

LEGAL ISSUES FOR ASCs & CRNAs



IASCA Convention

Kim C. Stanger

(07/2024)

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.

Caution

- This is a quick overview of the most relevant federal laws and regulations and application to common situations.
 - Beware other laws, including state laws
- Application may depend on—
 - Circumstances of your particular case
 - Payer involved (e.g., govt, insurer, patient)
 - Jurisdiction
- Be sure to confirm applicable laws and requirements when applying law to your facts.
- If you have questions,
 - Use chat feature, or
 - Email me at kcstanger@hollandhart.com

FTC Ban on Non-Competes



FTC Ban on Non-Competes

Effective 9/4/24, it is unfair method of competition for employer to:

Workers

- Enter non-compete,
- Enforce non-compete, or
- To represent worker is subject to non-compete.

(16 CFR 910.2(a))

Senior Executive

- Enter non-compete,
- Enforce non-compete entered after 9/4/24, or
- Represent that senior executive is subject to non-compete entered after 9/4/24.

FTC Ban on Non-Competes

“Worker” =

- Employees
- Independent contractors.
- Externs
- Interns
- Volunteers

“Senior Executive” =

- Was in policy-making position, i.e., president, secretary, treasurer, principal financial officers, or perform corresponding functions; and
- Total comp in preceding year at least \$151,164 in preceding year.
 - Includes salary, non-discretionary bonuses, and other nondiscretionary compensation.
 - Excludes medical insurance, life insurance, retirement plans, and similar fringe benefits.

(16 CFR 910.1)

FTC Ban on Non-Competes: Notice

- By 9/4/24: for each existing non-compete that is unenforceable, employer must provide clear and conspicuous written notice to worker that non-compete clause will not be, and cannot be, legally enforced.
- FTC has provided a model notice.

(16 CFR 910.2(b))

FTC Ban on Non-Competes: Exceptions

Ban on non-competes does not apply to:

- Non-competes that apply during term of employment.
- Bona fide sale of business.
- Cause of action accrued prior to the effective date.
- Good faith basis that non-compete ban does not apply.

(16 CFR 910.3)

FTC Ban on Non-Competes

- On 7/3/24, federal court in Texas entered preliminary injunction prohibiting enforcement of FTC rule as to the parties.
- Temporary remedy pending further proceedings on the merits.
- Court plans to issue final ruling by 8/30/24.

In meantime:

- Stay tuned...
- Continue to include non-competes.
 - If FTC rule takes effect, do not enforce them except as to senior executives.
 - If FTC rule is vacated, you have non-compete available.
- Consider alternatives, e.g.,
 - Non-disclosure and confidentiality.
 - Non-solicitation clauses.
 - Incentive forfeitures.
 - Training cost repayments.
 - Etc.

<https://oig.hhs.gov/compliance/general-compliance-program-guidance/>



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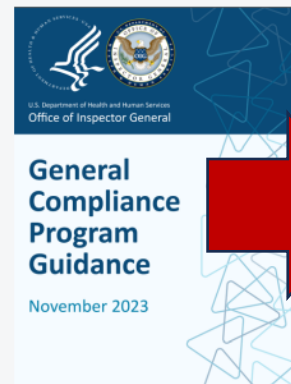
General Compliance Program Guidance

The General Compliance Program Guidance (GCPG) is a reference guide for the health care compliance community and other health care stakeholders. The GCPG provides information about relevant Federal laws, compliance program infrastructure, OIG resources, and other information useful to understanding health care compliance.

The GCPG is voluntary guidance that discusses general compliance risks and compliance programs. The GCPG is not binding on any individual or entity. Of note, OIG uses the word “should” in the GCPG to present voluntary, nonbinding guidance.

You may download the guidance in whole, or access individual sections below.

