COMPLIANCE CONCERNS: 2022 TO 2023

Kim C. Stanger

(12-22)

Holland & Hart

TODAY'S PRESENTER

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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. This year, the Idaho Business Review listed him as one of the Leaders in the Law. 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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OVERVIEW

- Transitioning to Post-COVID-19 Compliance
- Telehealth
- No Surprise Billing Rules
- Hospital Price Transparency Rules
- HIPAA and Patient Confidentiality
- Cybersecurity
- Information Blocking Rule
- Critical Access Hospital Proposed Rules
- Co-Location and Space Sharing
- Practitioner Credentialing
- Fraud and Abuse Concerns
- 1557 Discrimination

DISCLAIMER

- This is only a quick summary.
  - Will not cover all slides.
  - Check specifics when applying.
- Focus on some of the important federal requirements.
  - Beware additional fed requirements that may apply to your particular provider type.
  - Beware additional state requirements.

- To receive copy of the .ppts, contact cecobbins@hollandhart.com.
- To submit questions:
  - Use chat feature, or
  - kcstanger@hollandhart.com

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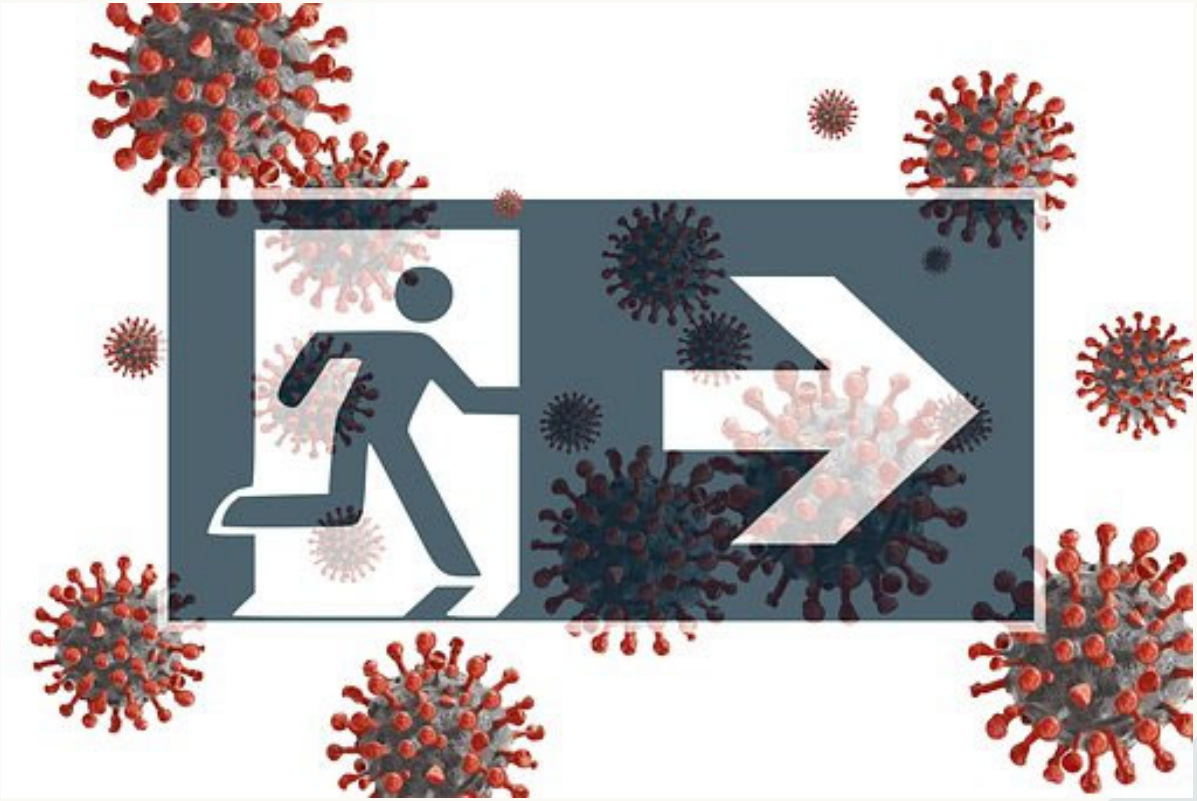
TRANSITIONING TO POST-PANDEMIC COMPLIANCE



