

# Compliance Update

## Year in Review

November 2, 2023

| Presented by Kim C. Stanger



# Today's Presenter



Kim C. Stanger

Partner, Holland & Hart LLP

(208) 383-3913

[kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com)

Kim Stanger is a partner in the Boise office of Holland & Hart LLP and the chair of the firm's Health Law Group. Mr. Stanger helps clients navigate complex state and federal regulations and practical uses facing the healthcare industry, including transactional, compliance, and administrative matters.

He is consistently named as one of the Best Lawyers in America® for Health Care Law by U.S. News and a Mountain States Super Lawyer. He has been repeatedly awarded the Best Lawyers® Health Care Law "Lawyer of the Year" for Boise. He is a member of the American Health Law, Past President of the Idaho Bar Association Health Law Section, and a frequent author and speaker on health law-related issues.

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# Agenda

- End of PHE
- Fraud and Abuse
- HIPAA and Data Privacy
- Information Blocking
- AI Issues
- Telehealth
- No Surprise Billing Rules
- Hospital Price Transparency
- Telephone Consumer Protection Act (TCPA)
- Antitrust
- Anti-Discrimination Laws
- Reproductive Rights
- Minor Consents

# End of Public Health Emergency

# PHE ended 5/11/23



## Hospitals and CAHs (including Swing Beds, DPUs), ASCs and CMHCs: CMS Flexibilities to Fight COVID-19

At the beginning of the COVID-19 Public Health Emergency (PHE), CMS used emergency waiver authorities and various regulatory authorities to enable flexibilities so providers could rapidly respond to people impacted by COVID-19. CMS developed a cross-cutting initiative to use a comprehensive, streamlined approach to reestablish certain health and safety standards and other financial and program requirements at the eventual end of the COVID-19 public health emergency.

This CMS cross-cutting initiative focused on evaluating CMS-issued PHE waivers and flexibilities to prepare the health care system for operation after the PHE. This review happened in three concurrent phases:

1. CMS assessed the need for continuing certain waivers based on the current phase of the PHE. Since the beginning of the PHE, CMS has both added and terminated flexibilities and waivers as needed. In doing so, CMS considered the impacts on communities — including underserved communities — and the potential barriers and opportunities that the flexibilities may address.
2. CMS assessed which flexibilities would be most useful in a future PHE, such as natural and man-made disasters and other emergencies, to ensure a rapid response to future emergencies, both locally and nationally, or to address the unique needs of communities that may experience barriers to accessing health care.
3. CMS is continuing to collaborate with federal partners and the health care industry to ensure that the health care system is holistically prepared for addressing future

- COVID-19 vaccination requirements
- Stark law waivers
- Telehealth
- Staff licensure
- Conditions of participation
- Discharge planning
- CAH bed count and length of stay
- ASC temporary hospital status
- Others

See <https://www.cms.gov/files/document/hospitals-and-cahs-ascs-and-cmhcs-cms-flexibilities-fight-covid-19.pdf>

# Beware PHE fraud and abuse issues...

The screenshot shows a web browser window with the URL <https://www.justice.gov/criminal-fraud/health-care-fraud-unit/case-summaries>. The page header includes the DOJ Menu, Criminal Division logo, and U.S. Department of Justice text. A search bar is visible. The main navigation menu includes links for About, Leadership, Press Room, Employment, FOIA, Resources, and Contact. The breadcrumb trail reads: Justice.gov > Criminal Division > About > Sections/Offices > Fraud Section > Health Care Fraud > Recent Enforcement Actions > 2022 COVID-19 Enforcement Action > Justice Department Announces Nationwide Coordinated Law Enforcement Action to Combat COVID-19 Health Care Fraud. The main content area features a sidebar with 'Case Summaries' (selected), 'Court Documents', and 'Press Release'. The main headline is 'Justice Department Announces Nationwide Coordinated Law Enforcement Action to Combat COVID-19 Health Care Fraud'. A 'Share' button is located below the headline. The Windows taskbar at the bottom shows the date and time as 12:50 PM on 10/28/2023.

# Fraud and Abuse



# 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, e.g.,
    - Conditions of payment
    - Anti-Kickback Statute and Stark
- 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 Developments

- FCA liability requires that the defendant act “knowingly,” i.e.,
  - Actual knowledge
  - Deliberate ignorance
  - Reckless disregard of the truth or falsity, including substantial and unjustifiable risk of falsity.
- Depends on plaintiff’s knowledge and subjective belief.
  - Cannot avoid liability by establishing objectively reasonable interpretation of ambiguous law.

*(US ex rel. Schutte v. SuperValue, Inc. (S.Ct. 2023))*

# False Claims Act: Penalties

The screenshot shows the top navigation bar of the U.S. Department of Justice Office of Public Affairs website. It includes the department's logo, the text "Office of Public Affairs U.S. Department of Justice", and links for "Our Offices", "Find Help", and "Contact Us". A search bar is also present. Below the navigation bar is a dark menu with links for "About", "News", "Documents", "Internships", "FOIA", "Contact", and "Information for Journalists". The breadcrumb trail reads: "Justice.gov > Office of Public Affairs > News > Press Releases > False Claims Act Settlements and Judgments Exceed \$2 Billion In Fiscal Year 2022".

**News**

- All News
- Blogs
- Photo Galleries
- Podcasts
- Press Releases**
- Speeches
- Videos

**PRESS RELEASE**

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

Tuesday, February 7, 2023

**For Immediate Release**  
Office of Public Affairs

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### Second-Highest Number of Settlements in History

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

# False Claims Act: Application

- Former VP brought qui tam action claiming health system violated FCA, AKS, and Stark:
  - Medical directorships > fair market value
  - Provide free PAs, billing, and admin support to referring physicians, including free support to help physicians catch up on documentation.
  - Paying overhead costs of referring physicians.
  - Billing Medicare/Medicaid for services provided without supervisory physicians onsite.
  - No oversight and no records maintained to justify compensation.
- Settled for \$69 million

United States Attorney's Office Eastern District of Michigan

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Justice.gov > U.S. Attorneys > Eastern District of Michigan > Press Releases > Covenant Healthcare System and Physicians Pay Over \$69 Million to Resolve False Claims Act Allegations Related to Improper Financial Relationships

PRESS RELEASE

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

Wednesday, March 29, 2023

For Immediate Release  
U.S. Attorney's Office, Eastern District of Michigan

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# Anti-Kickback Statute (AKS)

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

(42 USC 1320a-7b(b); 42 CFR 1003.300(d))

- “One purpose” test

(*US v. Greber*, 760 F.2d 68 (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)
- False Claims Act violation
  - Must report and repay
  - \$11,803 to \$23,607 per claim
  - Qui tam lawsuits

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

- Minimum \$100,000 settlement through self-disclosure protocol.

# Anti-Kickback Statute

**Remuneration  
+ Intent to induce  
referrals for items  
payable by federal  
program**  

---

**AKS violation**

**“One purpose” test**

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

# AKS Developments

- In 12/22, CCA 2023 enacted new AKS exception for physician wellness programs.
  - Hospitals, ASCs, SNFs and certain other entities may offer a bona fide mental health or behavioral health improvement or maintenance program to physicians who practice in the area serviced by the facility.
  - Effective for programs after 12/29/22.

(42 USC 1320a-7b(b)(3))

# AKS Developments

- OIG FAQs re Fraud and Abuse Authorities, <https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/>
  - Effect of failure to fit safe harbor
  - AKS v. CMPL v. Stark
  - Cash, cash equivalents, and “in-kind” gift cards
  - AKS and EHR vendors
  - Referrals between entities with common ownership
  - ASC safe harbor
  - Inflation caps
  - PBMs
  - Others

U.S. Department of Health and Human Services  
**Office of Inspector General**

About OIG ▾ Reports ▾ Fraud ▾ Compliance ▾ Exclusions ▾ Newsroom ▾ Careers ▾ COVID-19 Portal

Home > [Frequently Asked Questions](#) > General Questions Regarding Certain Fraud and Abuse Authorities

## General Questions Regarding Certain Fraud and Abuse Authorities

### (1) When an arrangement does not satisfy a safe harbor under the Federal anti-kickback statute, does that mean it's automatically illegal? If an arrangement satisfies most of a safe harbor's conditions, does that mean it is lower risk?

The safe harbor regulations at 42 CFR § 1001.952 describe various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute. Compliance with a safe harbor is voluntary; failure to satisfy a safe harbor does not mean that an arrangement is illegal.

There is no safe harbor protection for partial compliance with the conditions of a potentially applicable safe harbor. To receive the benefit of safe harbor protection, an arrangement must squarely satisfy



# 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))

## Beware:

- Few statutory safe harbors.
- No regulatory safe harbors.
- Cases suggest DOJ may interpret and apply EKRA broadly to combat fraud and abuse in labs. (See, e.g., *US v. Schena* (N.D. Cal. 2022); *S&G Labs Hawaii v. Graves* (D. Haw. 2021))



# 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 DHSunless 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.
    - \$27,750\* per claim submitted
    - \$174,172\* per scheme
- (42 CFR 411.353, 1003.310; 45 CFR 102.3)

## Beware

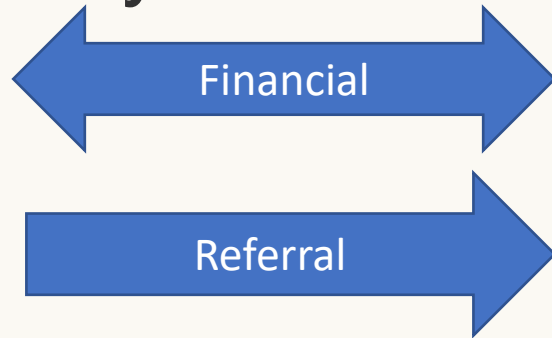
- Strict liability statute.
- Likely False Claims Act violation
- Likely Anti-Kickback Statute violation

# Stark

## Only applies if:

### Physician or Family Member

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



### 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

(42 CFR 411.351 and 411.353)

# 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 Law Resolutions

- CMS working to resolve backlog of self-disclosures.
- Settlements are small % of potential exposure.
- Recent Stark changes have made it easier to comply and withdraw from SRDP.