[Download Complete Guidance](#)



Individual Sections



I. Introduction

[Jump to Section I.](#)



II. Health Care Fraud Enforcement and Other Standards: Overview of Certain Federal Laws

[Jump to Section II](#)


OIG focuses on key statutes, e.g.,

1. Anti-Kickback Statute
2. Physician Self-Referral Law (Stark)
3. False Claims Act
4. Civil Monetary Penalty Authorities
 - Beneficiary Inducements
 - Information Blocking
 - Exclusion Authority
5. HIPAA Privacy and Security Rules

Fraud, Waste and Abuse Laws



Key Fraud and Abuse Laws



**“I want my
money
back!”**

- False Claims Act
- Anti-Kickback Statute (“AKS”)
- Eliminating Kickbacks in Referrals Statute (“EKRA”)
- Ethics in Physician Referrals Act (“Stark”)
- Civil Monetary Penalties Law (“CMPL”)
- Healthcare criminal statutes
- State laws and regulations

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: Examples

- Claims for services that were not provided or were different than claimed.
 - Upcoding, unbundling, miscoding, etc.
- Failure to comply with quality of care.
 - Express or implied certification of quality.
 - Provision of “worthless” care.
- Failure to comply with conditions of payment or relevant fraud and abuse laws (e.g., AKS, Stark, etc.)
 - Express or implied certification of compliance when submit claims, e.g., cost reports or claim forms. (See *Universal Health Serv., Inc. v. U.S. ex rel. Escobar* (S.Ct. 2016))

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

AKS Red Flags

Referring Providers

- Free items or services
- Paying or receiving more or less than FMV
- Compensation varies based on referrals
- Practice subsidies
- Investment opportunities
- Professional courtesies
- Kickbacks or referral fees
- Compensation for unnecessary items or services
- Others




Other Referral Sources (including Patients)

- Free items or services
- Paying or receiving more or less than FMV
- Waiving copays or deductibles
- “Refer a friend” incentives
- Others

AKS Safe Harbors

- Bona fide employment
- Personal services contracts
- Space and/or equipment rental
- Investments in certain entities
- Investments in group practice
- **Investments in ASCs**
- Sale of practice
- Practitioner recruitment
- Waiver of beneficiary copays, coinsurance and deductibles
- Transportation programs
- Electronic health records
- Value-based care arrangements
- Patient engagement incentives
- Others...

(42 CFR 1001.952)



**Check specific
requirements for
each applicable
safe harbor!**

AKS: ASC Safe Harbor

Applies to:

1. Surgeon-owned ASCs
2. Single Specialty ASCs
3. Multi-Specialty ASCs
4. Hospital-Physician ASCs

Concept:

- Allow investment in ASC if the ASC is an extension of the practitioner's practice.
- Not give practitioner an investment interest as way to incentivize provider's referrals to ASC.

AKS: ASC Safe Harbor

Common elements

- Terms of investment not related to referrals.
- Must not loan funds to investor.
- Return on investment directly proportional to capital investment.
- Must not discriminate against Medicare/Medicaid beneficiaries.
- At least 1/3 of medical practice income come from ASC procedures.
- **For multi-specialty ASCs, physician performs at least 1/3 of his/her ASC procedures at the relevant ASC.**
- **For hospital ASC:**
 - **Must not use hospital space/equipment/personnel for ASC purposes unless FMV lease.**
 - **Hospital must not be in position to make or influence referrals.**

(42 CFR 1001.952(r))



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Advisory Opinions

In accordance with section 1128(D)(b) of the Social Security Act (42 U.S.C. 1320a-7d(b)) and 42 CFR part 1008, OIG issues advisory opinions about the application of OIG's fraud and abuse authorities to the requesting party's existing arrangement. As required, advisory opinions are being made available to the public.

One purpose of the meaningful advice and other OIG sanctions. Note, however, that advisory opinions should be relied upon only for legal standards to which participants who provide specific information are bound by the advisory opinions.

We have redacted information associated with the advisory opinion.

