

TOP COMPLIANCE ISSUES FOR UTAH RURAL HOSPITALS



Kim C. Stanger
Rural 9 Meeting
(10-23)

This presentation is similar to any other legal education materials designed to provide general information on pertinent legal topics. The statements made as part of the presentation are provided for educational purposes only. They do not constitute legal advice nor do they necessarily reflect the views of Holland & Hart LLP or any of its attorneys other than the speaker. This presentation is not intended to create an attorney-client relationship between you and Holland & Hart LLP. If you have specific questions as to the application of law to your activities, you should seek the advice of your legal counsel.

Overview

- Fraud and abuse laws
- HIPAA and data security
- Information Blocking Rule
- EMTALA
- No Surprise Billing Rule
- Hospital Price Transparency
- Anti-Discrimination
- Antitrust
- Anything else...?



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)
- Utah state statutes

False Claims Act (FCA)

- Cannot knowingly submit a false claim for payment to the federal govt, e.g.,
 - Not provided as claimed
 - Substandard care
 - Failure to comply with applicable 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 \$11,803* to \$23,607* per claim
- Admin penalty \$22,427* per claim failed to return
- 3x damages
- Exclusion from Medicare/Medicaid
(42 USC 1320a-7a(a); 42 CFR 1003.210; 45 CFR 102.3; 86 FR 70740)
- Potential *qui tam* lawsuits

False Claims Act: Penalties



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PRESS RELEASE

False Claims Act Settlements and Judgments Exceed \$2 Billion in Fiscal Year 2022

Tuesday, February 7, 2023

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For Immediate Release

Office of Public Affairs

Second-Highest Number of Settlements in History

Settlements and judgments under the False Claims Act exceeded \$2.2 billion in the fiscal year

Hart

Utah False Claims Act

- Cannot knowingly, intentionally or recklessly submit a claim that is:
 - False.
 - Misrepresents type, quality or quantity.
 - Charges state higher than charged general public.
 - Not medically necessary.
 - Previously paid.
 - Unbundled.
- Cannot knowingly, intentionally or recklessly retain any unauthorized payment.

(UCA 26-20-7)

Penalties

- Criminal penalties.
- Civil penalties.
 - Repayment.
 - Cost of state's enforcement.
 - 3x damages.
 - \$5,000 to \$10,000 for each claim.

(UCA 26-20-9.5)

Anti-Kickback Statute (AKS)

- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by govt 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
- \$112,131* civil penalty
- 3x damages
- Exclusion from Medicare/Medicaid
(42 USC 1320a-7b(b); 42 CFR 1003.310; 45 CFR 102.3)
- Automatic FCA violation
(42 USC 1320a-7a(a)(7))
- Minimum \$100,000 settlement

Anti-Kickback Statute

**Remuneration
+ Intent to induce
referrals for items
payable by federal
programs
AKS violation;
“One purpose” test**

- ✓ **Safe Harbor, e.g.,**
 - **Employment**
 - **Personal services**
 - **Leases**
 - **Group practice**
 - **Others**
- ✓ **Advisory Opinion**

Anti-Kickback Statute: Penalties



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PRESS RELEASE

Covenant Healthcare System and Physicians Pay Over \$69 Million to Resolve False Claims Act Allegations Related to Improper Financial Relationships

Eliminating Kickback in Recovery Act (EKRA)

- Cannot solicit, receive, pay or offer any remuneration in return for referring a patient to a laboratory, recovery home 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))

Utah Anti-Kickback Statute

- May not knowingly and intentionally solicit, offer, pay or receive a kickback or bribe to include purchasing, leasing or ordering goods or service payable by govt medical benefit programs.

(UCA 26-20-4(2))

- No safe harbors.

Penalties

- Criminal penalties.
- Civil penalties
 - Repayment
 - Costs of state's enforcement
 - 3x damages
 - \$5,000 to \$10,000

(UCA 26-20-9 and -9.5)

Ethics in Patient Referrals Act (Stark)

- If physician (or family member) has financial relationship with entity:
 - Physician may not refer patients to the 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.
 - \$27,750* per claim
 - \$174,172* per scheme
- (42 CFR 411.353, 1003.310; 45 CFR 102.3)
- Likely FCA violation
 - Likely AKS violation

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**

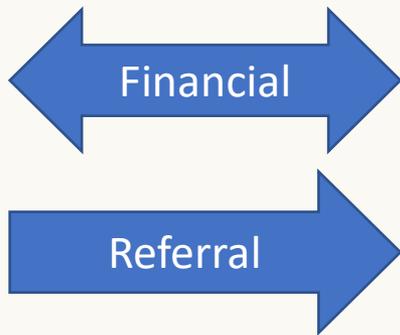
Stark

Only applies if:

Physician

- MD
- DO
- Dentist
- Oral surgeon
- Podiatrist
- Optometrist
- Chiropractor

(42 CFR 411.351 and
411.353)



Designated Health Service (“DHS”)

- Inpatient/outpatient hospital services
- Outpatient prescription drugs
- Radiology and certain imaging services
- Radiation therapy and supplies
- Clinical laboratory services
- Physical, occupational, or speech therapy
- Home health services
- Durable medical equipment and supplies
- Prosthetics and orthotics
- Parenteral and enteral nutrients, equipment, and supplies

Stark: Penalties



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PRESS RELEASE

United States Resolves \$237 Million False Claims Act Judgment against South Carolina Hospital that Made Illegal Payments to Referring Physicians

Stark and AKS: Employment Safe Harbors

Stark (Physicians or Family)

- Identifiable services.
- Compensation is:
 - Consistent with FMV;
 - Does not vary with volume or value of referrals for DHS.
 - Commercially reasonable absent referrals.
- Personally performed services do not vary with referrals.

(42 CFR 411.357(c))

AKS

- Compensation paid to bona fide employees for furnishing items or services payable by Medicare/Medicaid.
- Safe harbor may not apply to excess payments for referrals instead of “furnishing items or services”.