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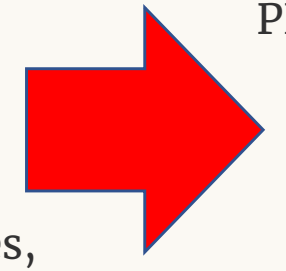
PHE RELAXED STANDARDS

- Federal and state govts relaxed regulatory requirements during the public health emergency (PHE), e.g.,
  - Reimbursement for COVID vaccinations and therapies
  - Reimbursement for other services, including Medicare/Medicaid
  - Conditions of Participation
  - Licensure
  - HIPAA
  - EMTALA
  - Stark and Anti-Kickback Statute
  - Others



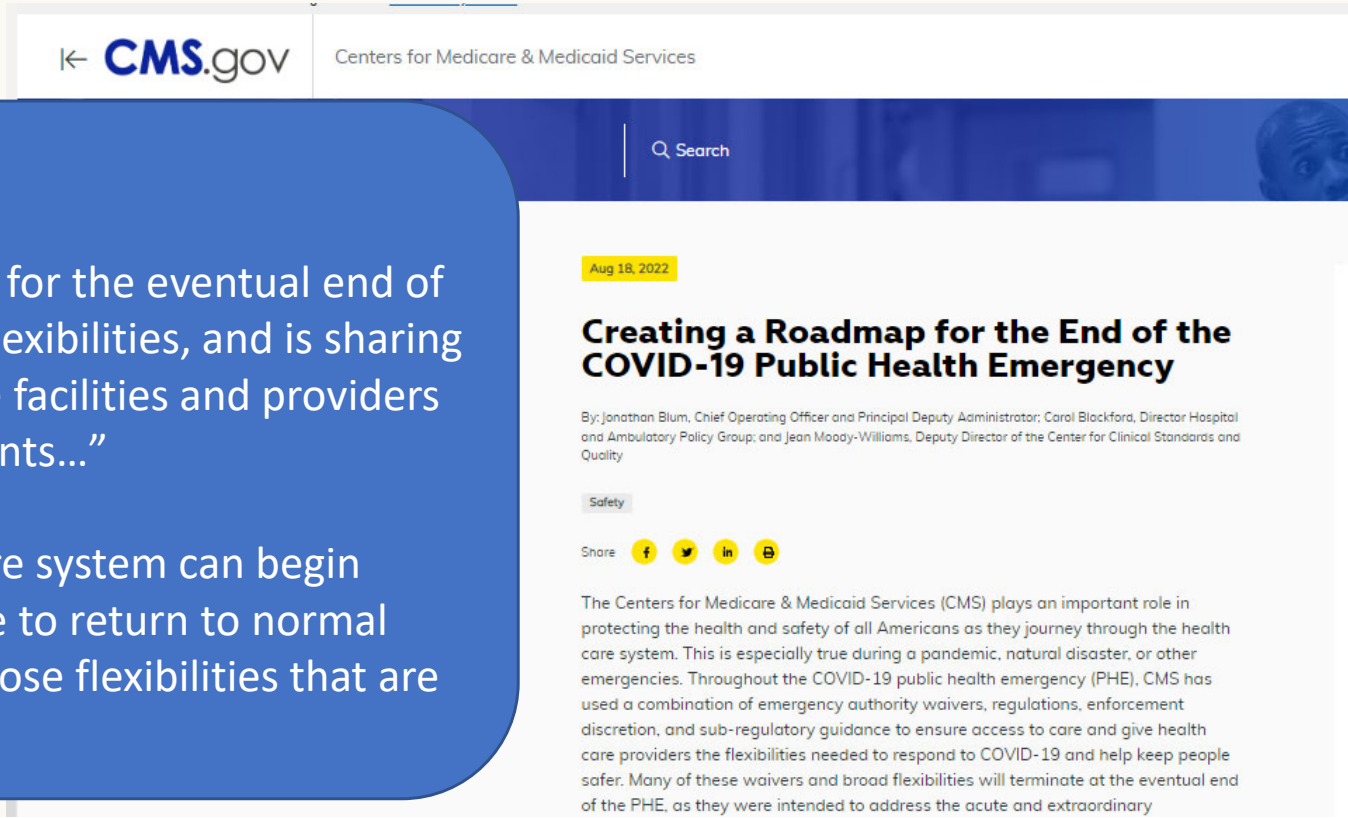
- Must return to pre-PHE standards after PHI ends.
  - Many states have ended their PHE.
  - Federal govt most recently extended PHE to **January 11, 2023.**
  - Biden administration has promised 60 days' notice before ending the PHE, so it is **likely the PHE will be extended into April 2023, but stay tuned…**