 Adobe® Acrobat®

Quick Links/F

- ❖ Preliminary
- ❖ Recommendation
- ❖ The full and current version of 42 CFR part 1008 is available on the Code of Federal Regulations Web site. 42 CFR part 1008.
- ❖  The OIG Final Rule (73 Fed. Reg. 40982) revising the procedural aspects for submitting payments for advisory opinion costs.
- ❖  The OIG Interim Final Rule (73 Fed. Reg. 15937) revising the procedural aspects for submitting

Related

I'm looking for

Let's start by choosing a topic

Select One

- OIG may issue advisory opinions.
- Listed on OIG fraud and abuse website, www.oig.hhs.gov/fraud.
- Not binding on anyone other than participants to the opinion.
- But you are fairly safe if you act consistently with favorable advisory opinion.



REPORT FRAUD

Civil Monetary Penalties Law ("CMPL")

- 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 and AKS Red Flags

- Free items or services to patients (e.g., gifts, services, supplies, drugs, equipment, etc.)
- Waive copays or deductibles
- Discounted services
- “Refer a friend” incentive
- Free meals or lodging
- Free transportation
- Reward or incentive to comply with treatment
- Paying patient premiums
- Anything else of value that does not reflect FMV
- Other?



CMPL Safe Harbors

CMPL excepts from the definition of “remuneration” certain acts, e.g.,

- Items covered by AKS safe harbor.
- Item or service less than \$15/\$75.
- Demonstrated financial need, including waivers or discounts of copayments or deductibles.
- Certain preventive care items or services.
- Items or services that promote access to care.
- Value-based care and patient engagement.

(42 CFR 1003.110)

- *Ensure you comply with all relevant conditions and limitations in the regulations.*
- *Remember such inducements may still violate the AKS.*

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))
- Applies to private or public payors.

Ethics in Patient Referrals Act ("Stark")

- If physician (or family member) has direct or indirect 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 Limits

Stark generally does not apply to:

CRNAs

- Stark only prohibits referrals by a “physician”, *i.e.*, MD, DO, DDS, DMD, DPM, OD, DC.
- Stark may apply to referrals by a physician to a CRNA if (i) there is a financial relationship between the physician and CRNA, and (ii) referral is for DHS.

ASCs

- Stark only prohibits referrals for “DHS,” which excludes services paid under the Medicare composite rate, *e.g.*, ASC services identified at 42 CFR § 416.164.

(42 CFR 411.351)

Stark Safe Harbors

Compensation Arrangements

- Employment relationships
- Personal services contracts
- Fair market value
- Space or equipment leases
- Timeshare arrangements
- Recruitment and retention
- Professional courtesy
- Isolated transactions, *e.g.*,
sale of practice or settlement
- Payments by a physician
- Others

(42 CFR 411.357)

Ownership and Investments

- Group practices
 - Physician services
 - In-office ancillary services
- Implants by an ASC
- Rural providers
- Whole hospital
- Intra-family rural referrals
- Others

(42 CFR 411.355-.356)

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 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

Data Security and Privacy



Cybersecurity

Cyberattack on Change Healthcare brings turmoil to healthcare operations nationwide

June 4 update: Federal regulators have provided updated guidance pertaining to breach notifications.



Nick Hut

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Change Healthcare cyberattack fallout continues

Change Healthcare, part of Optum, suffered a cyberattack in late February.

Resources

[A list of payer contact](#)

HHS Office for Civil Rights Issues Letter and Opens Investigation of Change Healthcare Cyberattack

Today, the U.S. Department of Health and Human Services' Office for Civil Rights (OCR) issued a "Dear Colleague" letter addressing the cybersecurity incident impacting Change Healthcare, a unit of UnitedHealthcare Group (UHG), and many other health care entities. The cyberattack is disrupting health care and billing information operations nationwide and poses a direct threat to critically needed patient care and essential operations of the health care industry.

OCR enforces the [HIPAA Privacy, Security, and Breach Notification Rules](#), which sets forth the requirements that HIPAA covered entities (most health care providers, health plans, and health care clearinghouses) and their business associates must follow to protect the privacy and security of protected health information and the required notifications to HHS and affected individuals following a breach.