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

EKRA: Employment Safe Harbors

EKRA (Labs, Tx Facilities, Recovery Homes)

- Bona fide employment
- Compensation does not vary by:
 - Number of individuals referred to lab, tx facility, or recovery home;
 - Number of tests or procedures performed; or
 - Amount billed or received from a health care benefit from individuals referred to the lab, tx facility or recovery home.

(18 USC 220(b)(2))

Stark and AKS: Contractor Safe Harbors

Stark (Physicians or Family)

- Writing signed by parties covering identifiable services.
- 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 physician.
- Arrangement is commercially reasonable even if no referrals.
(42 CFR 411.357(d) or (l))
- May modify compensation prospectively if other conditions met.
(42 CFR 411.354(d)(1); 85 FR 77595)

AKS

- Writing signed by parties for specified services.
- Term not less than 1 year.
- Compensation methodology is:
 - Set in advance.
 - Consistent with FMV.
 - Does not take into account the volume or value of referrals for federal program business.
- Aggregate services not more than reasonably necessary to accomplish commercially reasonable purpose.
(42 CFR 1001.952(d))

EKRA: Contractor Safe Harbors

EKRA (Labs, Tx Facilities, Recovery Homes)

Option 1

- Compensation does not vary by:
 - Number of individuals referred to lab, treatment facility, or recovery home;
 - Number of tests or procedures performed; or
 - Amount billed or received from a health care benefit from individuals referred to the lab, treatment facility or recovery home.

(18 USC 220(b)(2))

Option 2

- Satisfy AKS safe harbor for independent contractors at 42 CFR 1001.952(d)
(18 USC 220(b)((4))

Stark: Payment for Services \leq \$5000

Stark: may pay physician for services provided by physician if:

- Compensation
 - \leq \$5000* aggregate per calendar year if:
 - Does not take into account volume or value of referrals or other business generated by the physician.
 - Does not exceed FMV.
- Arrangement is commercially reasonable even if no referrals.
- If compensation is for use of space or equipment, compensation formula:
 - Not based on % of revenue, or
 - Per-unit (other than time-based) that depends on referrals by lessor.

(42 CFR 411.357(z))

- ✓ Allows entities to avoid *de minimus* violations.
- ✓ May be used with other safe harbors to establish compliance.

Stark and AKS: Other Safe Harbors

STARK

- Space or equipment leases
- Timeshares
- Fair market value
- Recruitment and retention
- OB malpractice subsidy
- Sale of practice
- Settlements
- Rural providers
- EHR subsidies
- Value-based enterprises
- Non-monetary compensation to physicians
- Medical staff incidental benefits
- Professional courtesies

(42 CFR 411.357)

ANTI-KICKBACK

- Leases
- Sale of
- ASC ownership
- Recruitment
- OB malpractice subsidy
- Sale of practice
- EHR subsidies
- Value-based enterprises

(42 CFR 1001.952)

Stark: Correcting Mistakes

MISTAKES IN PAYMENT

- May correct overpayment or underpayment if:
 - Reconcile all discrepancies in payments within 90 days after termination of the agreement; and
 - Agreement otherwise complies with Stark.

(42 CFR 411.353(h))

NO WRITTEN CONTRACT

- “Written arrangement” may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

(42 CFR 411.354(e)(2))

Civil Monetary Penalties Law (CMPL)

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.
- Failing to report adverse action against providers.
- **Contracting with or submitting claims for services ordered by an excluded entity.**
- **Offering inducements to program beneficiaries.**
- **Offering inducements to physicians to limit services.**

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

CMPL: Patient Inducements

- 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

- \$22,427* per violation.
- Exclusion from Medicare and Medicaid (42 CFR 1003.1010(a); 45 CFR 102.3)
- Likely also an Anti-Kickback Statute violation

CMPL: Physician Inducements

- 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

- \$5,606* per violation.
 - Exclusion from Medicare and Medicaid
(42 CFR 1003.1010(a); 45 CFR 102.3)
- *Beware gainsharing arrangements.*

Red Flags: Inducements to Patients

- Routinely waiving copays and deductibles.
- “Insurance only” billing.
- Prompt pay discounts.
- Free or discounted items or services, including free equipment, supplies, etc.
- Patient reward or incentive programs.
- Loss leaders.
- “Thank you” gifts.
- Free transportation.
- Paying premiums.
- Write offs.
- “Refer a friend” incentives.
- Raffles or give aways.
- Any other remuneration to induce referrals.

Consider:

- Payor source
- Statutory or regulatory safe harbors or exceptions
- Advisory opinions
- Risk of fraud/abuse/waste

Red Flags: Remuneration to Referral Sources

- Free or discounted space, items or services
- “Thank you” gifts
- Professional courtesies
- Payments based on referrals
- Payment more or less than FMV
- Payment for unnecessary services
- Sharing or splitting fees
- Subsidizing practice costs
- Investment opportunities with little or no risk or contributions
- Any other remuneration to induce referrals.

Consider:

- Statutory or regulatory safe harbors or exceptions
- Advisory opinions
- Risk of fraud and abuse

Health Insurance Portability and Accountability Act (HIPAA)



HIPAA Privacy Rule

- May not access, use or disclose protected health info (PHI) without patient's authorization or HIPAA exception.
 - Implement safeguards.
 - Train workforce members.
 - Execute business associate agreements.
 - Honor patient rights re PHI.
 - Mitigate any breaches.
 - Sanction employees.
- (45 CFR 164.501 et seq.)

Penalties

- Self-report breaches to patient and OCR (45 CFR 164.401 et seq.)
 - *In future, patient may recover portion of fines or settlements.*
- Civil penalties (45 CFR 160.401 et seq.)
 - No willful neglect: \$127 to \$63,973*
 - Willful neglect: mandatory \$12,794* to \$1,919,173*
- Criminal penalties (42 USC 1320d-6)
 - \$50,000 to \$250,000 fine.
 - 1 to 10 years in prison.
- State AG action
- Lawsuit

Criminal Penalties



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Doctor and Two Former Hospital Employees Plead Guilty to HIPAA Violations

U.S. Attorney's Office
July 20, 2009

Eastern District of Arkansas
(501) 340-2600

LITTLE ROCK—Jane W. Duke, United States Attorney for the Eastern District of Arkansas, along with Thomas J. Browne, Special-Agent-in-Charge of the Little Rock Division of the Federal Bureau of Investigation, announced today the guilty pleas of Dr. Jay Holland, age 56, of Little Rock, Arkansas; Sarah Elizabeth Miller, age 28, of England, Arkansas; and Candida Griffin, age 34 of Little Rock, Arkansas. Each pled to a misdemeanor violation of the health information privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) based on their accessing a patient's record without any legitimate purpose. The pleas were accepted by United States Magistrate Judge Henry L. Jones, Jr.