## Self-Referral Disclosure Protocol Settlements

The CMS Voluntary Self-Referral Disclosure Protocol (SRDP) enables providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute. The following table displays settlements to date and will be updated on a yearly basis.

Calendar Year	Number of Disclosures Settled	Range of Amounts of Settlements	Aggregate Amount of Settlements
2011	3	\$60-\$579,000	\$709,060
2020	36	\$33-\$952,300	\$4,344,966
2021	27	\$631-\$1,110,148	\$1,988,451
2022	104	\$299-\$1,171,174	\$9,287,866
<b>Totals</b>	<b>502</b>	<b>\$33-\$1,196,188</b>	<b>\$47,444,700</b>

As of December 31, 2022, an additional 232 disclosures to the SRDP were withdrawn, closed without settlement or settled by CMS' law enforcement partners.

confidentially on an aggregate basis.

Feedback

# Stark Law Developments

- In 12/22, CCA 2023 enacted new Stark exception for physician wellness programs.
  - Hospitals, ASCs, SNFs and certain other entities may offer a bona fide mental health or behavioral health improvement or maintenance program to physicians who practice in the area serviced by the facility.
  - Effective for programs after 12/29/22.  
(42 USC 1395nn(e)(9))
- In 12/22, CMS updated its Voluntary Self-Referral Disclosure Protocol effective for disclosures after 3/1/23. (<https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/self-referral-disclosure-protocol>)
- Effective 10/1/23, CMS modifies process for requesting exception for physician-owned hospital expansions. (<https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/spotlight>)

# Civil Monetary Penalties Law (CMPL)

Prohibits certain specified conduct, e.g.:

- Submitting false or fraudulent claims, misrepresenting facts relevant to services, etc.
- Violating Anti-Kickback Statute or Stark law.
- Violating EMTALA.
- Failing to report and repay an overpayment.
- Failing to grant timely access.
- Misusing “HHS”, “CMS”, “Medicare”, “Medicaid”, etc.
- Failing to report adverse action against providers.
- Submitting claims for services ordered by, or contracting with, an excluded entity.
- Offering inducements to program beneficiaries.
- Hospitals offering inducements to physicians to limit services.

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

# CMPL

## Beneficiary 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, i.e.,
  - AKS penalties
  - FCA violation
  - FCA penalties



# CMPL

## Inducement to Reduce Services

- 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.

# CMPL Excluded Individuals

- Excluded person cannot order or prescribe items payable by federal healthcare program.
- Cannot submit claim for item ordered or furnished by an excluded person.
- Excluded owners cannot retain ownership interest in entity that participates in Medicare.
- Cannot hire or contract with excluded entity to provide items payable by federal programs.

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

## Penalties

- \$22,427\* per item or service ordered.
- 3x amount claimed.
- Repayment of amounts paid.
- Exclusion from Medicare and Medicaid (42 USC 1320a-7a(a)(8); 42 CFR 1003.210; 45 CFR 102.3; OIG Bulletin, *Effect of Exclusion*)



U.S. Department of Health & Human Services

**Office of Inspector General**  
U.S. Department of Health & Human Services

Report #, Topic, Keyword..

Advanced

- About OIG
- Reports & Publications
- Fraud
- Compliance
- Recovery Act Oversight
- Exclusions
- Newsroom

Home > Exclusions > LEIE Downloadable Databases

## LEIE Downloadable Databases

E-mail me when this page is updated.

### Download the LEIE Database

**ANNOUNCEMENT:** As of the September 2013 update, only the LEIE files containing the NPI, Waiver, and Waiver States fields will be available.

[Instructions and information About the LEIE Files.](#)

Below files updated: 05-08-2015

#### LEIE Database

- 04-2015 Updated LEIE Database: EXE | ZIP

#### Current Monthly Supplements

- 04-2015 Exclusions: EXE | ZIP
- 04-2015 Reinstatements: EXE | ZIP
- Monthly Supplement Archive

#### Profile Updates

- 04-2015 Profile Corrections

#### Current Record Layout

**I'm looking for**

Let's start by choosing a topic

Select One

*Check the LEIE on regular basis!*

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



# Recent OIG Self-Disclosures

Date	Alleged Conduct	Amount
9/28/23	Baptist Medical Center knowingly <b>retained overpayments.</b>	\$131,000
9/20/23	Brickyard Healthcare submitted claims for <b>services provided by unlicensed person.</b>	\$35,000
9/14/23	Advanced Garden State Cardiology <b>employed excluded individual</b> and submitted claims by unlicensed and excluded individual.	\$159,000
9/8/23	Missouri Healthcare System submitted claims for <b>services that failed to meet standards of care or were medically unnecessary.</b>	\$619,000
8/17/23	IvyRehab paid <b>remuneration to physicians through discounts</b> and <b>waived patient cost-sharing obligations.</b>	\$171,000
8/3/23	Tarpon Interventional Spine submitted claims for services that <b>misidentified rendering provider.</b>	\$21,000
7/21/23	Team Rehab Services submitted claims for <b>services that were not reimbursable</b> and did not meet requirements for time-based codes.	\$12,200,000
6/29/23	Ascension St. Vincent's Birmingham paid <b>remuneration in form of free office space.</b>	\$100,000

# Advisory Opinions

## AKS and CMPL

The screenshot shows the homepage for the U.S. Department of Health and Human Services Office of Inspector General. The navigation menu includes: About OIG, Reports, Fraud, Compliance, Exclusions, Newsroom, Careers, and COVID-19 Portal. The breadcrumb trail is: Home > Compliance > Advisory Opinions. The main heading is "Advisory Opinions". Below it, the text reads: "HHS-OIG issues advisory opinions about the application of certain fraud and abuse enforcement authorities to the requesting party's existing or proposed business arrangements." A blue button labeled "View All Opinions" is visible. At the bottom, there is a search bar with the text "Search opinions" and a "Search" button.

## Stark

The screenshot shows the CMS.gov website. The navigation menu includes: Medicare, Medicaid/CHIP, Marketplace & Private Insurance, Priorities, and Training & Education. The breadcrumb trail is: Medicare > Regulations & guidance > Physician Self Referral > Advisory Opinions (AOs). The main heading is "Advisory Opinions (AOs)". Below it, the text reads: "Section 1877(g)(6) of the Social Security Act (the Act) requires that CMS issue certain written advisory opinions. These opinions provide guidance on whether a physician's referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship are prohibited under the Medicare program by section 1877 of the Act. We are making these advisory opinions available to the general public through this CMS website, as specified in our regulations at 42 CFR 411.384(b). The purpose of the advisory opinion process is to provide a binding opinion concerning the application of section 1877 of the Act to specific factual situations." Below this, there is a section titled "The requestor, who must be a party to the existing or proposed arrangement, is the only individual or entity that may rely on the advisory opinion. In each opinion, we apply legal standards to a set of facts involving certain known persons and/or entities that have provided specific statements about key factual issues. Because each opinion applies to specific individuals or entities in specific situations, no third parties are bound by, nor may they legally rely on, an advisory opinion."

- May request AO.
- AOs are not binding on others but provide helpful guidance.

# OIG Compliance Guidance



The screenshot shows the top navigation bar of the OIG website with the following menu items: About OIG, Reports, Fraud, Compliance (highlighted), Exclusions, Newsroom, and Careers. The main content area is titled "Compliance Guidance" and includes a sub-header "Compliance Guidance" and a list of categories: Accountable Care Organizations, Advisory Opinions, Compliance Guidance (highlighted), Corporate Integrity Agreements, Open Letters, RAT-STATS, Safe Harbor Regulations, Self-Disclosure Information, and Special Fraud Alerts, Bulletins, and Other Guidance. The main text states: "OIG has developed a series of voluntary compliance program guidance documents (CPGs) directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. The CPGs are listed below. On April 24, 2023, [OIG announced](#) its plans to improve and update existing CPGs and to deliver new CPGs specific to segments of the health care industry or entities involved in the health care industry that have emerged in recent years. In modernizing OIG's CPGs, our goal is to produce useful, informative resources—as timely as possible—to help advance the industry's voluntary compliance efforts in preventing fraud, waste, and abuse in the

- Existing guidance, e.g.,
  - Hospital Compliance Program Guidance (63 FR 8987 (2/23/98))
  - Supplemental Hospital Compliance Program Guidance (70 FR 4858 (1/31/05))
- In 4/23, OIG announced plans to update its compliance program guidance.
  - Federal fraud and abuse laws
  - Compliance program basics
  - Effective compliance operations
  - OIG processes and resources
  - General guidance for all segments by end of 2023
  - Specific guidance for segments in 2024.
  - Posted through OIG listserv. (88 FR 25000 (4/23))

# Common State Laws and Regulations

- False claims acts
- Anti-kickback statutes
- Self-referral prohibitions
- Fee splitting prohibition
- Disclosure of financial interests
- Insurance statutes
- Medicaid conditions
- Fraud or misrepresentation
- Consumer protection laws
- Bribery (may trigger federal Travel Act claims)
- Others?

## Penalties

- Civil penalties
- Criminal penalties
- Adverse licensure action
- Other

## *Beware*

- *May apply to private payers in addition to govt programs.*
- *May not contain the same exceptions or safe harbors as federal statutes.*

# HIPAA and Data Privacy



# HIPAA Criminal Penalties

Applies if individuals obtain or disclose PHI from covered entity without authorization.