Ransomware and hacking are the primary cyber-threats in health care. Over the past five years, there has been a 256% increase in large breaches reported to OCR involving hacking and a 264% increase in ransomware. In 2023,



World Business Markets Sustainability Legal Breakingviews Technology Investigations More

Lawsuits over Change Healthcare data breach centralized in Minnesota

By Brendan Pierson

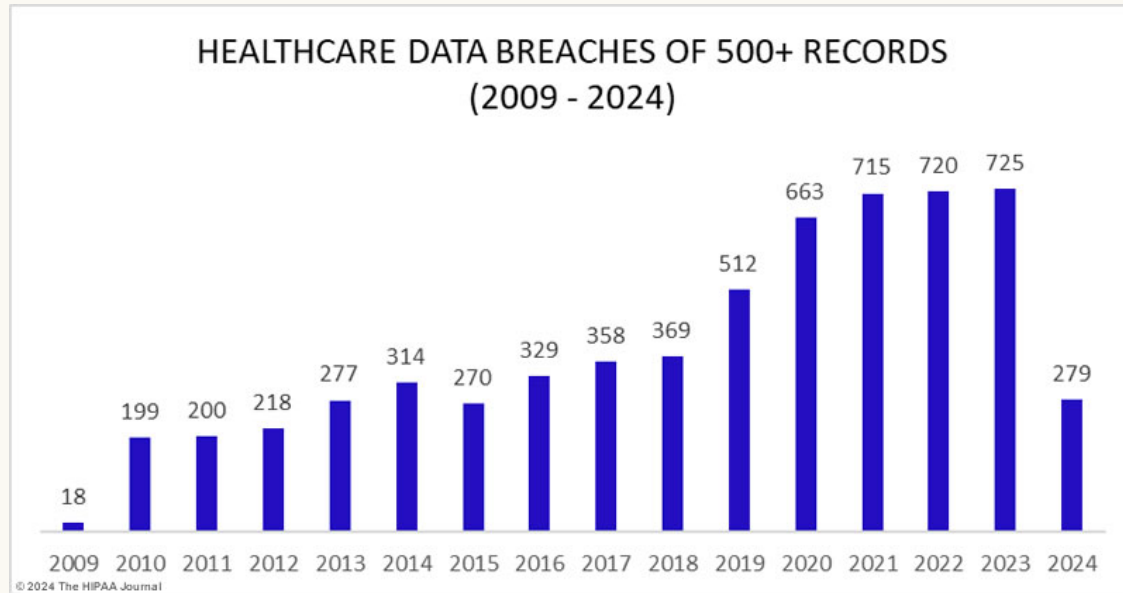
June 7, 2024 2:18 PM MDT - Updated a day ago



Cybersecurity

According to HHS:

- 2018-22: 93% increase in large breaches
- 2018-22: 278% increase in large breaches from ransomware.
- 2023: 77% of large breaches resulted from hacking.
- 2023: Persons affected by large breaches increased 60% to 80,000,000.



Source: The HIPAA Journal

<https://www.hipaajournal.com/healthcare-data-breach-statistics/>

HHS Strategy Paper

<https://aspr.hhs.gov/cyber/Documents/Health-Care-Sector-Cybersecurity-Dec2023-508.pdf>



On 12/6/23, HHS published strategy for strengthening cybersecurity for healthcare industry.

1. Establish voluntary cybersecurity performance goals.
2. Provide resources to incentivize and implement cybersecurity practices.
3. **Greater enforcement and accountability.**
 - **Cybersecurity requirements for hospitals through Medicare/Medicaid.**
 - **Update HIPAA Security Rule to include new cybersecurity rule requirements.**
 - **Increase civil penalties.**
 - **Increase resources for audits and investigation.**
4. HHS to provide one-stop shop for healthcare cybersecurity resources.

