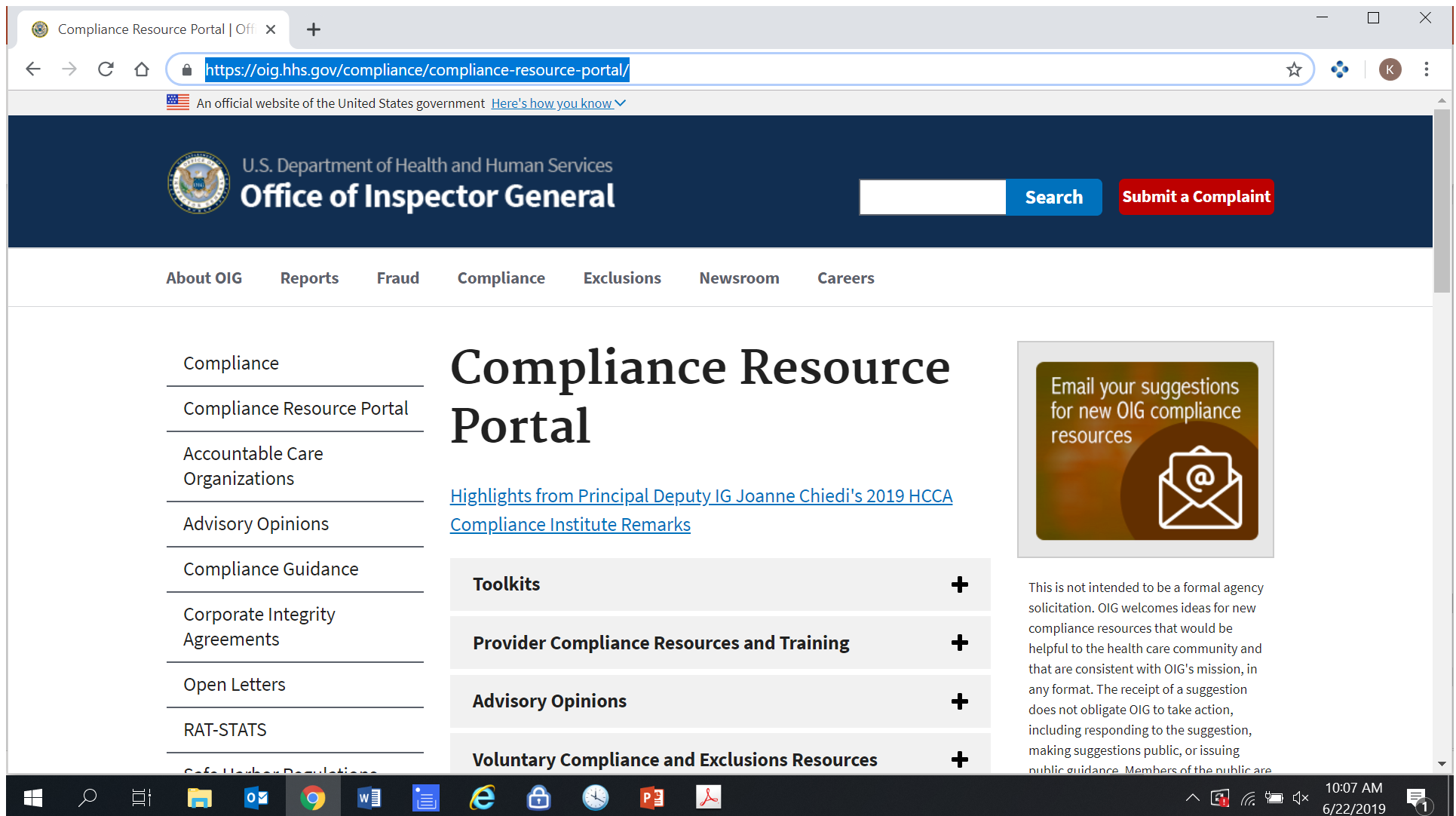


# Additional Resources

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



The screenshot shows a web browser displaying the Compliance Resource Portal. The browser's address bar shows the URL <https://oig.hhs.gov/compliance/compliance-resource-portal/>. The page header features the U.S. Department of Health and Human Services Office of Inspector General logo and a search bar. The main navigation menu includes links for About OIG, Reports, Fraud, Compliance, Exclusions, Newsroom, and Careers. The left sidebar lists various resources: Compliance, Compliance Resource Portal, Accountable Care Organizations, Advisory Opinions, Compliance Guidance, Corporate Integrity Agreements, Open Letters, RAT-STATS, and Safe Harbor Regulations. The main content area is titled "Compliance Resource Portal" and includes a link to "Highlights from Principal Deputy IG Joanne Chiedi's 2019 HCCA Compliance Institute Remarks". Below this, there are four expandable sections: Toolkits, Provider Compliance Resources and Training, Advisory Opinions, and Voluntary Compliance and Exclusions Resources. On the right, there is a call to action to "Email your suggestions for new OIG compliance resources" with an envelope icon. A disclaimer text is visible below the call to action.

Compliance Resource Portal | Off x +

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

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# Compliance Resource Portal

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

**Toolkits** +

**Provider Compliance Resources and Training** +

**Advisory Opinions** +

**Voluntary Compliance and Exclusions Resources** +

Email your suggestions for new OIG compliance resources

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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**Kim Stanger**  
Partner  
Boise



**Blaine Benard**  
Partner  
Salt Lake City



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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.

**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
- Medical device and life science companies
- Imaging centers
- Ambulatory surgery centers
- Medical device and life science companies

Most Popular Stories

# Upcoming Events



- **August 8:** Applying the laws to referring provider relationships, including:
  - Employment and services contracts.
  - Leases for space and equipment
  - Joint ventures
  - Gifts and perks
  - Practice subsidies
  - Professional courtesies
  - Incidental benefits
  - Etc., etc., etc.
- Contact [LDQuyres@hollandhart.com](mailto:LDQuyres@hollandhart.com)

# Questions?

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Kim C. Stanger  
office 208-383-3913  
cell 208-409-7907  
[kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com)