Conduct	Penalty
Knowingly obtain info in violation of the law	\$50,000 fine 1 year in prison
Committed under false pretenses	100,000 fine 5 years in prison
Intent to sell, transfer, or use for commercial gain, personal gain, or malicious harm	\$250,000 fine 10 years in prison

(42 USC 1320d-6(a))

# HIPAA Civil Penalties

Watch for new rule to give individuals a portion of settlements or penalties.  
(87 FR 19833 (4/6/22))

Conduct	Penalty
Did not know and should not have known of violation	<ul style="list-style-type: none"> <li>• \$127* to \$63,973* per violation</li> <li>• Up to \$1,919,173* per type per year</li> <li>• <b>No penalty if correct w/in 30 days</b></li> <li>• OCR may waive or reduce penalty</li> </ul>
Violation due to reasonable cause	<ul style="list-style-type: none"> <li>• \$1,280* to \$63,973* per violation</li> <li>• Up to \$1,919,173* per type per year</li> <li>• <b>No penalty if correct w/in 30 days</b></li> <li>• OCR may waive or reduce penalty</li> </ul>
<b>Willful neglect,</b> but correct w/in 30 days	<ul style="list-style-type: none"> <li>• \$12,794* to \$63,973* per violation</li> <li>• Up to \$1,919,173* per type per year</li> <li>• <b>Penalty is mandatory</b></li> </ul>
<b>Willful neglect,</b> but do not correct w/in 30 days	<ul style="list-style-type: none"> <li>• \$63,973 to \$1,919,173* per violation</li> <li>• Up to \$1,919,173* per type per year</li> <li>• <b>Penalty is mandatory</b></li> </ul>

(45 CFR 102.3, 160.404; 85 FR 2879)

# HIPAA

## Avoiding “Willful Neglect”

### 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.)

### 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.)

# Recent HIPAA Settlements

Date	Conduct	Settlement
9/11/23	L.A. Care Plan failed to secure patient portal, perform risk analysis, and mailed ID cards to wrong patients. Affected 2500+ persons.	\$1,300,000
8/24/23	UnitedHealthcare failed to timely provide copy of records.	\$80,000
6/28/23	iHealth Solutions' PHI of 267 persons was exfiltrated by unauthorized persons.	\$75,000
6/15/23	Yakima Valley Hospital security guards snooping through records of 419 persons.	\$240,000
6/4/23	Manesa Health Center disclosed PHI in response to negative online reviews.	\$30,000
5/16/23	MedEvolve (business associate) left server unsecured exposing PHI of 230,572 persons.	\$350,000
5/8/23	David Mente, LPC, failed to provide father with records of three minor children.	\$15,000
2/2/23	Banner Health hacked, exposing PHI of 2,810,000 persons; failure to implement security rule requirements.	\$1,250,000
1/23/23	Life Hope Labs failed to provide personal rep with records of deceased patient.	\$16,500
9/20/22	Great Expressions Dental failed to provide records and charged more than reasonable fee.	\$80,000
8/23/22	New England Derm put specimen containers with PHI in trash bin in parking lot.	\$300,640

# HIPAA Privacy Rule: Right of Access

**U.S. Department of Health and Human Services**  
Enhancing the health and well-being of all Americans

Home > About > News > UnitedHealthcare Pays \$80,000 Settlement to HHS to Resolve HIPAA Matter over Patient Medical Records Request

**FOR IMMEDIATE RELEASE**  
August 24, 2023

Contact: HHS Press Office  
202-690-6343  
[media@hhs.gov](mailto:media@hhs.gov)

**UnitedHealthcare Pays \$80,000 Settlement to HHS to Resolve HIPAA Matter over Patient Medical Records Request**

*OCR settles forty-fifth HIPAA Right of Access investigation*

Today, the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) has announced a

- Ensure you timely respond to patient's or personal rep's request to access records.
  - Applies to records in designated record set.
    - Limited exceptions.
  - Includes records from other providers.
  - 30-day / 60-day time limit.
    - Beware Info Blocking Rule implications.
  - Must send e-PHI to third party identified by patient.
  - May charge reasonable cost-based fee.

(45 CFR 164.524)

# HIPAA Privacy Rule Right of Access

- Review OCR Guidance at <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>.
  - General right of access
  - “Designated record set”
  - Exceptions
  - Form and format for access
  - Timelines
  - Fees
  - Denial of access
  - Patient’s right to direct ePHI to another person
  - FAQs

## Individuals’ Right under HIPAA to Access their Health Information 45 CFR § 164.524

This guidance remains in effect only to the extent that it is consistent with the court's order in *Ciox Health, LLC v. Azar*, No. 18-cv-0040 (D.D.C. January 23, 2020), which may be found at [https://ecf.dcd.uscourts.gov/cgi-bin/show\\_public\\_doc?2018cv0040-51](https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv0040-51). More information about the order is available at <https://www.hhs.gov/hipaa/court-order-right-of-access/index.html>. Any provision within this guidance that has been vacated by the *Ciox Health* decision is rescinded.

[Newly Released FAQs on Access Guidance](#)

[New Clarification – \\$6.50 Flat Rate Option is Not a Cap on Fees for Copies of PHI](#)

### Introduction

Providing individuals with easy access to their health information empowers them to be more in control of decisions regarding their health and well-being. For example, individuals with access to their health information are better able to monitor chronic conditions, adhere to treatment plans, find and fix errors in their health records, track progress in wellness or disease management programs, and directly contribute their information to research. With the increasing use of and continued advances in health information technology, individuals have ever expanding and innovative opportunities to access their health information electronically, more quickly and easily, in real time.

# OCR and FTC Warn Against Data Tracking Technologies

<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-online-tracking/index.html>

## Health Information Privacy

HIPAA for Individuals

Filing a Complaint

HIPAA for Professionals

Newsroom

HHS > HIPAA Home > For Professionals > Privacy > Guidance Materials > Use of Online Tracking Technologies by HIPAA Covered Entities and Business Asso...

HIPAA for Professionals	
Regulatory Initiatives	
Privacy	+
Security	+
Breach Notification	+
Compliance & Enforcement	+
Special Topics	+
Patient Safety	+
Covered Entities & Business Associates	+
Training & Resources	
FAQs for Professionals	
Other Administrative Simplification	

## Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) is issuing this Bulletin to highlight the obligations of Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entities<sup>1</sup> and business associates<sup>2</sup> (“regulated entities”) under the HIPAA Privacy, Security, and Breach Notification Rules (“HIPAA Rules”) when using online tracking technologies (“tracking technologies”).<sup>3</sup> OCR administers and enforces the HIPAA Rules, including by investigating breach reports and complaints about regulated entities’ noncompliance with the HIPAA Rules. A regulated entity’s failure to comply with the HIPAA Rules may result in a civil money penalty.<sup>4</sup>

Tracking technologies are used to collect and analyze information about how users interact with websites or mobile applications (“apps”). For example, a regulated entity may engage a third party to perform such analysis as part of the regulated entity’s health care operations.<sup>5</sup> The HIPAA Rules apply when the information that regulated entities collect through tracking technologies or disclose to tracking technology vendors



12/1/22



July 20, 2023

[Company]  
[Address]  
[City, State, Zip Code]  
Attn: [Name of Recipient]

Re: Use of Online Tracking Technologies

Dear [Name of Recipient],

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) and the Federal Trade Commission (FTC) are writing to draw your attention to serious privacy and security risks related to the use of online tracking technologies that may be present on your website or mobile application (app) and impermissibly disclosing consumers’ sensitive personal health information to third parties.

Recent research,<sup>1</sup> news reports,<sup>2</sup> FTC enforcement actions,<sup>3</sup> and an OCR bulletin<sup>4</sup> have highlighted risks and concerns about the use of technologies, such as the Meta/Facebook pixel and Google Analytics, that can track a user’s online activities. These tracking technologies

<sup>1</sup>See, e.g., Mingjia Huo, Maxwell Bland, and Kirill Levchenko, *All Eyes on Me: Inside Third Party Trackers’ Exfiltration of PHI from Healthcare Providers’ Online Systems*, Proceedings of the 21st Workshop on Privacy in the Electronic Society (Nov. 7, 2022), <https://dl.acm.org/doi/10.1145/3559613.3563190>.

<sup>2</sup>See, e.g., Todd Feathers, Katie Palmer, and Simon Fondrie-Teitler, *Out of Control: Dozens of Telehealth Startups Sent Sensitive Health Information to Big Tech Companies*, THE MARKUP (Dec. 13, 2022), <https://themarkup.org/pixel-hunt/2022/12/13/out-of-control-dozens-of-telehealth-startups-sent-sensitive-health-information-to-big-tech-companies>.

<sup>3</sup>*U.S. v. Easy Healthcare Corp.*, Case No. 1:23-cv-3107 (N.D. Ill. 2023), <https://www.ftc.gov/legal-library/browse/cases-proceedings/2023-3186-easy-healthcare-corporation-us-v>; *In the Matter of BetterHelp, Inc.*, FTC Dkt. No. C-4796 (July 14, 2023), <https://www.ftc.gov/legal-library/browse/cases-proceedings/2023169-betterhelp-inc-matter>; *U.S. v. GoodRx Holdings, Inc.*, Case No. 23-cv-460 (N.D. Cal. 2023), <https://www.ftc.gov/legal-library/browse/cases-proceedings/2023090-goodrx-holdings-inc>; *In the Matter of Flo Health Inc.*, FTC Dkt. No. C-4747 (June 22, 2021), <https://www.ftc.gov/legal-library/browse/cases-proceedings/192-3133-flo-health-inc>.

<sup>4</sup>U.S. Dept. of Health and Human Svcs. Office for Civil Rights, *Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates* (Dec. 1, 2022), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-online-tracking/index.html>.

7/20/23

# HIPAA and Telehealth

- OCR has emphasized privacy and security in telehealth
  - On 8/9/23, relaxed security standards for telehealth platforms ended.
  - In 10/23, OCR published guidance for providers and patients concerning privacy and security risks in telehealth.
  - In 10/22, OCR published guidance for concerning HIPAA concerns in audio-only telehealth.

