Compliance "To Do's" for 2020

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(1-20)

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DISCLAIMER

- This is a brief program designed to flag potential problems.
- Application of law depends on facts, including:
  - Parties to transaction.
  - Purpose of transaction.
  - Payors involved.
  - State or federal law.
- Check relevant law and facts when evaluating situation.

1. CYBERSECURITY

Laws

- HIPAA
  - Security Rules
  - Privacy Rules
- Prohibits unfair or deceptive acts affecting commerce.

(Federal Trade Comm'n Act, 15 USC 45(a))

  - Deceipt: misrepresentations re privacy policies
  - Unfair = inadequate security measures
- State laws
  - Privacy laws
  - Breach notification laws
  - Consumer protection

Risks

- Per HHS:
  1. E-mail phishing attacks
  2. Ransomware attacks
  3. Loss or theft of equipment or data
  4. Insider, accidental or intentional data loss
  5. Attacks against connected medical devices that may affect patient safety.

https://www.phe.gov/Preparedness/planning/405d/Pages/hic-practices.aspx

➢ ***HIPAA security risk assessment***

CYBERSECURITY

2. FALSE CLAIMS

Laws

- Cannot knowingly submit a false claim for payment to the federal govt.
- 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)

- State false claims acts.

(e.g., IC 56-209h)

Risks

- Billing errors, including:
  - Miscoding
  - Services not provided as claimed
  - Medically unnecessary services
  - Substandard care
  - Services by unlicensed or unprivileged providers
  - Insufficient documentation
- Don't comply with material conditions of payment
- Don't comply with fraud and abuse laws, e.g., Stark, Anti-Kickback Statute, Civil Monetary Penalties Law.
- Don't repay overpayment.

3. AUDITING AND MONITORING

Requirements

- Providers are expected to implement "proactive compliance activities … to monitor for the receipt of overpayments…."

(HHS Repayment Rule, 81 FR 7661)

- "[Providers] should develop detailed annual audit plans designed to minimize the risks associated with improper claims and billing practices."

(OIG Supplemental Hospital Compliance Program Guidance, 70 FR 4875)

Suggestions

- *See* OIG Compliance Program Guidance
  - Physicians, 65 FR 59437
  - Hospitals, 70 FR 4875 and 63 FR 8987
  - Nursing Facilities, 73 FR 56832 and 65 FR 14289
  - Hospices, 64 FR 54031
  - Home Health Agencies, 63 FR 42410
  - Others

https://www.oig.hhs.gov/compliance/compliance-guidance/index.asp

4. CREDENTIALING, LICENSING AND BACKGROUND CHECKS

Laws

- Cannot hire, contract with, or submit claim for items or services ordered or furnished by a person excluded from federal programs.

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

- Medicare/Medicaid will generally only pay for services provided by licensed and/or credentialed providers.
- State laws require background checks for certain personnel.
- Payer contracts generally require credentialing.

Risks

- Hiring or contracting with excluded person
  - Check the List of Excluded Individuals and Entities.
  - Establish processes.
- Submitting claims for services provided by excluded person
- Unlicensed persons
- No background checks
- No medical staff membership or privileges
- Telehealth arrangements
- Billing under wrong provider number
- Misuse of “locum tenens”

5. CHANGE IN PROVIDER STATUS OR OPERATIONS

Requirements

- Medicare generally requires timely notice for changes in program status.
- New facilities may affect favorable provider status, e.g., CAH, rural providers, etc.
- New services may implicate new regulations.

Risks

- Adverse legal history, e.g., program exclusion.
- Change of ownership.
- New locations.
- New service lines, e.g.,
  - Labs
  - Substance use disorders
  - Telehealth
  - HHAs
  - Others

6. PATIENT INDUCEMENTS

Laws

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

(Anti-Kickback Statute, 42 USC 1320a-7b(b); 42 CFR 1003.300(d))

- Cannot offer or transfer remuneration to Medicare or Medicaid beneficiaries if you know or should know that the remuneration is likely to influence the beneficiaries to order or receive items or services payable by federal or state programs from a particular provider.