HPH Cybersecurity Gateway

<https://hphcyber.hhs.gov/>



**Welcome to
Health & Human Services**

HPH Cybersecurity Gateway

Connecting the Healthcare and Public Health (HPH) Sector with specialized healthcare specific cybersecurity information & resources from across the U.S. Department of Health and Human Services and other federal agencies.

**A NOTE
FROM
HHS**

- ✓ **HPH**
- ✓ **Cybersecurity**
- ✓ **Performance**
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**Questions?
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HIPAA Penalties for Cyberlapses



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FOR IMMEDIATE RELEASE
July 1, 2024

HHS Office for Civil Rights Settles HIPAA Security Rule Failures for \$950,000

Settlement with Heritage Valley Health System marks OCR's third ransomware settlement as the agency sees 264% increase in large ransomware breaches since 2018

Health system paid \$950,000 for HIPAA security violations following ransomware attack.

HIPAA Civil Penalties

Watch for new rule that will 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">• \$127* to \$63,973* per violation• Up to \$1,919,173* per type per year• No penalty if correct w/in 30 days• OCR may waive or reduce penalty
Violation due to reasonable cause	<ul style="list-style-type: none">• \$1,280* to \$63,973* per violation• Up to \$1,919,173* per type per year• No penalty if correct w/in 30 days• OCR may waive or reduce penalty
Willful neglect, but correct w/in 30 days	<ul style="list-style-type: none">• \$12,794* to \$63,973* per violation• Up to \$1,919,173* per type per year• Penalty is mandatory
Willful neglect, but do not correct w/in 30 days	<ul style="list-style-type: none">• \$63,973 to \$1,919,173* per violation• Up to \$1,919,173* per type per year• Penalty is mandatory

(45 CFR 102.3, 160.404; 85 FR 2879)

Recent HIPAA Resolutions

<https://www.hhs.gov/hipaa/newsroom/index.html>

Date	Conduct	Resolution
4/1/24	Essex Residential Care failed to provide personal representative timely access to records.	\$100,000
3/29/24	Phoenix Healthcare failed to provide personal representatives timely access to records.	\$35,000
2/6/24	Montefiore Medical Center failed to protect against malicious insider selling info.	\$4,750,000
11/20/23	St. Joseph's Medical Center failed to protect against malicious insider selling info.	\$80,000
10/31/23	Doctor's Management Services failed to protect against malicious insider selling info.	\$100,000
9/11/23	L.A. Care Plan failed to protect against malicious insider selling info. and mailed ID cards	\$1,300,000
8/24/23	UnitedHealthcare failed to protect against malicious insider selling info.	\$80,000
6/28/23	iHealth Solutions' failed to protect against malicious insider selling info. and persons.	\$75,000
6/15/23	Yakima Valley Hospital failed to protect against malicious insider selling info. 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	\$1,250,000

Top HIPAA Risks



1. Cyberattacks
2. Security rule violations
3. Right of access violations

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

Avoiding Civil Penalties

- ✓ Appoint qualified privacy/security officers
- ✓ Have required policies and safeguards in place.
 - Privacy Rule
 - Use and disclosure rules
 - Individual rights
 - Security Rule
 - Breach Notification Rule
- ✓ Have compliant forms (e.g., authorization, NPP, etc.)
- ✓ Perform and document periodic security risk assessment.
- ✓ Execute business associate agreements.
- ✓ Train members of your workforce and document training.
- ✓ Respond immediately to mitigate and correct any violation.
- ✓ Timely report breaches if required.

(45 CFR part 164; <https://www.hollandhart.com/hipaa-checklist-covered-entities>)

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

HIPAA

Use and Disclosure Rules

- General rule: must have patient's or personal rep's authorization to use or disclose protected health info ("PHI").
- Exceptions:
 - Treatment, payment or healthcare operations.
 - To family members and others involved in care if patient consents or unable to consent and it is reasonable under circumstances.
 - Another specific HIPAA exception applies, e.g.,
 - Another law requires disclosure.
 - To avert serious threat of harm.
 - For certain govt or regulatory purposes.
- Use/disclose minimum necessary.