CMS GUIDE FOR ENDING THE PHE

https://www.cms.gov/blog/creating-roadmap-end-covid-19-public-health-emergency

On 8/18/22:

- "CMS has developed a roadmap for the eventual end of the Medicare PHE waivers and flexibilities, and is sharing information on what health care facilities and providers can do to prepare for future events…"
- "[W]e expect that the health care system can begin taking prudent action to prepare to return to normal operations and to wind down those flexibilities that are no longer critical in nature."



CMS.gov | Centers for Medicare & Medicaid Services

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Aug 18, 2022

Creating a Roadmap for the End of the COVID-19 Public Health Emergency

By: Jonathan Blum, Chief Operating Officer and Principal Deputy Administrator; Carol Blackford, Director Hospital and Ambulatory Policy Group; and Jean Moody-Williams, Deputy Director of the Center for Clinical Standards and Quality

Safety

Share

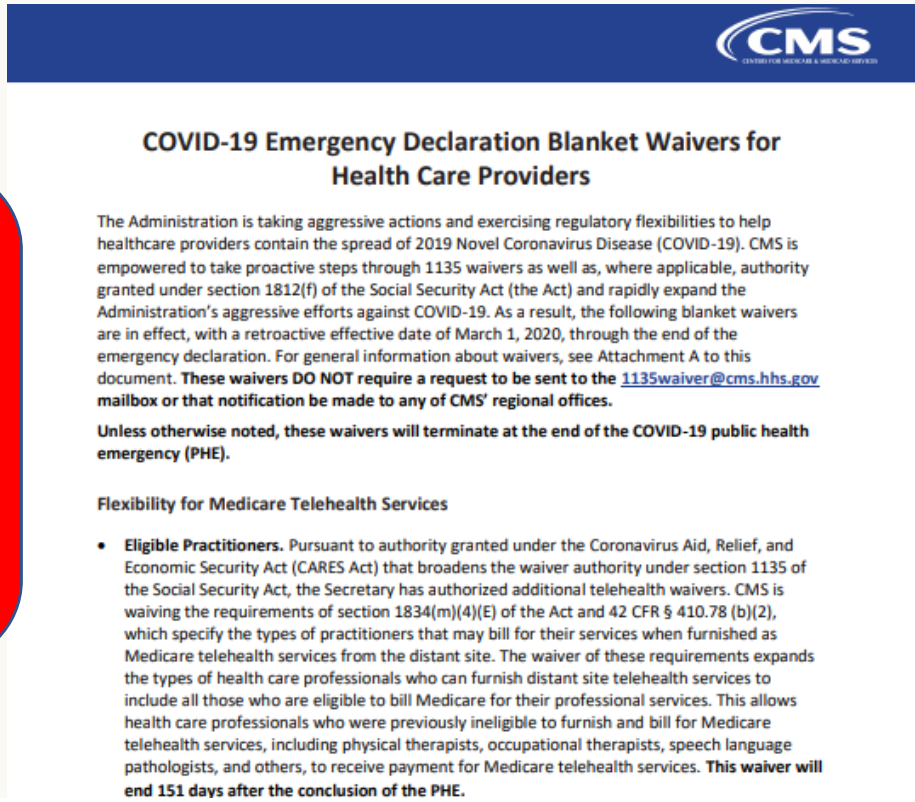
The Centers for Medicare & Medicaid Services (CMS) plays an important role in protecting the health and safety of all Americans as they journey through the health care system. This is especially true during a pandemic, natural disaster, or other emergencies. Throughout the COVID-19 public health emergency (PHE), CMS has used a combination of emergency authority waivers, regulations, enforcement discretion, and sub-regulatory guidance to ensure access to care and give health care providers the flexibilities needed to respond to COVID-19 and help keep people safer. Many of these waivers and broad flexibilities will terminate at the eventual end of the PHE, as they were intended to address the acute and extraordinary