(Civil Monetary Penalties Law, 42 USC 1320a-7a(5); 42 CFR 1003.1000(a))

Risks

- Less than fair market value
- Marketing programs
- Free items or services, e.g.,
  - Gifts, e.g., gift basket, gift card, etc.
  - Supplies
  - Screening exams or clinics
  - Transportation
  - Paying premiums
- Drawings, raffles, etc.
- Discounts
- "Refer a friend" rewards
- Writing off or discounting copays or deductibles; insurance-only billing
- Paying premiums

PATIENT INDUCEMENTS

Safe harbors/low risk situations

- $15 per gift/$75 per patient per year.
- Demonstrated financial need or failed collection efforts.
- Specified preventive care services.
- Promote access to Medicare services and low risk of fraud or abuse.

(42 CFR 1003.110, definition of "remuneration")

Common elements

- Not intended or likely to induce or reward federal program business.
- Not advertised or used as gimmick to induce business.
- Not conditioned on or otherwise tied to other items or services paid by federal programs.
- Low risk of over-utilization or interference with clinical decision making.

7. REMUNERATION FOR REFERRALS

Laws

- Anti-Kickback Statute
- Civil Monetary Penalties Law ("CMPL")
- Cannot pay remuneration for to a laboratory, recovery home, or clinical treatment facility unless arrangement fits within regulatory exception.

(Eliminating Kickbacks in Recovery Act ("EKRA"), 18 USC 220(a))

- State laws, e.g.,
  - Anti-kickback statutes
  - Fee-splitting
  - Anti-rebates
  - Others.

Risks

- Paying commissions to contractors.
- Paying commissions to employees to refer labs or other items covered by EKRA
- Remuneration to referral sources
  - Gifts (e.g., "thank you", gift cards, free items or services)
  - "Refer a friend" rewards
  - Marketing programs
- Remuneration from vendors or others to whom you refer business.

8. REMUNERATION TO REFERRING PROVIDERS

Laws

- Anti-Kickback Statute
- CMPL
- EKRA
- Physician may not refer designated health services ("DHS") to entity with which the physician or family member has a financial relationship unless arrangement fits within regulatory exception.

(Ethics in Patient Referrals Act ("Stark"), 42 USC 1395nn; 42 CFR 411.353 and 1003.300)

- State laws, e.g.,
  - Anti-kickback statutes
  - Fee splitting
  - Rebating
  - Similar statutes

Risks

- Remuneration to referring providers.
  - Gifts (e.g., "thank you")
  - Professional courtesy
  - Discounts
  - Referral rewards
  - Fee-splitting
  - Practice subsidies
  - Practice support
  - Investment opportunities
  - Failure to recoup amounts owed
- Remuneration from entities to which provider refers.
  - Vendors, manufacturers, etc.
  - Other providers

REMUNERATION TO REFERRING PHYSICIANS

Stark safe harbors applicable to physicians

- Contracts
- Recruitment payments
- Retention payments
- Non-monetary compensation < $416/year
- Medical staff incidental benefits
- Professional courtesy
- Compliance training
- OB malpractice insurance subsidy
- Information systems
- Indirect compensation arrangements
- Others

(42 CFR 411.357)

Must satisfy specific elements of applicable safe harbor.

9. CONTRACTS WITH REFERRING PROVIDERS

Laws

- Anti-Kickback
- Stark
- Civil Monetary Penalties Law
- EKRA
- State laws
  - Anti-kickback statutes
  - Fee splitting
  - Mini-Stark laws
  - Disclosure of financial relationships
  - Others

Risks

- No agreement.
- Compensation:
  - Not fair market value.
  - Not set in advance.
  - Based on volume/value of referrals, e.g.,
    - Share of profits.
    - Share of revenue from services performed by others.
    - Share of ancillary services.
- Items or services not needed.
- Services not performed.
- Items or services don't match contract.
- Contract changes < 1 year.
- "Sham" arrangement.