Dr. Holland, Medical Director of Select Specialty Hospital, located on the 6th floor of the St. Vincent Infirmary Medical Center (SVIMC), admitted that after watching news reports on television, he

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HIPAA: Avoiding Civil Penalties

You can likely avoid HIPAA civil penalties if you:

- Have required policies and safeguards in place.
- Execute business associate agreements.
- Train personnel and document training.
- Respond immediately to mitigate and correct any violation.
- Timely report breaches if required.

*No “willful neglect”
= No penalties if
correct violation
within 30 days.*

HIPAA Security Rule

- Perform and document periodic risk assessment.
- Implement safeguards.
 - Administrative
 - Technical, including encryption
 - Physical
- Execute business associate agreements.

(45 CFR 164.301 et seq.)

Penalties

- Self-report breaches to patient and OCR (45 CFR 164.401 et seq.)
- Civil penalties (45 CFR 102.3 and 160.401 et seq.)
 - No willful neglect: \$127 to \$63,973*
 - Willful neglect: mandatory \$12,794 to \$1,919,173* (45 CFR 102.3 and 160.401 et seq.)
- Criminal penalties
- Lawsuits

HIPAA Security Rule

HHS Office for Civil Rights Settles HIPAA Investigation with Arizona Hospital System Following Cybersecurity Hacking

Banner Health pays \$1.25 million to settle cybersecurity breach that affected nearly 3 million people

OCR has announced a settlement with Banner Health Affiliated Covered Entities (“Banner Health”), a nonprofit health system headquartered in Phoenix, Arizona, to resolve a data breach resulting from a hacking incident by a threat actor in 2016 which disclosed the protected health information of nearly 3 million people. The violations specifically include: the lack of an analysis to determine the extent of the breach, the failure to protect health information across the organization, insufficient measures to protect against a cyber-attack, failure to implement an audit to identify and protect health information, and failure to have security measures in place to protect health information from unauthorized access when it was being transmitted.

OCR and Banner Health agreed to implement a corrective action plan, which identifies steps Banner Health will take to resolve these potential violations of the HIPAA Security Rule and protect the security of electronic patient health information:

- [Read the HHS Press Release](#)
- [Read the Resolution Agreement and Correction Action Plan](#)

Banner Health pays \$1.25 million from hacking

Cyberattack on Mountain View Hospital still ongoing after two weeks

🕒 Published at 9:00 am, June 10, 2023 | Updated at 9:17 am, June 10, 2023



Logan Ramsey, EastIdahoNews.com

**Why you need to
comply with
Security Rule**



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Cyberattack forces Idaho hospital to send ambulances elsewhere

By Sean Lyngaas, CNN
Published 5:33 PM EDT, Wed May 31, 2023

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Cybersecurity

- How would your hospital operate if your EHR and all your other e-systems were inaccessible—
 - Provide care?
 - Document care?
 - Bill for care?
 - Process accounts receivable and payable?
 - Pay employees?
 - Other?

Risks

- Malpractice
- HIPAA fines and penalties
- Cost of mitigating effects and recovery
- Cost of replacing systems
- Defending lawsuits
- Adverse public relations

Cybersecurity

“I cannot underscore enough the importance of enterprise-wide risk analysis.... You should fully understand where all electronic protected health information (ePHI) exists across your organization – from software, to connected devices, legacy systems, and elsewhere across your network.... Some best practices include:

- Maintaining offline, encrypted backups of data and regularly test your backups;
- Conducting regular scans to identify and address vulnerabilities, especially those on internet-facing devices, to limit the attack surface;
- Regular patches and updates of software and Operating Systems; and
- Training your employees regarding phishing and other common IT attacks.”

(Lisa Pino, Director of Office for Civil Rights (2/28/22))

<https://www.hhs.gov/about/news/2023/04/17/hhs-cybersecurity-task-force-provides-new-resources-help-address-rising-threat-cyberattacks-health-public-health-sector.html>

HHS Cybersecurity Task Force Provides New Resources to Help Address Rising Threat of Cyberattacks in Health and Public Health Sector

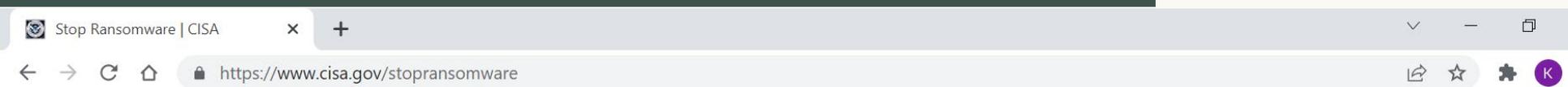
Effort is led by the HHS 405(d) Program and the Health Sector Coordinating Council Cybersecurity Working Group (HSCC CWG), as a collaborative effort between the federal government and industry, to address cybersecurity in the health sector

Resources include a new platform, Knowledge on Demand, to provide free cybersecurity training to the health sector workforce as well as an updated Health Industry Cybersecurity Practices 2023 Edition and a Hospital Cyber Resiliency Initiative Landscape Analysis

On April 17, 2023, The U.S. Department of Health and Human Services (HHS) 405(d) Program announced the release of the following resources to help address cybersecurity concerns in the Healthcare and Public Health (HPH) Sector:

- [Knowledge on Demand](#) – a new online educational platform that offers free cybersecurity trainings for health and public health organizations to improve cybersecurity awareness.
- [Health Industry Cybersecurity Practices \(HICP\) 2023 Edition](#) – a foundational publication that aims to raise awareness of cybersecurity risks, provide best practices, and help the HPH Sector set standards in mitigating the most pertinent cybersecurity threats to the sector.
- [Hospital Cyber Resiliency Initiative Landscape Analysis - PDF](#) – a report on domestic hospitals' current state of cybersecurity preparedness, including a review of participating hospitals benchmarked against standard

[HTTPS://WWW.CISA.GOV/STOPRANSOMWARE](https://www.cisa.gov/stopransomware)



 An official website of the United States government [Here's how you know](#) ▾

WHAT IS RANSOMWARE?