(45 CFR 164.502-.514)

HIPAA

Patient Rights

- Communication by alternative means or alternative locations.
 - Request limitations on use or disclosure for treatment, payment or healthcare operations.
 - *But you are not required to agree to restrictions.*
 - Access or obtain copies of PHI in designated record set.
 - Subject to limited exceptions.
 - Amend PHI in designated record set.
 - Subject to limitations.
 - Accounting of certain disclosures of PHI.
 - Subject to limitations.
- For each, beware time limits, procedural requirements, etc.

(45 CFR 164.522-.528)

HIPAA and ePHI Transmissions

- General rule: encryption is an addressable standard under the HIPAA rule. (45 CFR 164.312(e))
 - ✓ Secure personal devices such as smartphones.
 - ✓ Use secure (encrypted) platform to transmit e-PHI, including e-mail and text.
- Exception: patient has right to request communication by alternative means, including unsecure means. (45 CFR 164.522(b)).
 - ✓ Notify patient that communication may not be secure and obtain patient's consent to send by unsecure means.
(<https://www.hhs.gov/hipaa/for-professionals/faq/570/does-hipaa-permit-health-care-providers-to-use-email-to-discuss-health-issues-with-patients/index.html>)

HIPAA Enforcement

- Must self-report breaches of unsecured protected health info
 - To affected individuals.
 - To HHS.
 - To media if breach involves > 500 persons.
- In future, individuals may recover portion of penalties or settlement.
 - On 4/6/22, HHS issued notice soliciting input. (87 FR 19833)
- State attorney general can bring lawsuit.
 - \$25,000 fine per violation + fees and costs
- Must sanction employees who violate HIPAA.
 - In 10/23, HHS issued bulletin re sanctioning workforce members.
- Possible lawsuits by affected individuals or others.
 - See, e.g., recent class action lawsuits over privacy violations.

HIPAA Reproductive Rights Rule

Effective 6/25/24:

- Limits disclosure of PHI re reproductive health for civil, criminal or administrative action if reproductive health is legal.

(45 CFR 164.502(a)(5)(iii))

- Must obtain attestation before using or disclosing reproductive health PHI for:

- Health oversight activities.
- Judicial or administrative proceedings.
- Law enforcement purposes.
- Coroners or medical examiners.

(45 CFR 164.509)

- Modify notice of privacy practices by 2/16/26.

(45 CFR 164.520)

HIPAA Proposed Changes

COMING
SOON

Proposed rule published 1/21/21; still waiting...

- Strengthens individual's right of access.
 - Individuals may take notes or use other personal devices to view and capture images of PHI.
 - Must respond to requests to access within 15 days instead of 30 days.
 - Must share info when directed by patient.
 - Additional limits to 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))

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



Search

In June 2026, federal court in Texas vacated rule; however, principles may still apply.

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HIPAA for Professionals	
Regulatory Initiatives	
Privacy	+
Security	+
Breach Notification	+
Compliance & Enforcement	+
Special Topics	+
Patient Safety	+



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

On March 18, 2024, OCR updated this guidance to increase clarity for regulated entities and the public.

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) is issuing this Bulletin to



Advertisement

Beware Private Lawsuits

Litigation Trends for 2023: Surge in Web Tracking Class Actions

by: John C. Cleary, Pavel (Pasha) A. Sternberg, Catherine A. Green, Elizabeth M. Marden, Elizabeth (Liz) Harding, and Colin H. Black of Polsinelli PC - *Intelligence*

© Posted On Wednesday, January 18, 2023



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- Negligence per se based on violation of statute
 - Unfair or deceptive trade practices acts
 - Federal and state wire-tapping laws
 - Negligent misrepresentation
 - Invasion of privacy
 - Breach of contract
 - Others?