➢ ***Check safe harbor requirements.***

CONTRACTS WITH PROVIDERS: 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)

CONTRACTS WITH PROVIDERS: 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))

10. GROUP PRACTICES

Laws

- Stark generally applies to referrals within physician groups; therefore, structure to comply with either:
  - Rural provider exception.
  - Physician services exception.
  - In-office ancillary services exception.

(45 CFR 511.355 and .356)

"Group Practice" Risks

- Member of multiple groups.
- Not functioning as a single, unified group.
- Compensation formula:
  - Not set in advance.
  - Pure "eat what you kill", including items or service you order but performed by others.
  - Profit sharing in subgroups of less then 5 physicians.

(See 42 CFR 411.352)

10. SPACE OR EQUIPMENT TO REFERRING PROVIDERS

Laws

- Stark
- Anti-Kickback Statute
- Civil Monetary Penalties Law
- Medicare requirements
  - Co-location in hospital
  - Provider-based billing

Risks

- Free or discounted use of space or equipment.
- Free supplies.
- Free support services.
- Free storage.
- No written lease or timeshare agreement.
- Shared space or equipment.
- Not distinct from hospital space.
- Not commercially reasonable.
- Wrong site of service modifier.

➢ ***Check safe harbor requirements.***

LEASE SPACE OR EQUIPMENT

Stark (Physicians)

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

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

Anti-Kickback Statute

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

(42 CFR 1001.952(b))

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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))

11. TELEHEALTH

Laws

- Professional licensing statutes and regulations
- Telehealth practices acts
- E-prescribing, internet pharmacies, and remote prescribing laws
- Medicare/Medicaid rules
- HIPAA and data privacy
- Standard of care

Risks

- Practicing without a license
- Don't credential providers
- Don't satisfy credentialing by proxy rules
- Unintended patient relationship
- Patient abandonment
- Insufficient consent
- Unsecure communications
- No insurance coverage
- Insufficient documentation
- False claims based on telehealth services

12. MARKETING PROGRAMS

- Anti-Kickback Statute
- Stark
- EKRA
- Civil Monetary Penalties Law
- HIPAA
- Deceptive Trade Practices Act
- Telephone Consumer Protection Act ("TCPA")
- Medicare regulations
- State laws
  - Anti-Kickback Statute
  - Fee splitting
  - Unethical advertising
  - Others
- Patient inducements
- Referral rewards
  - Commission-based compensation
  - Leads v. referrals
- Advertising physician's private practice
- Using or disclosing PHI without authorization
  - Receiving remuneration
  - Marketing third party products
  - Social media
- Telemarketing
- False or deceptive advertising
- White coat marketing
- Testimonials and endorsements
- DMEPOS contacting beneficiaries

13. HIPAA SECURITY RISK ASSESSMENT

Law

- Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of e-PHI held by the covered entity or business associate.

(45 CFR 164.308)

➢ ***Document assessment***

Some risk areas

- Cyberthreats
- Software
- Hardware
- Mobile devices
- No encryption
  - Devices
  - E-mails and texts
- Insecure networks
- Social media
- Disposition and destruction
- Vendors
- Business associates
- Employees working offsite
- Hybrid entities
- Others