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A 3D rendered cityscape with buildings in shades of red and grey. The background is dark with vertical columns of white binary code (0s and 1s).

HAVE YOU BEEN HIT BY RANSOMWARE?

[LEARN MORE](#)

A close-up of a laptop screen displaying the word "RANSOMWARE" in large, white, bold letters. The background of the screen is filled with red binary code.

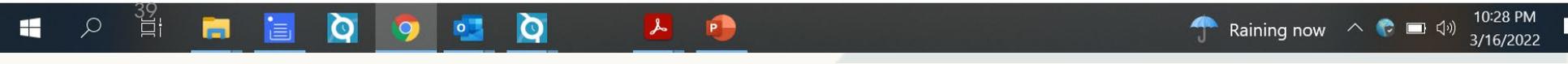
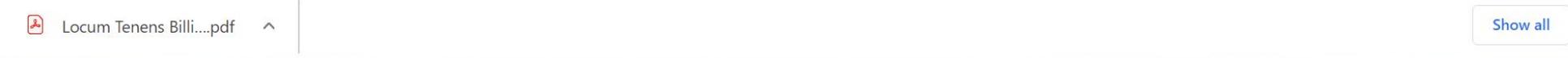
Known Exploited Vulnerabilities Catalog

[cisa.gov](#)

UPdated

The official seal of the United States Cyber Intelligence and Security Agency (CISA).

[Show all](#)

A dark blue rectangular area with a thick red border. The text is white and red.

<https://www.phe.gov/Preparedness/planning/405d/Documents/HICP-Main-508.pdf>

Recommended Practices

1. E-mail protection system
 2. Endpoint protection system
 3. Access management
 4. Data protection and loss prevention
 5. Network management
 6. Vulnerability management
 7. Incident response
 8. Medical device security
 9. Cybersecurity policies
- Sample Forms
 - Resources

Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients



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Health Sector Cybersecurity Coordination Center (HC3)

A Prescription for Health Sector Cybersecurity

Health Sector Cybersecurity Coordination Center (HC3) was created by the Department of Health and Human Services to aid in the protection of vital, healthcare-related controlled information and ensure that cybersecurity information sharing is coordinated across the Health and Public Health Sector (HPH).



HC3 Products

Threat Briefs

Highlights relevant cybersecurity topics and raise the HPH sector's situational awareness of current cyber threats, threat actors, best practices, and mitigation tactics.

Sector Alerts

Provides high-level, situational background information and context for technical and executive audiences. Designed to assist the sector with defense of large scale and high level vulnerabilities.

FTC Enforcement Actions

FTC is using Unfair Trade Practices Act § 5 to go after entities for info security violations.

(<https://www.ftc.gov/news-events/topics/protecting-consumer-privacy-security/privacy-security-enforcement>)

Privacy and Security Enforcement

When companies tell consumers they will safeguard their personal information, the FTC can and does take law enforcement action to make sure that companies live up these promises. The FTC has brought legal actions against organizations that have violated consumers' privacy rights, or misled them by failing to maintain security for sensitive consumer information, or caused substantial consumer injury. In many of these cases, the FTC has charged the defendants with violating Section 5 of the FTC Act, which bars unfair and deceptive acts and practices in or affecting commerce. In addition to the FTC Act, the agency also enforces other federal laws relating to consumers' privacy and security.

Cases

- [Epic Games, In the Matter of](#) (September 19, 2023)
- [1Health.io/Vitagene, In the Matter of](#) (September 7, 2023)
- [Edmodo, LLC, U.S. v.](#) (August 28, 2023)
- [Amazon.com \(Alexa\), U.S. v.](#) (July 21, 2023)
- [BetterHelp, Inc., In the Matter of](#) (July 14, 2023)
- [Facebook, Inc., In the Matter of](#) (July 13, 2023)
- [Easy Healthcare Corporation, U.S. v.](#) (June 26, 2023)
- [Microsoft Corporation, U.S. v.](#) (June 9, 2023)
- [Ring, LLC](#) (May 31, 2023)
- [GoodRx Holdings, Inc.](#) (February 17, 2023)
- [Epic Games, Inc., U.S. v.](#) (February 7, 2023)
- [Chegg](#) (January 26, 2023)
- [Drizly, LLC., In the Matter of](#) (January 10, 2023)
- [FTC v Kochava, Inc.](#) (August 29, 2022)
- [CafePress, In the Matter of](#) (June 24, 2022)

Other Privacy and Security Developments

- FTC/OCR have warned against online tracking technologies. (<https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-hhs-warn-hospital-systems-telehealth-providers-about-privacy-security-risks-online-tracking>)
- NIST published guidance for security practices.
- OCR's right of access initiative.
- End of PHE flexibility for HIPAA security rule standards.
- State data security law proliferation.
- OCR has proposed changes to HIPAA privacy rule.
- SAMHSA has proposed changes to Part 2 rules to align with HIPAA.

Information Blocking Rule



Info Blocking Rule

- Applies to “actors”
 - Healthcare providers.
 - Developers or offerors of certified health IT.
 - Not providers who develop their own IT.
 - Health info network/exchange.

(45 CFR 171.101)

- Prohibits info blocking, i.e., practice that is likely to interfere with access, exchange, or use of electronic health info, and
- Provider: knows practice is unreasonable and likely to interfere.
- Developer/HIN/HIE: knows or should know practice is likely to interfere.

(45 CFR 171.103)

Info Blocking Rule: Penalties

DEVELOPERS, HIN, HIE

- Complaints to ONC
 - <https://www.healthit.gov/topic/information-blocking>.
- ONC investigations
- Civil monetary penalties of up to \$1,000,000 per violation
(42 CFR 1003.1420)

HEALTHCARE PROVIDERS

- “Appropriate disincentives to be established by HHS.”
- Enforcement rule expected at anytime.