(See <https://www.hhs.gov/hipaa/for-professionals/special-topics/telehealth/index.html>)

## Telehealth Privacy Tips for Providers

### How do I communicate privacy protections to patients?

- Make privacy part of the workflow by confirming identities of everyone present at each telehealth session and communicate how any third-parties may be involved.
- Set up and communicate the below safeguards to your patients:**
  - Create unique user identification numbers
  - Use password protected platforms
  - Establish automatic logoff

### How do I protect my own privacy and reduce risk of breaches?

- Health data breaches are costly and can involve investigations, notifying patients, and recovering data, so providers need to be familiar with their security features.
- Establish the below processes:**
  - Routinely review your telehealth privacy and security policies.
  - Schedule regular deletion of files on mobile devices.
  - Utilize data back-up and recovery processes in case of breach.
- Conduct a **security evaluation** from an independent party on your telehealth system to verify security features such as authentication, encryption, authorization, and data management.
- Check out more security [tips](#) from the Office of the National Coordinator for Health Information Technology.

### What are the data privacy and security risks in telehealth?

- Privacy risk** is when an individual lacks control over the collection, use, and sharing of their health data.
- Security risk** is when there is unauthorized access to an individual's health data during the collection, transmission, or storage.
- These risks can affect trust between the patient and provider and contribute negatively to adherence and continuity of care.

### How do I fulfill privacy obligations during a telehealth session?

- Privacy and security risks** are present for in-person, remote monitoring, and virtual visits. Electronic transmission of data means greater privacy and security risks.
- Make sure you are up-to-date on security and protections requirements for [HIPAA compliance](#) and are aware of other [legal considerations](#).
- Providers have an **ethical obligation** to discuss privacy and security risks. These discussions can be part of a patient-centered care plan to help ensure confidentiality.



# HIPAA: Other Developments

- HHS proposed changes to HIPAA Privacy Rule.
  - Strengthened individual's right of access.
    - Allows individuals to take notes or use other personal devices to view and capture images of PHI.
    - Must respond to requests to access within 15 days.
    - Requires providers to share info when directed by patient.
    - Further limits charges for producing PHI.
  - Facilitates individualized care coordination.
  - Clarifies the ability to disclose to avert threat of harm.
  - Not required to obtain acknowledgment of Notice of Privacy Practices.
  - Modifies content of Notice of Privacy Practices.

(86 FR 6446 (1/21/21))

# HIPAA: Other Developments

- OCR webinar re How HIPAA Security Rule Can Help Defend Against Cyber-Attacks (10/30/23),  
<http://youtube.com/watch?v=VnbBxxyZLc8>
- OCR webinar re Risk Assessment (10/31/23)  
([https://kauffmaninc.zoom.us/webinar/register/WN\\_xaRWAC3qTYSykYAAbLL\\_ew](https://kauffmaninc.zoom.us/webinar/register/WN_xaRWAC3qTYSykYAAbLL_ew))
- CMS updated Security Risk Assessment Tool (version 3.4) (9/23)  
(<https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool>).
- OCR video re recognized security practices (10/31/22)  
(<https://www.youtube.com/watch?v=e2wG7jUiRjE>)
- OCR webinar re how Security Rule compliance can protect against cyberattacks.  
(OCR listserv)

Consider impact on:

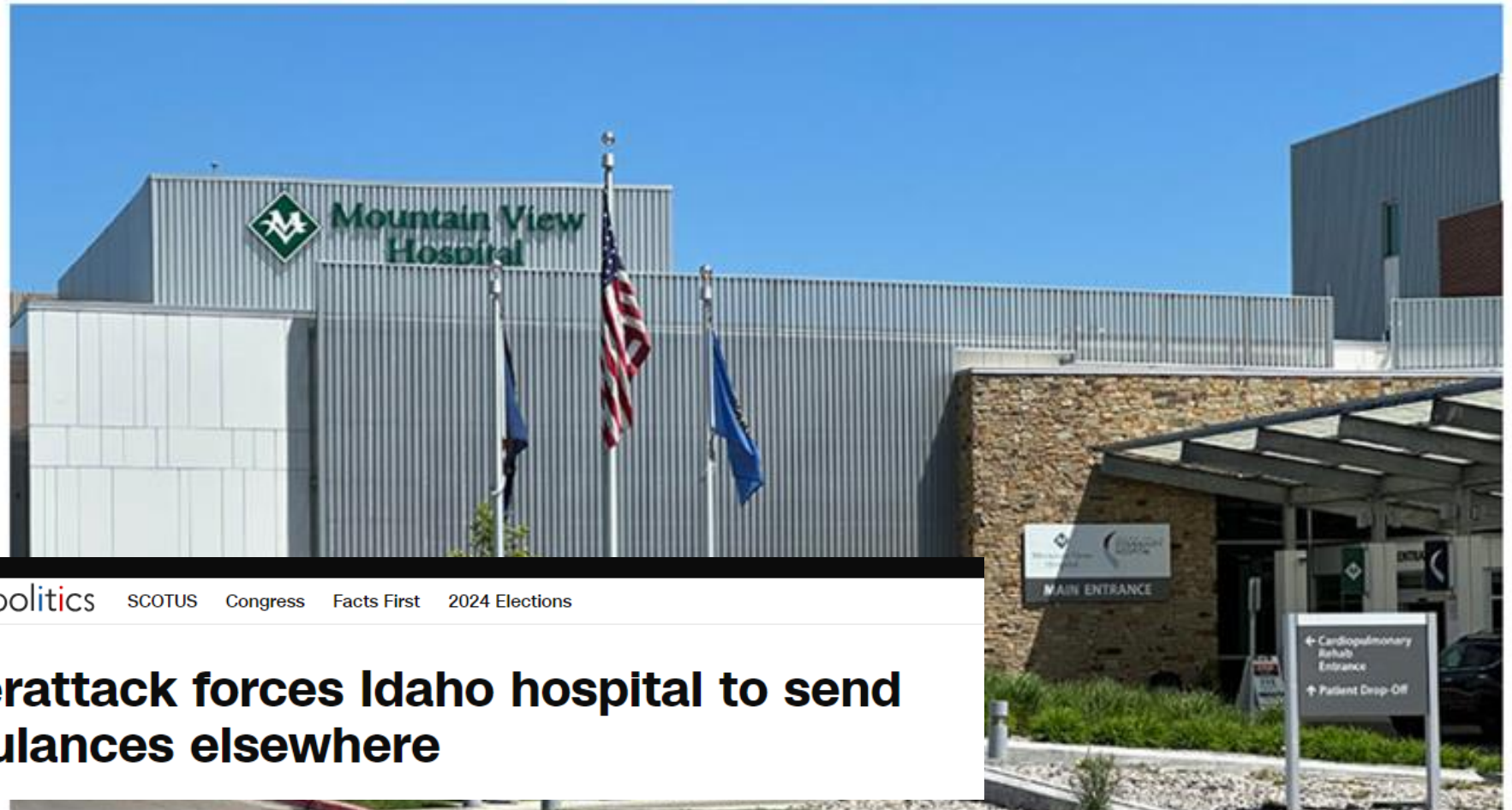
- Patient safety.
- Ability to function without data or with compromised data.
- Inability to bill.
- Damage to IT infrastructure.
- Cost of responding to and mitigating breach.
- FTC or state law violations.
- Lawsuits.
- Bad press.

## Cyberattack on Mountain View Hospital still ongoing after two weeks

Published at 9:00 am, June 10, 2023 | Updated at 9:13 am, June 10, 2023



Logan Ramsey, EastIdahoNews.com



☰ CNN politics SCOTUS Congress Facts First 2024 Elections

### Cyberattack forces Idaho hospital to send ambulances elsewhere

# Cybersecurity

The screenshot shows the TechTarget Health IT Security website. The main navigation bar includes links for Home, News, Features, Interviews, and Podcasts. A secondary navigation bar lists categories: HIPAA and Compliance, Cybersecurity, Cloud, Mobile, Patient Privacy, Data Breaches, and Disaster Preparedness. A promotional banner for a White Paper Library is visible, along with a 'VIEW NOW' button. The article title 'Average Cost of Healthcare Data Breach Reaches \$11M' is circled in red. Below the title is a sub-headline: 'The cost of a healthcare data breach has soared 53% since 2020, IBM's latest report revealed.' The article image shows a yellow background with a pair of tweezers.

TechTarget | HEALTH IT SECURITY  
xtelligent HEALTHCARE MEDIA

Home News Features Interviews Pod

HIPAA and Compliance Cybersecurity Cloud Mobile Patient Privacy Data Breaches Disaster Prepa

Learn more about Data Encryption in our White Paper Library  
Case studies, webcasts, eBooks and white papers all available now! [VIEW NOW](#)

**CYBERSECURITY NEWS**

## Average Cost of Healthcare Data Breach Reaches \$11M

The cost of a healthcare data breach has soared 53% since 2020, IBM's latest report revealed.

# OCR Cyber Security Guidance

<https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html>

The screenshot shows the HHS Health Information Privacy website. At the top, there are four navigation buttons: "HIPAA for Individuals", "Filing a Complaint", "HIPAA for Professionals", and "Newsroom". Below these, a breadcrumb trail reads: "HHS > HIPAA Home > For Professionals > The Security Rule > Security Rule Guidance Material > Cyber Security Guidance Material". A left sidebar menu includes "HIPAA for Professionals", "Regulatory Initiatives", "Privacy", "Security" (highlighted), "Summary of the Security Rule", "Security Guidance", "Cyber Security Guidance", "Breach Notification", "Compliance & Enforcement", "Special Topics", "Patient Safety", and "Covered Entities & Business Associates". The main content area is titled "Cyber Security Guidance Material" and contains the text: "In this section, you will find educational materials specifically designed to give HIPAA covered entities and business associates insight into how to respond to a cyber-related security incidents." Below this, there is a section titled "Cyber Security Checklist and Infographic" with two links: "Cyber Security Checklist - PDF" and "Cyber Security Infographic [GIF 802 KB]".