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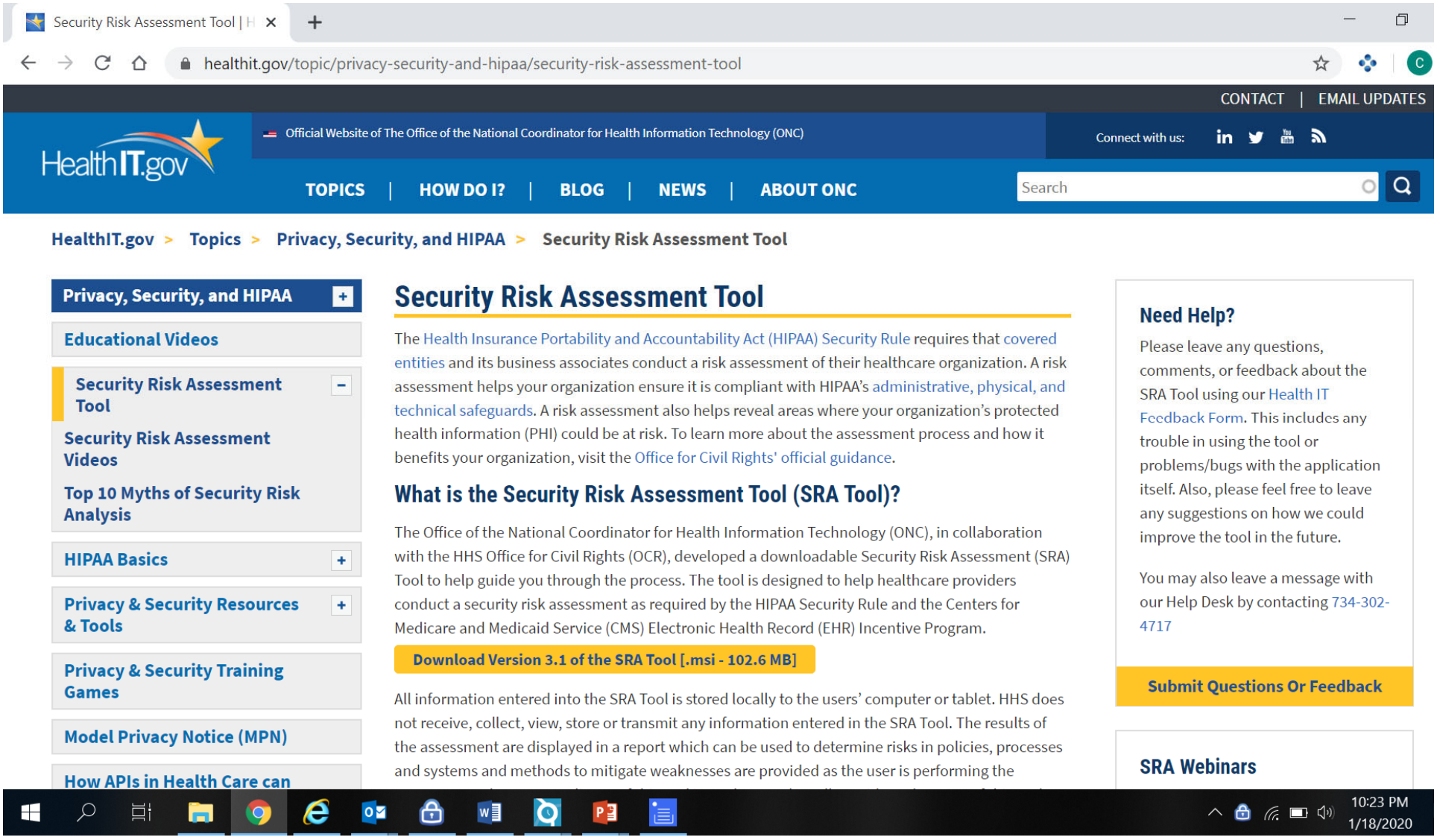
HIPAA SECURITY RISK ASSESSMENT



14. HIPAA BUSINESS ASSOCIATE AGREEMENTS

Law

- May not disclose PHI to business associates (including subcontractors) unless you have a business associate agreement ("BAA").
- BAA must contain required terms.

(45 CFR 164.314 and .502)

Risks

- Vendors with access to PHI, EMR, HIE
- Data storage, cloud service provider
- Document destruction
- Managers, billing company, coding company, auditors
- Consultants, accountants, lawyers
- Collection agencies
- Answering, transcription, interpreters
- Marketing or public relations firm
- TPAs for employee benefit plans
- Accreditation organizations
- Medical directors
- Others

15. HIPAA BREACH NOTIFICATION

Laws

- Notice to affected individuals no later than 60 days after discovered.
- Notice to HHS:
  - <500 persons: by March 1, 2020
  - >500 persons: w/in 60 days after discovered

(45 CFR 164.400-.410)

Risks

- The acquisition, access, use, or disclosure of protected health information in a manner not permitted by the HIPAA Privacy Rule which compromises the security or privacy of the protected health information unless low probability that data has been compromised..