Info Blocking Examples

- Refusing to timely respond to requests.
- Charging excessive fees.
- Imposing unreasonable administrative hurdles.
- Imposing unreasonable contract terms, e.g., EHR agreements, BAAs, etc.
- Implementing health IT in nonstandard ways that increase the burden.
- Others?

Not Info Blocking

- Action required by law.
 - HIPAA, 42 CFR part 2, state privacy laws, etc.
 - Laws require conditions before disclosure, e.g., patient consent.
- Action is reasonable under the circumstances.
- Action fits within regulatory exception.

Info Blocking Exceptions



PREVENTING HARM EXCEPTION



PRIVACY EXCEPTION



SECURITY EXCEPTION



INFEASIBILITY EXCEPTION



HEALTH IT PERFORMANCE EXCEPTION



LICENSING EXCEPTION



FEES EXCEPTION



CONTENT AND MANNER EXCEPTION

EXCEPTIONS THAT INVOLVE not fulfilling requests to access, exchange, or use EHI

8

EXCEPTIONS TO THE INFORMATION BLOCKING PROVISION

EXCEPTIONS THAT INVOLVE procedures for fulfilling requests to access, exchange, or use EHI

<https://www.healthit.gov/topic/information-blocking>

Information Blocking | HealthIT.g x

https://www.healthit.gov/topic/information-blocking

NEW: Health IT Feedback Portal

CONTACT EMAIL UPDATES

HealthIT.gov Official Website of The Office of the National Coordinator for Health Information Technology (ONC)

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TOPICS | BLOG | NEWS | DATA | ABOUT ONC

Search

HealthIT.gov > Topics > Information Blocking

Information Blocking

Report Information Blocking

Information Blocking

What is information blocking?

In general, information blocking is a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information (EHI).

Have questions about information blocking? [View our Information Blocking Frequently Asked Questions \(FAQs\)](#)

What are examples of practices that could constitute information blocking?

Section 4004 of the Cures Act specifies certain practices that could constitute information blocking:

- Practices that restrict authorized access, exchange, or use under applicable state or federal law of such information for treatment and other permitted purposes under such applicable law.

Additional Resources

- Fact Sheets
- Webinars
- FAQs
- Report Information Blocking

Locum Tenens Billi...pdf

Windows taskbar: 10:54 PM 3/16/2022

Emergency Treatment and Active Labor Act (EMTALA)



EMTALA

- If patient comes to the hospital, hospital must:
 - Medical screening exam,
 - Stabilizing treatment, and/or
 - Appropriate transfer.
- Cannot delay to inquire about payment.
- Hospital with specialized capabilities must accept transfer.

(42 USC 1935dd; 42 CFR 489.24)

Penalties

- Termination of Medicare/Medicaid.
- Civil penalties
 - Hospital:
 - < 100 beds: \$55,800*
 - > 100+ beds: \$11,597*
 - Physicians: \$111,597*
- Hospital may be sued for damages.

(42 USC 1395dd; 42 CFR 1003.510; 82 FR 9174)

EMTALA

Person comes to hospital:

- Main campus + 250 yards.
- Off-campus facility with a dedicated emergency dept.
- In hospital-owned ambulance.
- *Beware diverting inbound ambulance.*
- *Beware encouraging people to leave.*

Screening exam

- By qualified medical person,
- Within hospital capability, and
- Sufficient to determine if patient has emergency medical condition, i.e. (a) absence of care seriously jeopardizes health, or (b) pregnant woman in labor.

No emergency medical condition or admitted as inpatient

Yes emergency medical condition

or

EMTALA ends;
May transfer or discharge patient; beware malpractice, COPs, Joint Comm'n, etc.

Stabilizing treatment

- Transfer: emergency condition resolved
- Discharge: may receive care later with instructions

Appropriate transfer

- Consent or physician certifies benefits > risk; and
- Stabilizing treatment,
- Receiving facility accepts transfer,
- Use appropriate means to transfer, and
- Send records.

Document, Document, Document

***If it's not in the chart,
it didn't happen.***

- Appropriate exam.
- No emergency condition.
- Stable condition.
- Patient refused care or requested transfer.
- Certification that benefits of transfer > risks
- Appropriate transfer
- Patient refused care or left AMA



No Surprise Billing Rules



No Surprise Billing Rules

INSURED PATIENTS

- Limits amount out of network (OON) provider/facility may bill patient and payer.
- Only applies to:
 - Hospital or freestanding emergency dept.
 - Hospital, hospital outpatient dept, or ASC.
- Independent dispute resolution (IDR) process to re resolve disputes about charges.

(45 CFR 149.410-.450)

SELF-PAY PATIENTS

- Providers/facilities must give patient a good faith estimate of charges.
- Patient-provider dispute resolution (PPDR) process if actual bill is substantially in excess (i.e., > \$400) of good faith estimate.
- Notice of rights to patient.

(45 CFR 149.610-.620)

No Surprise Billing Rules Enforcement

- Limited payment from patients and payers.
 - Self-pay patients: payment may be capped through PPDR process if actual charges are substantially in excess of GFE.
 - Insured patients: OON provider's payment from patients and payers may be limited.
- State has primary enforcement obligations.
- If state fails to enforce, CMS may impose:
 - \$10,000 civil penalty
 - Corrective action plan

(42 USC 300g-118; 45 CFR 102.3 and 150.513; 86 FR 51730)