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>)

- [Monument, Inc., U.S. v.](#) (June 7, 2024)
- [Facebook, Inc., In the Matter of](#) (June 7, 2024)
- [Blackbaud, Inc.](#) (May 20, 2024)
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- [X-Mode Social, Inc.](#) (April 11, 2024)
- [Rite Aid Corporation, FTC v.](#) (March 8, 2024)
- [Global Tel Link Corporation](#) (February 23, 2024)
- [Avast](#) (February 22, 2024)
- [FTC v Kochava, Inc.](#) (February 5, 2024)
- [Epic Games, In the Matter of](#) (January 10, 2024)
- [CafePress, In the Matter of](#) (January 10, 2024)
- [TruthFinder, LLC, FTC v.](#) (October 11, 2023)
- [1Health.io/Vitagene, In the Matter of](#) (September 7, 2023)
- [Edmodo, LLC, U.S. v.](#) (August 28, 2023)
- [Vivint Smart Home, Inc.](#) (August 23, 2023)
- [Amazon.com \(Alexa\), U.S. v.](#) (July 21, 2023)
- [BetterHelp, Inc., In the Matter of](#) (July 14, 2023)
- [Easy Healthcare Corporation, U.S. v.](#) (June 26, 2023)

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FTC Action on Data Privacy



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Protecting Consumer Privacy and Security

FTC POLICY WORK

PRIVACY AND SECURITY ENFORCEMENT

FINANCIAL PRIVACY

KIDS' PRIVACY (COPPA)

Privacy and Security Enforcement

PRIVACY AND SECURITY ENFORCEMENT

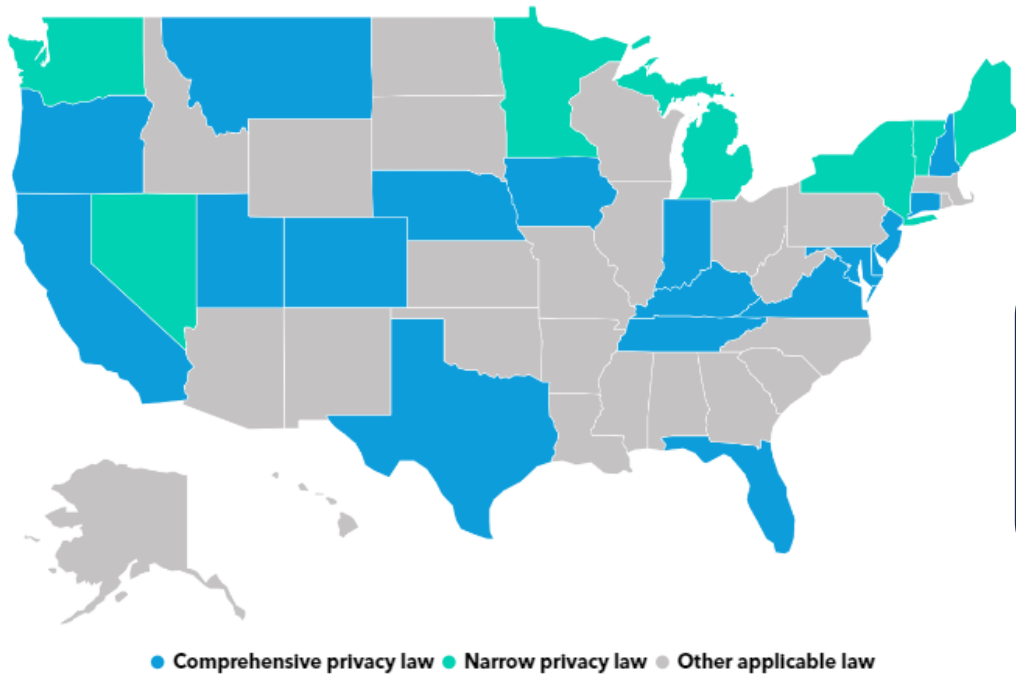
When companies tell consumers they will safeguard their personal information, the FTC can and does take law enforcement action to make sure that companies live up these promises. The FTC has brought legal actions against organizations that have violated consumers' privacy rights, or misled them by failing 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 prohibits unfair and deceptive acts and practices in or affecting commerce.