- Cyber Security Resources
- Cyber Security Newsletters
  - Sanction policies (10/23)
  - Authentication (6/23)
  - Security rule incident procedures (10/22)
  - Defending against common cyber attacks (3/22)
  - Others?
- Cyber incident response checklist
- Sign up for OCR listserv at <https://www.hhs.gov/hipaa/for-professionals/list-serve/index.html?language=es>

# HHS Cybersecurity Task Force

<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

- Online educational platform for cybersecurity training
- Health Industry Cybersecurity Practices (2023)
  - Outlines top threats
  - Recommends best practices to prepare and fight against threats

# Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients (2023)

<https://405d.hhs.gov/Documents/HICP-Main-508.pdf>

- Top threats
  - Social engineering
  - Ransomware
  - Loss or theft of equipment or data
  - Insider, accidental or malicious data loss
  - Attacks against network connected medical devices
- Best practices to protect against or respond to risks



# HHS Health Sector Cybersecurity Coordination Center (HC3),

<https://www.hhs.gov/about/agencies/asa/ocio/hc3/index.html>

About HHS Programs & Services Grants & Contracts Laws & Regulations

[Home](#) > [About](#) > [Agencies](#) > [ASA](#) > [Office of the Chief Information Officer \(OCIO\)](#) > Health Sector Cybersecurity Coordination Center (HC3)

Assistant Secretary for Administration (ASA)

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Cybersecurity

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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.

- Threat briefs
- Sector alerts, e.g.,

- [\\*July 20, 2023 - Citrix ADC and Citrix Gateway Vulnerabilities Sector Alert - PDF](#)
- [\\*July 13, 2023 - AI, Cybersecurity and the Health Sector - PDF](#)
- [\\*July 13, 2023 - June 2023 Vulnerability Bulletin - PDF](#)
- [June 22, 2023 - SEO Poisoning Analyst Note - PDF](#)

- Additional resources



# FTC Enforcement of Privacy and Security

FTC is using FTCA § 5 to go after entities for data security breaches.

- Bars unfair and deceptive trade practices, e.g.,
  - Mislead consumers re security practices.
  - Misusing info or causing harm to consumers.

(<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 )

# FTC Enforcement

<https://www.ftc.gov/business-guidance/resources/collecting-using-or-sharing-consumer-health-information-look-hipaa-ftc-act-health-breach>



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## Collecting, Using, or Sharing Consumer Health Information? Look to HIPAA, the FTC Act, and the Health Breach Notification Rule

**Tags:** [Privacy and Security](#) | [Consumer Privacy](#) | [Data Security](#) | [Health Privacy](#)

Does your business collect, use, or share consumer health information? When it comes to privacy and security, you've probably thought about the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the HIPAA Privacy, Security, and Breach Notification Rules (HIPAA Rules). But did you know you also may need to comply with the Federal Trade Commission Act and the FTC's Health

# Other Privacy and Security Developments

- SAMHSA has proposed changes to Part 2 rules to align with HIPAA (87 FR 74216 (12/2/22))
- Health Information Breach Notification Rule (16 CFR part 316)
  - Applies to vendors of personal health information.
  - Not entities covered by HIPAA (covered entities and business associates)
- FTC NPRM strengthens HBNR (88 FR 37819 (6/9/23))
- FTC actively enforcing Health Information Breach Notification Rules
  - GoodRx pas \$1.5 million
- SEC regulations require public entities to report:
  - Material cybersecurity incidents within four days, and
  - Material information about regarding cybersecurity management.

<https://www.sec.gov/news/press-release/2023-139>.



# Information Blocking

# 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 OIG
  - <https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/6>
  - OIG Hotline
- **Effective 9/1/23, civil monetary penalties of up to \$1,000,000 per violation**

(42 CFR 1003.1420; see 88 FR 42820 (7/3/23);  
<https://oig.hhs.gov/reports-and-publications/featured-topics/information-blocking/>)

## HEALTHCARE PROVIDERS

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

# Info Blocking Rule: Examples

## **INFO BLOCKING**

- 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

[HTTPS://WWW.HEALTHIT.GOV/TOPIC/INFORMATION-BLOCKING](https://www.healthit.gov/topic/information-blocking)



# Info Blocking Rule: OIG Enforcement Priorities

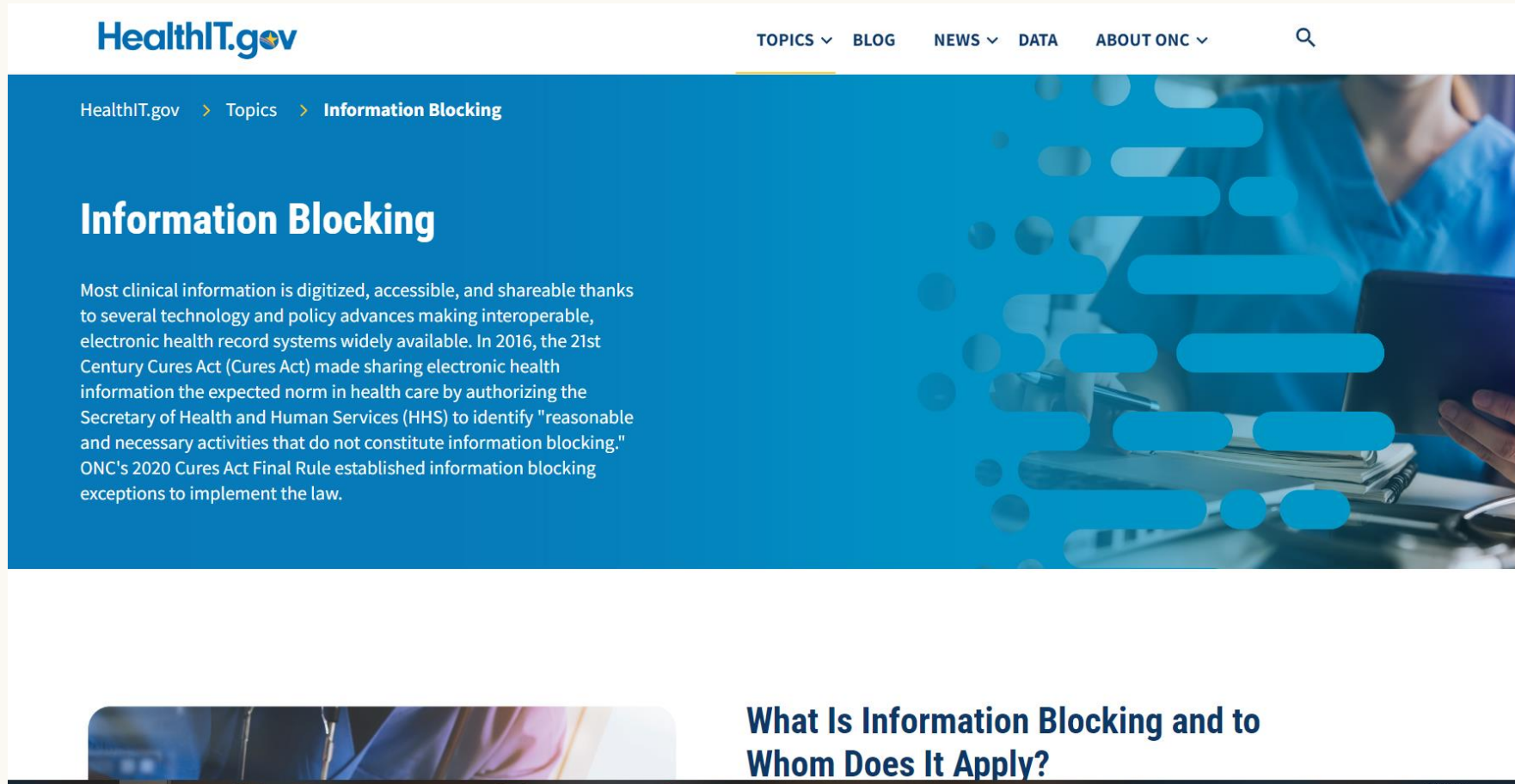
OIG will use the following priorities to select cases for investigation:

- resulted in, is causing, or had the potential to cause patient harm;
- significantly impacted a provider's ability to care for patients;
- was of long duration;
- caused financial loss to Federal health care programs, or other government or private entities; or
- was performed with actual knowledge.

[\(https://oig.hhs.gov/reports-and-publications/featured-topics/information-blocking/\)](https://oig.hhs.gov/reports-and-publications/featured-topics/information-blocking/)

# Info Blocking Rule Guidance

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



The screenshot shows the HealthIT.gov website. At the top left is the HealthIT.gov logo. To the right is a navigation menu with links for TOPICS, BLOG, NEWS, DATA, and ABOUT ONC, each with a dropdown arrow. A search icon is also present. Below the navigation is a blue header bar with the breadcrumb "HealthIT.gov > Topics > Information Blocking". The main content area has a blue background with a white text box containing the following text:

## Information Blocking

Most clinical information is digitized, accessible, and shareable thanks to several technology and policy advances making interoperable, electronic health record systems widely available. In 2016, the 21st Century Cures Act (Cures Act) made sharing electronic health information the expected norm in health care by authorizing the Secretary of Health and Human Services (HHS) to identify "reasonable and necessary activities that do not constitute information blocking." ONC's 2020 Cures Act Final Rule established information blocking exceptions to implement the law.

Below the text is a large blue graphic with a pattern of horizontal bars and circles. At the bottom of the page, there is a white box with a blue header "What Is Information Blocking and to Whom Does It Apply?" and a small image of a person in a blue lab coat.

# Telehealth

# Telehealth

- Most PHE waivers or relaxed standards have ended, e.g.,
  - Licensure rules
  - HIPAA security rules for platforms
  - Electronic prescribing
  - Location for services
  - Payer reimbursement requirements
    - Medicare has extended or retained some changes, especially for behavioral health.

# Beware Applicable Law

As a general rule, telehealth provider must comply with both

- Law of state in which **telehealth provider is located**,  
and
- Law of state in which **patient is located**.
  - States want to protect patients.
  - Likely sufficient contacts to establish jurisdiction over telehealth provider



Beware!