<https://insurance.utah.gov/consumer/health/no-surprises-act>

The screenshot shows the Utah Insurance Department website. The header includes the Utah logo and the text 'Utah Insurance Department'. Below this is a navigation bar with links for 'Consumer', 'Licensee', 'News', 'Fraud', and 'About Us'. A secondary navigation bar lists categories: 'Auto/Home, Etc.', 'Health', 'Life/Annuity', 'Legal', 'Seniors', 'Other', and 'About Us'. A left sidebar contains a list of links under the 'Health' category, including 'Contact the Health & Life Division', 'Bulletins', 'Consumer Information', 'Health Discount Programs', 'Health Reform', 'HIPAA', 'Independent Review', 'Long-Term Care', 'Medicare / Medigap / Med Advantage', 'No Surprises Act', 'Related Links', 'Reports', and 'Utah Pharmacy Drug Information'. The main content area features the title 'No Surprises Act' and a sub-section 'No Surprises Act: Protections Against Surprise Billing'. The text explains that as of January 1, 2022, consumers have new billing protections for emergency and non-emergency care from out-of-network providers. It also mentions that the Consolidated Appropriations Act, 2021 (CAA) signed in December 2020 included the No Surprises Act. A link is provided for more information: <https://www.cms.gov/nosurprises>. Below this, there are two sub-sections: 'What is surprise billing?' and 'What protections are in place?'. The 'What is surprise billing?' section explains that surprise billing occurs when a patient receives a balance bill from an out-of-network provider or facility. The 'What protections are in place?' section begins with 'The No Surprises Act is a new federal law intended to offer certain protections related to health care services:'.

Utah Insurance Department

UTAH INSURANCE DEPARTMENT

Consumer Licensee News Fraud About Us

Auto/Home, Etc. Health Life/Annuity Legal Seniors Other About Us

No Surprises Act

No Surprises Act: Protections Against Surprise Billing

As of January 1, 2022, consumers have new billing protections when getting emergency care; non-emergency care from out-of-network providers at in-network facilities, including ancillary services such as x-ray, drug, laboratory, or other services; and air ambulance services from out-of-network providers. Through new rules aimed at protecting consumers, out-of-pocket costs will be restricted, and emergency services must continue to be covered without any prior authorization regardless of whether or not a provider or facility is in-network.

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA) was signed into law, which included the No Surprises Act. The information below summarizes information about the new protections and some examples of how they can protect consumers.

Visit <https://www.cms.gov/nosurprises> for more information about your rights under this new federal law.

What is surprise billing?

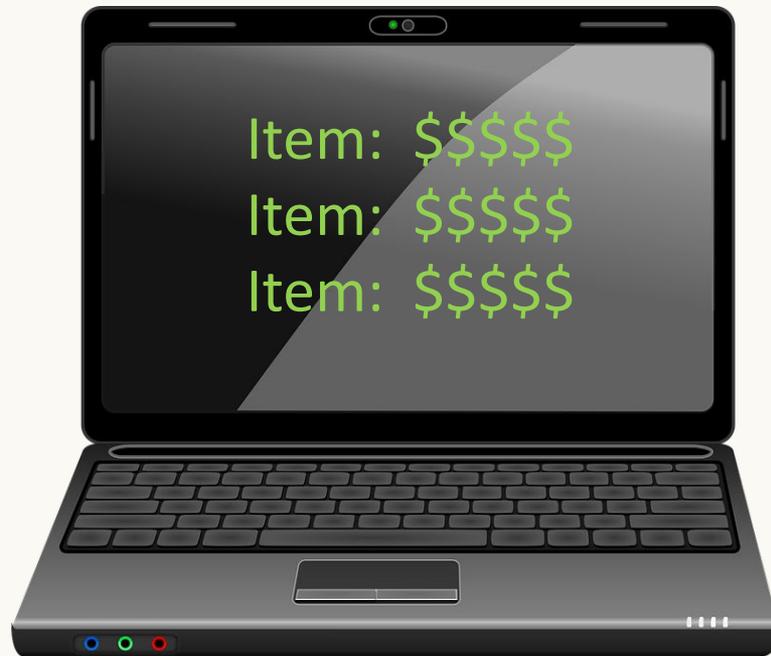
Surprise billing happens when a patient receives a balance bill after they receive care from an out-of-network provider or at an out-of-network facility, such as a hospital. It can happen for both emergency and non-emergency care. Sometimes, patients don't know the provider or facility is out-of-network until they receive the bill.

What protections are in place?

The No Surprises Act is a new federal law intended to offer certain protections related to health care services:

Give Feedback

Hospital Price Transparency



Hospital Price Transparency

- Hospital must publish list of the hospital's "standard charges".
 - See regulations for specifics.
- Must be posted through hospital's website.
- Must update at least annually.

(45 CFR 180.70)

Penalties

- Written warning, corrective action plan, fines
- Increased penalties
 - Small hospitals (≤ 30 beds)
 - Maximum of \$300 per day
 - Large hospitals (> 30 beds)
 - Minimum of \$10 per bed per day, and
 - Maximum of \$5,500 per day.
 - Range of \$109,500 to \$2,007,500 per year

(45 CFR 180.70-.90; CMS Fact Sheet,

<https://www.cms.gov/newsroom/press-releases/cms-oppasc-final-rule-increases-price-transparency-patient-safety-and-access-quality-care>)

Price Transparency: Enforcement

Hospital price
transparency

Enforcement actions

14 reported actions at

<https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency/enforcement-actions>

In most cases, appears CMS sent warning letter first.

Enforcement Actions

Below is a list of civil monetary penalty (CMP) notices issued by CMS.

Date Action Taken	Hospital Name	CMP Amount	Effective Date
2022-06-07	Northside Hospital Atlanta	\$883,180.00	2021-09-02
2022-06-07	Northside Hospital Cherokee	\$214,320.00	2021-09-09
2023-04-19	Frisbie Memorial Hospital	\$102,660.00	2022-10-24
2023-04-19	Kell West Regional Hospital <i>Under Review *</i>	\$117,260.00	2022-07-08
2023-07-20	Falls Community Hospital & Clinic	\$70,560.00	2023-01-06
2023-07-20	Fulton County Hospital <i>Under Review *</i>	\$63,900.00	2022-12-22
2023-07-24	Community First Medical Center <i>Under Review *</i>	\$847,740.00	2022-06-22
2023-08-22	Hospital General Castaner <i>Under Review *</i>	\$101,400.00	2022-09-19
2023-08-22	Samaritan Hospital - Albany Memorial Campus <i>Under Review *</i>	\$56,940.00	2023-06-06