“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...”.

► [PUBLIC EVENTS](#)

State Data Privacy Laws

U.S. states with consumer data privacy laws



Source: Bloomberg Law,
<https://pro.bloomberglaw.com/insights/privacy/state-privacy-legislation-tracker/#row-66725b4d4cdd5>

Remember:
HIPAA requires you to comply with more restrictive law, including state laws.

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

(42 CFR 1003.1420).

HEALTHCARE PROVIDERS

- Final rule 6/24/24:
 - Hospitals: loss of status as meaningful user of EHR
 - Providers: loss of status as meaningful user under MIPS
 - ACOs: ineligible to participate.
 - Loss of federal payments.

Info Blocking Rule Examples

Information 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 Information Blocking:

- Action required by law.
 - HIPAA, 42 CFR part 2, state privacy laws, etc.
 - Laws require conditions before disclosure and condition not satisfied, e.g., patient consent.
- Action is reasonable under the circumstances.
- Action fits within regulatory exception.

Anti-Discrimination Rules



Anti-Discrimination Laws

LAWS

- Civil Rights Act Title VI
- Americans with Disability Act
- Age Discrimination Act
- Rehabilitation Act § 504
- Affordable Care Act § 1557
 - HHS issued new rules on 5/6/24.
 - Effective 7/5/24 (45 CFR part 92)
- 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.

New 1557 Rule

By 7/5/24

- Provide meaningful access, e.g., interpreters and translators; auxiliary aids, facility accessibility, information technology, telehealth.
- Equal access on basis of sex.

By 11/2/24

- If have 15+ employees, designate 1557 Coordinator.
- Publish notice of nondiscrimination.

By 5/1/25

- Don't discriminate in decision support tools (e.g., AI).
- Train employees.

By 7/5/25

- Implement written policies and procedures.
- Publish Notice of Availability of Services

(45 CFR part 92)

Anti-Discrimination Laws: Recent OCR Enforcement

Date	Alleged Conduct	Resolution
6/21/24	Puerto Rico agency failed to provide sign language interpreters.	Policy and training
6/4/24	ENT practice failed to provide aids to persons with hearing challenges.	Policy and training
11/13/23	SNF allegedly denied admission to individuals because they were taking Suboxone or methodone to treat opioid use disorder.	Policy and training
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. <ul style="list-style-type: none"> 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

Additional Resources



www.HollandHart.com/Healthcare



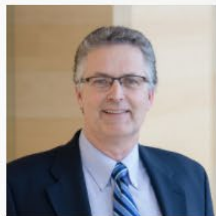
CLICK HERE FOR
COVID-19 RESOURCES FOR
HEALTHCARE PROFESSIONALS

PEOPLE

PRACTICES/INDUSTRIES

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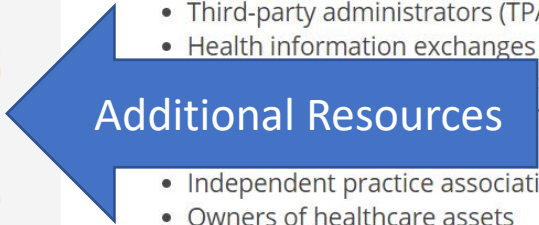
PUBLICATIONS
Click here to get access to our health law publications and more on our Health Law blog.

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

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

Clients We Serve

- Hospitals
- Individual medical providers
- Medical groups
- Managed care organizations (MCOs)
- Third-party administrators (TPAs)
- Health information exchanges (HIEs)
- Administrators and facilities
- Independent practice associations (IPAs)
- Owners of healthcare assets
- Imaging centers
- Ambulatory surgery centers



Questions?

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