- Licensure
- Permissible telehealth methods
- Provider-patient relationship
- Scope of practice
- Standard of care
- Informed consent
- Remote prescribing
- Credentialing telehealth providers
- Reimbursement
- Malpractice liability and insurance
- Corporate practice of medicine
- Others?

# Ryan Haight Online Pharmacy Consumer Protection Act

- Prohibits providers from prescribing controlled substances via the internet without having previously performed an in-person medical evaluation of the patient.
- Exceptions:
  - Prescribing provider is temporarily covering for another provider with a treatment relationship; or
  - Patient being treated in DEA-registered facility, provider has DEA registration in state in which patient is located, and provider renders telehealth through 2-way interactive audio and video communication system.

(21 USC 829; 21 CFR 1306.09)

# Ryan Haight Act: Remote Prescribing

- In 2/23, DEA issued proposed rules that would modify the regulations for remote prescribing.
- In meantime, DEA has issued temporary rules extending COVID-19 PHE flexibilities through 12/31/24.
  - Registered practitioner may prescribe schedule II–V controlled substances via telemedicine to a patient without having in-person medical evaluation if:
    - The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;
    - The prescription is issued pursuant to a communication between a practitioner and a patient using an interactive telecommunications system satisfying certain conditions;
    - The prescription is consistent with all other requirements of 21 CFR part 1306.

(21 CFR 1307.41; 88 FR 69879 (10/10/23))



# Ryan Haight Act: Remote Prescribing

- DEA NPRM would allow telehealth prescription without in-person evaluation for:
  - 30-day supply of Schedule III-V non-narcotic controlled medications; and
  - 30-day supply of buprenorphine for treatment of opioid use disorder.

(88 FR 12875; <https://www.dea.gov/press-releases/2023/02/24/dea-announces-proposed-rules-permanent-telemedicine-flexibilities>)

# SUPPORT Act

- Facilitates telehealth for substance use disorders (SUD) by:
  - DEA required to establish a telehealth registration process to facilitate prescriptions for SUD.
    - See new proposed rule
  - State Medicaid programs required to allow for prescription of controlled substances to SUD patients via telehealth.
  - Medicare beneficiaries allowed to receive telehealth in their home.
    - Home is an approved “originating site”.

(21 USC 831(h)(2) and 42 USC 1395m and 1396a)

# Artificial Intelligence (AI)

# Artificial Intelligence in Healthcare

- Rapidly developing area of the law.
  - Watch for federal and state regulation.
- Common uses
  - Imaging
  - Clinical decision support tools
  - Research
  - Virtual assistant for transcription, administration, or practice management
  - Others
- Concerns
  - Bias
  - “Garbage in, garbage out” → incorrect results
  - Lack of transparency in algorithms, i.e., “black box” results
  - Others

# Artificial Intelligence

<https://www.whitehouse.gov/ostp/ai-bill-of-rights/>

- Safe and effective systems.
- Algorithmic discrimination protections.
- Data privacy
- Notice and explanation
- Human alternatives, considerations and fallback



# Artificial Intelligence: Compliance Considerations

- Privacy of data input to AI
  - HIPAA (e.g., use of de-identified PHI, permissible use, etc.)
  - 42 CFR part 2
  - FTCA § 5
  - State laws
- Unlicensed practice of medicine
  - Licensed provider must retain ultimate decision-making authority
- Malpractice
  - Reliance on AI may be inconsistent with applicable standard of care
- Billing compliance
  - AI may not incorporate all applicable regulations or payer requirements.

# Artificial Intelligence: Compliance Considerations

- Anti-Kickback Statute or other fraud and abuse concerns
  - Incorrect or false claims.
  - Improper inducements, e.g., AI developer builds AI in a manner that recommends a particular item or service payable by federal healthcare programs. (See 88 FR 23777 (4/18/23); OIG FAQs, <https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/>)
- Anti-Discrimination laws
  - AI may result in prohibited discrimination against persons. (See DOJ, EEOC, FTC *Joint Statement on Enforcement Efforts Against Discrimination and Bias in Automated Systems* (6/3/23), [https://www.ftc.gov/system/files/ftc\\_gov/pdf/EEOC-CRT-FTC-CFPB-AI-Joint-Statement%28final%29.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/EEOC-CRT-FTC-CFPB-AI-Joint-Statement%28final%29.pdf))
  - HHS proposed 1557 rule prohibits discrimination “through use of clinical algorithms in its decisionmaking.” (87 FR 47914 (8/4/22))

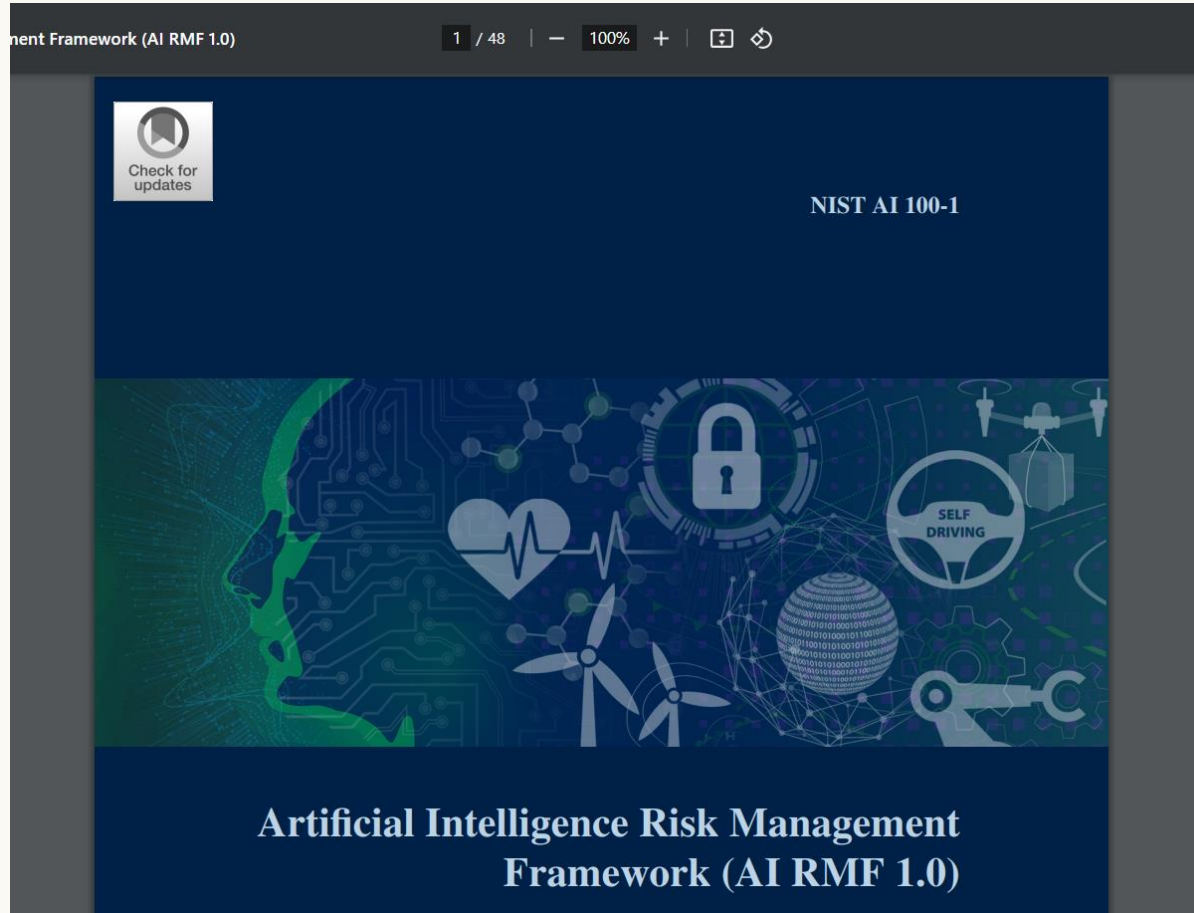
# Artificial Intelligence: Compliance Considerations

- FDA Regulation of Devices
  - Cures Act amended FDCA to exclude certain software functions from device if satisfy criteria, generally including that the software is:
    - Not intended to analyze certain info;
    - Intended to support or provide recommendations to treating clinician; and
    - Intended to enable clinician to independently review basis of software recommendations so clinician does not rely primarily on software's recommendation to diagnose or treat patient.  
(See 21 USC 360j(o))
  - FDA rules exclude certain software functions from definition of "device" regulated by FDA.  
(86 FR 20278 (4/19/21))
- Electronic health record certification
  - In 4/23, ONC issued proposed rule (HTI-1) for certified health technologies to increase trust in predictive technologies. (88 FR 23746 (4/18/23))
  - May serve as basis for legislation in other contexts.



# NIST Artificial Intelligence Risk Management Framework

<https://nvlpubs.nist.gov/nistpubs/ai/NIST.AI.100-1.pdf>



- Understanding and addressing risks, impacts and harms
- Challenges for AI risk management
- AI risks and trustworthiness
  - Valid and reliable
  - Safe
  - Secure and resilient
  - Accountable and transparent
  - Explainable and interpretable
  - Privacy-enhanced
  - Fair, with harmful bias managed

# AMA Policy re Augmented Intelligence in Healthcare

<https://www.ama-assn.org/system/files/2019-08/ai-2018-board-policy-summary.pdf>

- AI enhances human intelligence rather than replaces it.
- Requires oversight and regulation considering benefit and risk of harm.
- Payment and coverage must be practical and advance affordability.
- Use should not be mandate.
- Liability and incentives aligned, with developers accountable.



## Policy

The American Medical Association House of Delegates has adopted policies to keep the focus on advancing the role of augmented intelligence (AI) in enhancing patient care, improving population health, reducing overall costs, increasing value and the support of professional satisfaction for physicians.