Price Transparency Resources

- <https://www.cms.gov/hospital-price-transparency/hospitals>

- Regulations
- FAQs
- Technical guidance
- Updated sample formats
- Quick reference checklist
- Sample corrective action plan response

The screenshot shows the CMS.gov website with the following elements:

- Top navigation: Home | About CMS | Newsroom | Archive | Help | Print
- Search bar: Search CMS [Search]
- Primary navigation menu: Medicare, Medicaid/CHIP, Medicare-Medicaid Coordination, Private Insurance, Innovation Center, Regulations & Guidance, Research, Statistics, Data & Systems, Outreach & Education
- Breadcrumbs: Home > Hospital Price Transparency
- Secondary navigation menu: Home | Hospitals | Consumers | Resources | Contact Us
- Section header: Hospital Price Transparency (with a dollar sign icon)
- Text: Hospital price transparency helps Americans know the cost of a hospital item or service before receiving it. **Starting January 1, 2021**, each hospital operating in the United States will be required to provide clear, accessible pricing information online about the items and services they provide in two ways:
- List:
 1. As a comprehensive machine-readable file with all items and services.
 2. In a display of shoppable services in a consumer-friendly format.
- Text: This information will make it easier for consumers to shop and compare prices across hospitals and estimate the cost of care before going to the

Anti-Discrimination Laws



Anti-Discrimination Laws

LAWS

- Civil Rights Act Title VI
- Americans with Disability Act
- Age Discrimination Act
- Rehabilitation Act § 504
 - HHS has proposed new rules
- Affordable Care Act § 1557
 - HHS has proposed expansive new rules.
- State discrimination laws

RISKS

- Persons with disabilities
- Persons with limited English proficiency
- Sex discrimination
- Physical access
- Websites
- Service animals
 - Dogs and mini-horses
 - Not emotional support animals

Anti-Discrimination Laws

DISABILITIES

- Must provide reasonable accommodation to ensure effective communication.
 - Auxiliary aids
- Includes person with patient.
- May not charge patient.
- May not rely on person accompanying patient.

LIMITED ENGLISH

- Must provide meaningful access
 - Interpreter
 - Translate key documents
- Includes person with patient.
- May not charge patient.
- May not require patient to bring own interpreter.
- May not rely on person accompanying patient.

OCR Disability Resources

- <https://www.hhs.gov/civil-rights/for-individuals/special-topics/hospitals-effective-communication/disability-resources-effective-communication/index.html>

- Sample policies and procedures
- Charts
- Bulletins
- FAQs
- Links to other resources

The screenshot shows the HHS.gov Civil Rights website. The header includes the HHS.gov logo and the text 'U.S. Department of Health & Human Services'. Below the header is a search bar with the text 'I'm looking for...' and a magnifying glass icon. To the right of the search bar is an 'A-Z Index' link. Below the search bar are four navigation buttons: 'Information for Individuals', 'Filing a Complaint', 'Information for Providers', and 'Newsroom'. Below these buttons is a breadcrumb trail: 'HHS > Civil Rights Home > For Individuals > Special Topics in Civil Rights > Effective Communication in Hospitals > Disability Resources for Effective Communication'. Below the breadcrumb trail is a table of contents with a minus sign icon. The table lists: 'Civil Rights for Individuals and Advocates', 'Race, Color, National Origin', 'Disability', 'Age Discrimination', 'Sex Discrimination & Harassment', 'Title IX', 'Section 1557', 'Hill-Burton', and 'Section 1553'. To the right of the table is a 'Text Resize' section with 'A A A' and 'Print', 'Share' (Facebook, Twitter, Email) icons. Below the table and share icons is the main heading 'Disability Resources for Effective Communication OCR Resources'. Below the heading are two bullet points: 'OCR signs effective communication Dear Colleague Letter with the Health Resources and Services Administration (08/30/2016)' and 'OCR signs effective communication Dear Colleague Letter with the Puerto Rico Hospital Association. (06/09/2015)'. Each bullet point has three links: 'Read the Bulletin', 'Read the Letter - PDF', and 'En Español - PDF'.

HHS.gov
Civil Rights

U.S. Department of Health & Human Services

I'm looking for... 

A-Z Index

Information for Individuals Filing a Complaint Information for Providers Newsroom

HHS > Civil Rights Home > For Individuals > Special Topics in Civil Rights > Effective Communication in Hospitals > Disability Resources for Effective Communication

Civil Rights for Individuals and Advocates -

Race, Color, National Origin

Disability

Age Discrimination

Sex Discrimination & Harassment

Title IX

Section 1557

Hill-Burton

Section 1553

Text Resize A A A Print Share   

Disability Resources for Effective Communication OCR Resources

- OCR signs effective communication Dear Colleague Letter with the Health Resources and Services Administration (08/30/2016)
 - [Read the Bulletin](#)
 - [Read the Letter - PDF](#)
 - [En Español - PDF](#)
- OCR signs effective communication Dear Colleague Letter with the Puerto Rico Hospital Association. (06/09/2015)

ReproductiveRights.Gov

HHS has website concerning reproductive rights.