CMS GUIDE TO ENDING THE PHE

https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf

Unless otherwise indicated in the document, the waivers will end with PHE:

- ✓ Review list to identify applicable waivers
- ✓ Evaluate and modify practices accordingly



CMS

COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers

The Administration is taking aggressive actions and exercising regulatory flexibilities to help healthcare providers contain the spread of 2019 Novel Coronavirus Disease (COVID-19). CMS is empowered to take proactive steps through 1135 waivers as well as, where applicable, authority granted under section 1812(f) of the Social Security Act (the Act) and rapidly expand the Administration's aggressive efforts against COVID-19. As a result, the following blanket waivers are in effect, with a retroactive effective date of March 1, 2020, through the end of the emergency declaration. For general information about waivers, see Attachment A to this document. **These waivers DO NOT require a request to be sent to the 1135waiver@cms.hhs.gov mailbox or that notification be made to any of CMS' regional offices.**

Unless otherwise noted, these waivers will terminate at the end of the COVID-19 public health emergency (PHE).

Flexibility for Medicare Telehealth Services

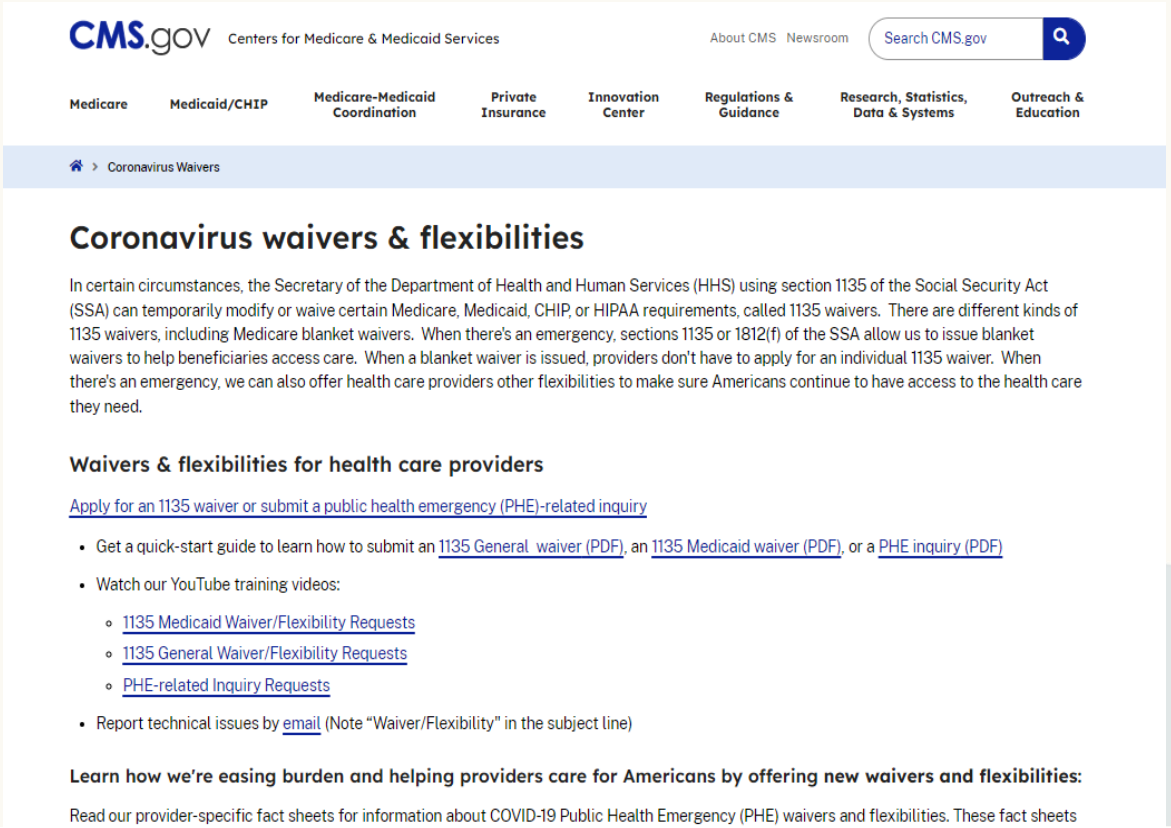
- **Eligible Practitioners.** Pursuant to authority granted under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that broadens the waiver authority under section 1135 of the Social Security Act, the Secretary has authorized additional telehealth waivers. CMS is waiving the requirements of section 1834(m)(4)(E) of the Act and 42 CFR § 410.78 (b)(2), which specify the types of practitioners that may bill for their services when furnished as Medicare telehealth services from the distant site. The waiver of these requirements expands the types of health care professionals who can furnish distant site telehealth services to include all those who are eligible to bill Medicare for their professional services. This allows health care professionals who were previously ineligible to furnish and bill for Medicare telehealth services, including physical therapists, occupational therapists, speech language pathologists, and others, to receive payment for Medicare telehealth services. **This waiver will end 151 days after the conclusion of the PHE.**