(45 CFR 164.400)

- Failure to report = willful neglect = mandatory penalties.

(75 FR 40879)

16. HIPAA PATIENT RIGHT OF ACCESS

Laws

- Patient or personal representative generally has right to access or obtain copy of protected health info ("PHI") maintained in their designated record set.
  - Subject to limited exceptions.

(45 CFR 164.524)

Risks

- Process for requests for info.
- Unwarranted denial of access.
- Limiting info provided, e.g.,
  - Records from others.
  - Records that may adversely affect someone
- Don't send records as requested.
- Don't provide records on timely basis.
- Don't provide records in form and format requested.
- Charging too much for copies.

17. HIPAA DOCUMENTS AND FORMS

Laws

- HIPAA forms must contain certain elements, e.g.,
  - Authorization
  - Notice of privacy practices
  - Business associate agreements
  - Patient requests to:
    - Access
    - Amend
  - Accounting of disclosures log
  - Breach notification

(45 CFR 164.314, .504, .508, .520, .524, .528, .530)

Risks

- Pre-2013 forms
- Non-compliant forms
  - Authorizations
  - Notice of privacy practices
- Morphed forms
- Practices don't conform
- No accounting of disclosures.
- No privacy/security officer designation

18. NON-DISCRIMINATION

Laws

- Affordable Care Act § 1557
  - HHS has issued proposed rule:
    - Rescind gender identity rules
    - Eliminates compliance coordinator and grievance procedure
    - Eliminates notice and tagline requirements
- Civil Rights Act Title VI
- Rehabilitation Act § 504
- Age Discrimination Act
- State discrimination laws

Risks

- Persons with disabilities
  - Auxiliary aids
- Persons with limited English proficiency
  - Interpreters
  - Translations
- Sex discrimination
- Physical access
- Websites
- Service animals
  - Dogs and mini-horses
  - Probably not emotional support animals

19. COMPLIANCE PLANS

Requirements

- Providers should "regularly review the implementation and execution of their compliance program elements."

(70 FR 4874)

- ACA requires compliance plans, but final rules not issued except for nursing facilities

Suggested elements

1. Internal auditing and monitoring
2. Compliance program standards
3. Designated compliance officer
4. Appropriate training
5. Responding to problems
6. Open lines of communication
7. Enforcing compliance

20. COMPLIANCE TRAINING

Laws

- Should conduct "annual" training "to ensure that each employee, contractor or any other individual that functions on behalf of the hospital is fully capable of executing his or her role in compliance with rules, regulations and other standards."

(70 FR 4875)

- Must provide periodic privacy and security training to workforce members.

(45 CFR 164.308(a)(5) and 164.530(b))

To Do

- Provide training.
  - Fraud and abuse
  - Coding and billing
  - Payments for referrals
  - HIPAA
  - Compliance plan
  - Policies
  - Reporting and responding to non-compliance
  - Updates
- Document training.
- Document agreement to comply.
  - Employee confidentiality agreement
  - Compliance agreement