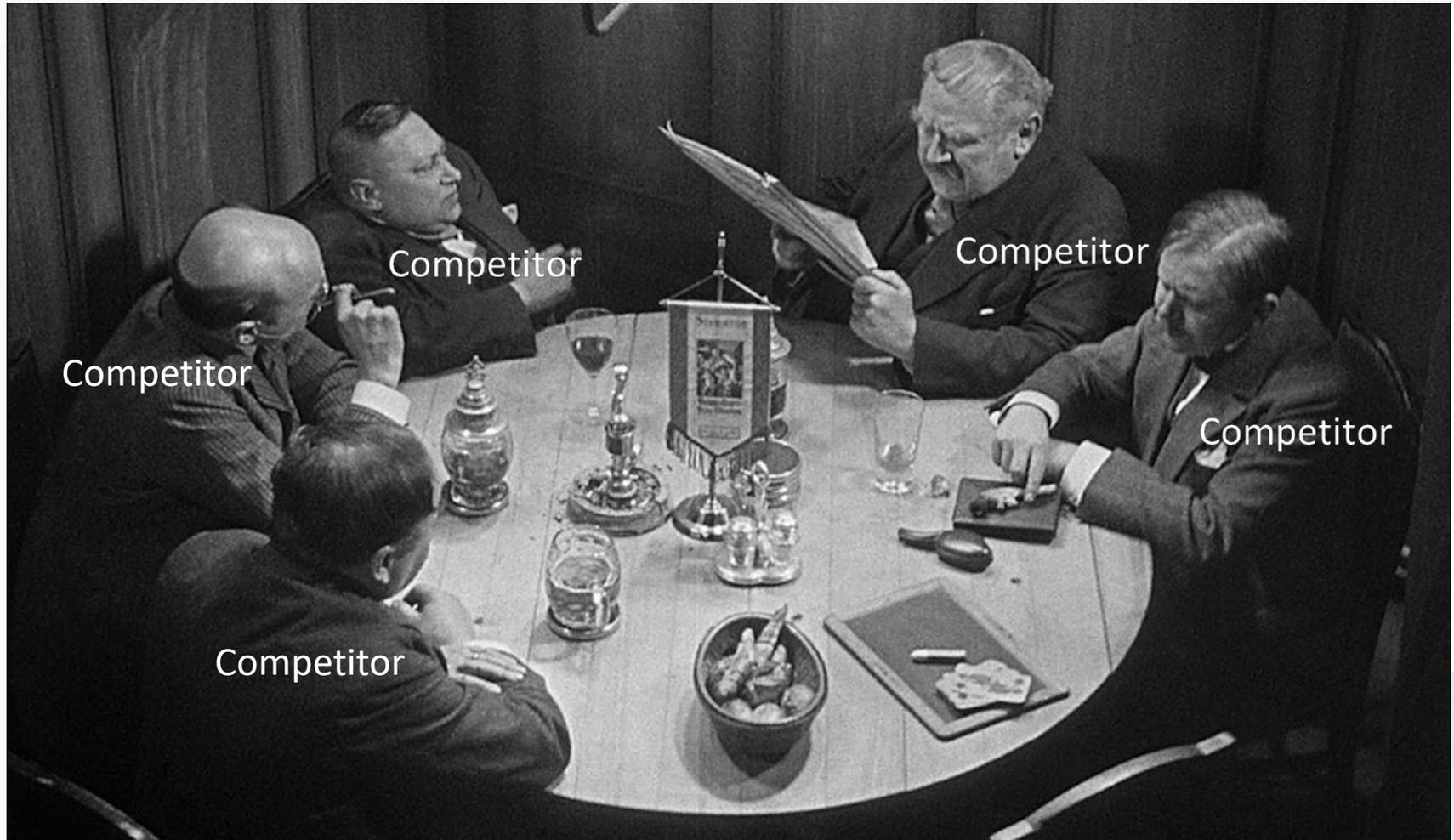
- Emergency care
 - EMTALA requires stabilizing treatment
- Birth control
 - ACA plans must cover birth control
- Medication
 - OCR guidance to pharmacies
- Access to abortion services
 - Depends on state law
- Other preventative health services
 - Insurance requirements

(<https://reproductiverights.gov/>)



Know Your Rights:
Reproductive Health
Care

Antitrust Laws



Antitrust Laws

- Sherman Act § 1
 - Prohibits agreement and conspiracy in restraint of trade.
 - Sherman Act § 1
 - Prohibits monopolies or attempted monopolies.
 - Clayton Act § 7
 - Prohibits mergers or acquisitions if effect would lessen competition or result in monopoly.
 - Federal Trade Comm'n Act
 - Prohibits unfair methods of competition and unfair or deceptive acts or practices.
 - State laws
 - Criminal penalties
 - \$1,000,000 to \$100,000,000 fine
 - Prison up to 10 years
 - Civil penalties
 - Action by state or federal govt
 - Treble (3x) damages
 - Injunctive relief, e.g., divestiture, restrictions, etc.
 - Attorneys' fees
 - Private lawsuit
 - Treble damages
 - Injunctive relief
 - Attorneys' fees
- *But see Local Govt Antitrust Act*

Sherman Act § 1

- As defined by Supreme Court, only prohibits agreements that unreasonably restrain trade.
- Rule of reason v. per se violations



FTC / DOJ Guidelines Withdrawn



FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

Enforcement

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For Release

Federal Trade Commission Withdraws Health Care Enforcement Policy Statements

Outdated statements no longer serve as useful guidance or reflect market realities

July 14, 2023 | [f](#) [t](#) [i](#)

Tags: [Competition](#) | [Office of Policy Planning](#) | [Bureau of Competition](#) | [Nonmerger](#) | [Health Care](#)

Related resources

The Federal Trade Commission announced today the withdrawal of two antitrust policy statements

Federal Trade Commission Withdraws



Maintaining CAH Status



CAH Risks

- CAH or Necessary Provider CAH opens or relocates off-campus provider-based dept within 35/15 miles of another hospital or CAH.
- Necessary provider CAH relocates or replaces its facility.
 - Not renovation or expansion of existing facility.
 - Must document 75% same population served, 75% same services, and 75% same staff.
 - Must continue satisfy state necessary provider criteria.
- New hospital or CAH opens within 35/15-miles of CAH.
- Co-location with another hospital or CAH.
- Termination of Medicare provider agreement.

(42 CFR 485.610(d); SOM Ch. 2 at 2265F; 70 FR 47472)

Additional Resources



<https://www.hollandhart.com/healthcare>

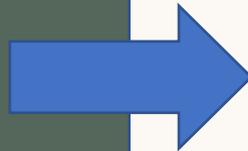
Healthcare is a massive industry that needs specialized legal advice.

Healthcare spending represents about a fifth of US GDP. Few sectors are as complex and highly regulated. In an ultra-competitive environment, our industry-experienced team takes care of clients' legal issues so they can focus on business.

regulatory issues, including Stark, Anti-Kickback Statute, HIPAA, handle provider and payor contracting; mergers, acquisitions, and joint credentialing and medical staff issues; government investigations and regulation; employment; real estate; tax; employee benefits; and With our extensive experience, there is not much our healthcare clients face that we

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- Recorded webinars
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- Other



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