### Foundational policy Annual 2018

As a leader in American medicine, our AMA has a unique opportunity to ensure that the evolution of AI in medicine benefits patients, physicians and the health care community. To that end our AMA seeks to:

- ▶ Leverage ongoing engagement in digital health and other priority areas for improving patient outcomes and physician professional satisfaction to help set priorities for health care AI
- ▶ Identify opportunities to integrate practicing physicians' perspectives into the development, design, validation and implementation of health care AI
- ▶ Promote development of thoughtfully designed, high-quality, clinically validated health care AI that:
  - Is designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team
  - Is transparent
  - Conforms to leading standards for reproducibility
  - Identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities, including when testing or deploying new AI tools on vulnerable populations

“Medical experts are working to determine the clinical applications of AI—work that will guide health care in the future. These experts, along with physicians, state and federal officials must find the path that ends with better outcomes for patients. We have to make sure the technology does not get ahead of our humanity and creativity as physicians.”

—Gerald E. Harmon, MD, AMA Board of Trustees

- Safeguards patients' and other individuals' privacy interests and preserves the security and integrity of personal information
- ▶ Encourage education for patients, physicians, medical students, other health care professionals and health administrators to promote greater understanding of the promise and limitations of health care AI
- ▶ Explore the legal implications of health care AI, such as issues of liability or intellectual property, and advocate for appropriate professional and governmental oversight for safe, effective, and equitable use of and access to health care AI

# Artificial Intelligence

- Stay tuned as the law attempts to catch up...
  - Federal laws and regulations
  - State laws and regulations
  - Industry standards and reliability
- In the meantime, beware its limitations and risks under the current framework.



# 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 resolve disputes about charges.

(45 CFR 149.410-.450)

## SELF-PAY PATIENTS

- Providers/facilities must:
  - Post notices.
  - Give patient a good faith estimate of charges.
  - **Co-Provider Rules Postponed.**
  - See forms at <https://www.cms.gov/nosurprises/policies-and-resources/overview-of-rules-fact-sheets> )
- Patient-provider dispute resolution (PPDR) process if actual bill is substantially in excess (i.e., > \$400) of good faith estimate.  
(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)

# No Surprise Billing Rules Developments

- Texas federal district court has repeatedly struck down govt application of qualifying payment amount (QPA), IDR process, and fees. (*Texas Medical Ass'n v. HHS* (E.D. Tex. 2022))
  - Govt has indicated it intends to appeal.
- Govt has proposed new rule addressing IDR process. (88 FR 65888 (9/26/23))
- Govt suspended IDR process for a time but has resumed individual claims on 10/6/23. (<https://www.cms.gov/files/document/federal-idr-partial-reopening-faqs-oct-23.pdf>)
- Govt has issued FAQs addressing No Surprise Billing Rules and IDR process. (<https://www.cms.gov/files/document/federal-idr-partial-reopening-faqs-oct-23.pdf>)

# FAQs re Reopening IDR Process

<https://www.cms.gov/files/document/federal-idr-partial-reopening-faqs-oct-23.pdf>

## Federal Independent Dispute Resolution (IDR) Process Partial Reopening of Dispute Initiation Guidance

October 2023

This communication was printed, published, or produced and disseminated at U.S. taxpayer expense.

- For individual disputes:
  - Provides limited grace period for initiating IDRs.
  - Check deadlines for pending IDRs.
- For batched disputes:
  - Watch for future guidance.





# CMS Website re No Surprise Billing

<https://www.cms.gov/nosurprises>

The screenshot shows the CMS.gov website header with the logo and navigation links. The main navigation menu includes Medicare, Medicaid/CHIP, Marketplace & Private Insurance, Priorities (which is underlined), and Training & Education. A breadcrumb trail indicates the current page is 'No Surprises Act' under 'Recent Legislation' and 'Priorities'. A secondary navigation bar contains Home, Policies & Resources, Resolving out-of-network payment disputes, and Consumers. A text box provides information about the Federal IDR portal reopening. The main content area features a large heading 'Ending Surprise Medical Bills' and a sub-heading 'Learn how providers, facilities, plans and issuers can comply with surprise billing protections and resolve out-of-network'.

**CMS.gov** Centers for Medicare & Medicaid Services

About CMS Newsroom Data & Research

Medicare ▾ Medicaid/CHIP ▾ Marketplace & Private Insurance ▾ Priorities ▾ Training & Education ▾

Home > Priorities > Recent Legislation > No Surprises Act

Home Policies & Resources ▾ Resolving out-of-network payment disputes ▾ Consumers

Effective October 6, 2023, the Departments have reopened the Federal IDR portal for the initiation of certain new single and bundled disputes. Processing and initiation of batched disputes and initiation of new air ambulance disputes remains temporarily suspended. The Departments are conducting a phased reopening of the portal and will make additional announcements regarding other suspended dispute categories soon.

## Ending Surprise Medical Bills

Learn how providers, facilities, plans and issuers can comply with surprise billing protections and resolve out-of-network

# Hospital Price Transparency Rules

# 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 ( $\leq 30$  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-oppsasc-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/ke-y-initiatives/hospital-price-transparency/enforcement-actions>
- Penalties range from \$56,940 to \$979,000.
- 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
<a href="#">2022-06-07</a>	Northside Hospital Atlanta	\$883,180.00	2021-09-02
<a href="#">2022-06-07</a>	Northside Hospital Cherokee	\$214,320.00	2021-09-09
<a href="#">2023-04-19</a>	Frisbie Memorial Hospital	\$102,660.00	2022-10-24
<a href="#">2023-04-19</a>	Kell West Regional Hospital <i>Under Review *</i>	\$117,260.00	2022-07-08
<a href="#">2023-07-20</a>	Falls Community Hospital &Clinic	\$70,560.00	2023-01-06
<a href="#">2023-07-20</a>	Fulton County Hospital <i>Under Review *</i>	\$63,900.00	2022-12-22
<a href="#">2023-07-24</a>	Community First Medical Center <i>Under Review *</i>	\$847,740.00	2022-06-22
<a href="#">2023-08-22</a>	Hospital General Castaner <i>Under Review *</i>	\$101,400.00	2022-09-19
<a href="#">2023-08-22</a>	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 interface. At the top right, there are navigation links: Home | About CMS | Newsroom | Archive | Help | Print. Below this is the CMS.gov logo and the text "Centers for Medicare & Medicaid Services". A search bar with the text "Search CMS" and a "Search" button is located to the right. A horizontal menu of yellow buttons includes: Medicare, Medicaid/CHIP, Medicare-Medicaid Coordination, Private Insurance, Innovation Center, Regulations & Guidance, Research, Statistics, Data & Systems, and Outreach & Education. Below the menu, a breadcrumb trail reads "Home > Hospital Price Transparency". A dark blue navigation bar contains links for Home, Hospitals, Consumers, Resources, and Contact Us. The main content area features a large blue circle with a white dollar sign and a price tag icon, followed by the heading "Hospital Price Transparency". Below the heading, a paragraph states: "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:" followed by a numbered list: "1. As a comprehensive machine-readable file with all items and services." and "2. In a display of shoppable services in a consumer-friendly format." At the bottom, a partial sentence reads: "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".

# Telephone Consumer Protection Act (TCPA)

# Telephone Consumer Protection Act (TCPA)

## Generally prohibits:

- Using automatic phone dialing system (“robo-call”) to call a hospital emergency line or guest room, cell phone, or other line if recipient is charged for call.
- Robo-calling or using pre-recorded voice to deliver message unless:
  - Emergency,
  - Have prior written consent,
  - Have consent if made by tax-exempt nonprofit organization, or
  - “health care” message by HIPAA-covered entity or business associate.

(47 USC 227; 47 CFR 64.1200)

## Penalties

- Recipient of more than 1 call within prior 12-month period may sue for:
  - Actual damages or \$500 per call, whichever is greater.
- State AGs may sue.

(47 USC 227)

# TCPA: Healthcare Message Exception

- Exception only applies to three types of calls, whether “live” or prerecorded, by a healthcare provider or its business associates without a patient’s prior authorization:
  - calls to describe a health-related product or service that is provided by the covered entity making the communication;
  - calls for treatment of the individual (e.g., appointment reminder; prescription refill reminders; etc); and
  - calls for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

<https://www.ftc.gov/business-guidance/resources/complying-telemarketing-sales-rule#healthcare>



# TCPA: Developments

- Effective 7/20/23:
  - For healthcare calls, must limit to no more than 1 call per day up to 3 calls per week;
  - For other calls, must limit number of robocalls to landline phone number to 3 during consecutive 30-day period;
  - Honor request to opt-out; and
  - Stricter requirements for obtaining consent.

(47 CFR 64.1200)

# TCPA: Developments

- FCC has issued proposed rule that would:
  - Strengthens consumers' rights to grant or revoke consent, and
  - Simplify opt-out process.