➢ ***Stay informed.***

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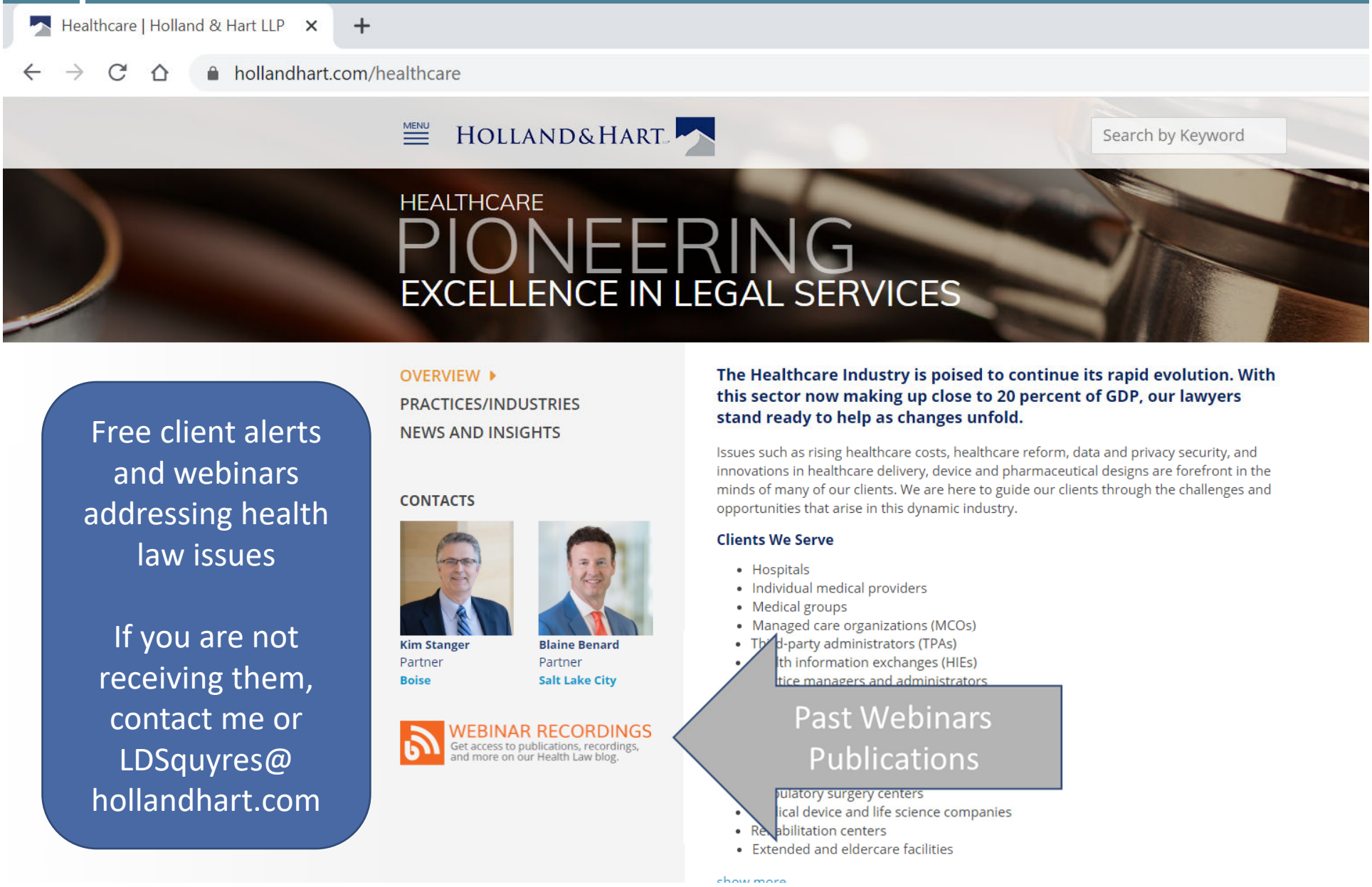
ADDITIONAL RESOURCES

- https://oig.hhs.gov/compliance/
- OIG, *A Roadmap for New Physician: Compliance Programs for Physicians*, available at https://www.oig.hhs.gov/compliance/physician-education/01laws.asp
- OIG Compliance Program for Individual and Small Group Physician Practices (65 FR 59434)
- OIG Compliance Program Guidance for Hospitals (63 FR 8987 and 70 FR 4858)
- OIG Compliance Program Guidance for Nursing Homes (65 FR 14289 and 73 FR 56832)
- Others?

HTTPS://WWW.HOLLANDHART.COM/HEALTHCARE



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Past Webinars
Publications

ANNUAL COMPLIANCE BOOTCAMP

February 28, 2020
8:30 am to 5:00 pm

- Complimentary
- In-person or telebroadcast
- To register or for more info, contact LDSquyres@hollandhart.com.

- Fraud and abuse laws
- HIPAA
- Informed consent
- Terminating patient relationships
- Interpreters, translators and auxiliary aids
- EMTALA
- Cybersecurity
- Telehealth
- Employment issues

QUESTIONS?

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