(88 FR 42034 (6/29/23))
- On 1/23/23, FCC stated state Medicaid agencies and their partners may send Medicaid enrollment calls without violating TCPA.  
<https://docs.fcc.gov/public/attachments/DOC-390794A1.pdf>
- 9<sup>th</sup> Circuit held that texts are not an “artificial or prerecorded voice” triggering TCPA.  
*(Trim v. Reward Zone (9<sup>th</sup> Cir. 2023))*

# TCPA Resources

<https://www.ftc.gov/business-guidance/resources/complying-telemarketing-sales-rule>



FEDERAL TRADE COMMISSION  
PROTECTING AMERICA'S CONSUMERS

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## Complying with the Telemarketing Sales Rule

**Tags:** [Advertising and Marketing](#) | [Telemarketing](#)

**Related Rules:** [Telemarketing Sales Rule](#)

[Introduction](#)

[Who Must Comply with the Amended TSR?](#)

[Charities and For-Profit Telemarketers Calling on Their Behalf](#)

[Exemptions to the TSR](#)

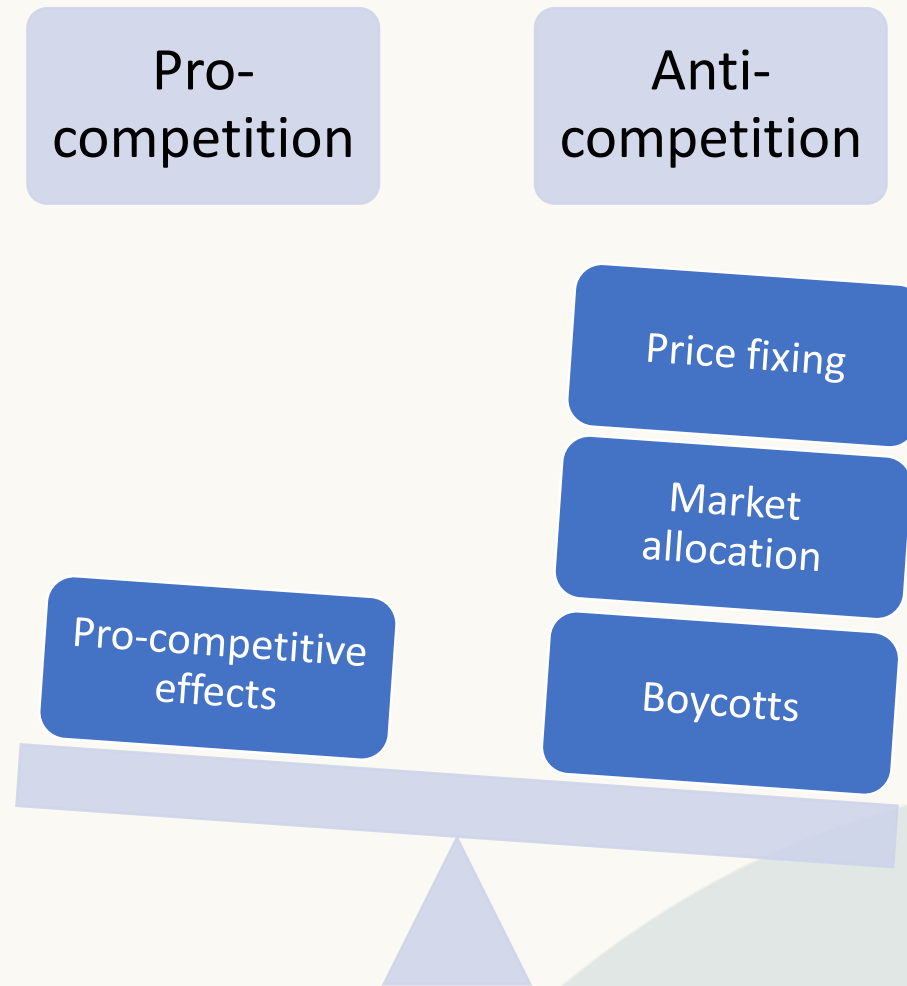
# Antitrust

# 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



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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](#) [in](#)

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](#)

# Anti-Discrimination Rules



# Anti-Discrimination Laws

## LAWS

- Civil Rights Act Title VI
- Americans with Disability Act
- Age Discrimination Act
- Rehabilitation Act § 504
  - HHS has proposed new rules.  
(88 FR 63392 (9/14/23))
- Affordable Care Act § 1557
  - HHS has proposed new rules.  
(87 FR 47824 (8/4/22))
- 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.

# Anti-Discrimination Laws: Recent OCR Enforcement

Date	Alleged Conduct	Resolution
8/30/23	Home Health agency denied home health care services based on HIV status	policy and training
8/8/23	Pa DHS denied application as foster parent because she receives SUD medication	Policy and training
6/16/23	CVS and Walgreens failed to fill prescriptions for methotrexate and misoprostol unrelated to abortion	Policy and training
5/15/23	MCR Health failed to provide auxiliary aid to deaf wife who accompanied patient; Should give “primary consideration” to request for aid from person with disability	Policy and training
3/23/23	Dearborn OBGYN refused request for sign language interpreter, cancelled appointment and terminated her as patient	Policies, training \$7,500 in damages

# Anti-Discrimination Law: Other Developments

- HHS issued report to increase language access for LEPs, including focus areas:
  - Internet access.
  - Telephone access.
  - Access to programs and activities.

<https://www.hhs.gov/about/news/2023/05/24/hhs-releases-report-increase-language-access-persons-with-limited-english-proficiency.html>
- DOJ proposes rule on Accessibility for Web and Mobile App Access re State and Local Govt Entities (88 FR 51948 (8/4/23))
  - Standards for web accessibility.
  - May portend standards for private businesses.
- HHS proposes rule prohibiting discrimination against LGBTQI+ in HHS funded grants, programs and services. (88 FR 44750 (9/11/23)).

# 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 U.S. Department of Health & Human Services. A search bar is present with the text "I'm looking for..." and a magnifying glass icon. Below the search bar is an "A-Z Index" link. The main navigation area features four buttons: "Information for Individuals", "Filing a Complaint", "Information for Providers", and "Newsroom". The breadcrumb trail reads: "HHS > Civil Rights Home > For Individuals > Special Topics in Civil Rights > Effective Communication in Hospitals > Disability Resources for Effective Communication". On the left side, there is a sidebar menu with a dropdown arrow, listing categories: "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". On the right side, there are links for "Text Resize", "Print", and "Share" (with icons for Facebook, Twitter, and Email). The main content area is titled "Disability Resources for Effective Communication OCR Resources" and contains two bullet points: "OCR signs effective communication Dear Colleague Letter with the Health Resources and Services Administration (08/30/2016)" with links for "Read the Bulletin", "Read the Letter - PDF", and "En Español - PDF"; and "OCR signs effective communication Dear Colleague Letter with the Puerto Rico Hospital Association. (06/09/2015)".

# Reproductive Rights

# 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/>)



# Reproductive Rights

- Availability of mifepristone for chemical abortions.
  - In 2000, FDA modified mifepristone subject to limitations.
  - In 2016, FDA updated regulations to extend mifepristone from 49 to 70 days of pregnancy and allowed APPs to prescribe.
  - In 2023, FDA modified rules to allow retail and online pharmacies to directly provide mifepristone via mail if prescribed in person or via telehealth.
  - In 4/23, Texas district court invalidated FDA's approval of mifepristone in 2000. (*Alliance for Hippocratic Medicine v. FDA* (N.D. Tex. 2023)). 5<sup>th</sup> Circuit upheld decision.
  - In 4/23, Supreme Court temporarily stayed district court order pending 5<sup>th</sup> Circuit appeal and writ of cert. (*Alliance for Hippocratic Medicine v. FDA* (S.Ct. 2023)).
  - In 8/23, 5th Circuit reversed district court's decision striking FDA's approval in 2000, but struck down FDA's 2016 and 2023 rules. (*Alliance for Hippocratic Medicine v. FDA* (5th Cir. 2023))
    - May not obtain mifepristone via mail or telehealth.
    - Limited to 49 days post-pregnancy.
  - DOJ intends to seek Supreme Court review.



# Minor Consents

# Minor Consents

- *Dobbs v. Jackson Women's Health Org.* undermined constitutional basis for allowing minors to consent contrary to state laws.
- Title X grantees
  - HHS regulations prohibit Title X grantees from requiring parental consent and notification for broad range of services to minors, e.g., pregnancy test and counseling, contraceptives, infertility, STDs, etc. (42 CFR 59.10(b))
  - In 12/22, Texas district court held that Title X regulations impermissibly infringe on parent's state law right to parental consent and federal constitutional right to direct upbringing of children. (*Deanda v. Becerra* (N.D. Tex. 2022))
  - On appeal to 5<sup>th</sup> Circuit.

## Title X Parental Consent for Contraceptive Services Litigation: Overview and Initial Observations (Part 1 of 2)

February 10, 2023

Enacted in 1970, the [Title X Family Planning Program](#) (Title X) is a federal program that provides grants to public and nonprofit agencies to deliver family planning and related preventive health services. The Program directs grantees to furnish such services in a manner that [prioritizes](#) low-income individuals, with reduced or no cost to such individuals. At [more than 3,000 service sites](#), Title X projects offer a range of clinical [services](#) including pregnancy testing and counseling, contraceptive services and counseling, basic infertility services, breast and cervical cancer screening, services related to sexually transmitted infection (STI), and adolescent-friendly health services. As to adolescent services, for almost four decades, lower courts—including the U.S. Courts of Appeals for the [District of Columbia](#), [Second](#), [Eighth](#), and [Tenth](#) Circuits—have uniformly concluded that Title X precludes the imposition of a parental notification or consent requirement, including under relevant state laws. Consistent with this case law, current Department of Health and Human Services (HHS) regulations codified at [42 C.F.R. § 59.10\(b\)](#) prohibit Title X projects from requiring parental consent and notification for services provided to minors.

In December 2022, however, the U.S. District Court for the Northern District of Texas issued an [order](#) in *Deanda v. Becerra*, ruling in favor of a parent who challenged Title X's parental consent and notification prohibition, objecting on religious grounds to his daughters' access to prescription contraception and other family planning services. The district court held that Title X's prohibition infringes upon the plaintiff's statutory right to parental consent under Texas law as well as his fundamental parental right under the U.S. Constitution to direct the upbringing of his children. Based on this conclusion, the court set aside the relevant portion of § 59.10(b). The court's constitutional ruling has potentially broad implications beyond Title X.

This two-part Sidebar series provides an overview of this litigation. Part 1 provides an overview of the relevant legal background. [Part 2](#) provides a summary of the district court's order, as well as certain preliminary observations for Congress's consideration

<https://crsreports.congress.gov/product/pdf/LSB/LSB10916>

# Additional Resources



## 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.

Our team handles a wide range of legal issues, including Stark, Anti-Kickback Statute, HIPAA, provider and payor contracting; mergers, acquisitions, and joint ventures; and medical staff issues; government investigations and compliance; employment; real estate; tax; employee benefits; and more. With our experience, there is not much our healthcare clients face that we

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#### IDAHO PATIENT ACT TIMELINE

## Primary Contacts



**Kim Stanger**

Partner

Boise  
208.383.3913



**Blaine Benard**

Partner

# Questions