CMS FACT SHEETS FOR PROVIDERS

https://www.cms.gov/coronavirus-waivers

Fact sheets for specific providers, e.g.,

- Physicians and Other Clinicians
- Hospitals and CAHs
- ASCs
- Long Term Care Facilities
- Home Health Agencies
- Hospice
- RHCs and FQHCs
- Laboratories
- DMEPOS
- Ambulances
- End Stage Renal Disease (ESRD)



CMS.gov Centers for Medicare & Medicaid Services

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Coronavirus Waivers

Coronavirus waivers & flexibilities

In certain circumstances, the Secretary of the Department of Health and Human Services (HHS) using section 1135 of the Social Security Act (SSA) can temporarily modify or waive certain Medicare, Medicaid, CHIP, or HIPAA requirements, called 1135 waivers. There are different kinds of 1135 waivers, including Medicare blanket waivers. When there's an emergency, sections 1135 or 1812(f) of the SSA allow us to issue blanket waivers to help beneficiaries access care. When a blanket waiver is issued, providers don't have to apply for an individual 1135 waiver. When there's an emergency, we can also offer health care providers other flexibilities to make sure Americans continue to have access to the health care they need.

Waivers & flexibilities for health care providers

Apply for an 1135 waiver or submit a public health emergency (PHE)-related inquiry

- Get a quick-start guide to learn how to submit an 1135 General waiver (PDF), an 1135 Medicaid waiver (PDF), or a PHE inquiry (PDF)
- Watch our YouTube training videos:
  - 1135 Medicaid Waiver/Flexibility Requests
  - 1135 General Waiver/Flexibility Requests
  - PHE-related Inquiry Requests
- Report technical issues by email (Note "Waiver/Flexibility" in the subject line)

Learn how we're easing burden and helping providers care for Americans by offering new waivers and flexibilities:

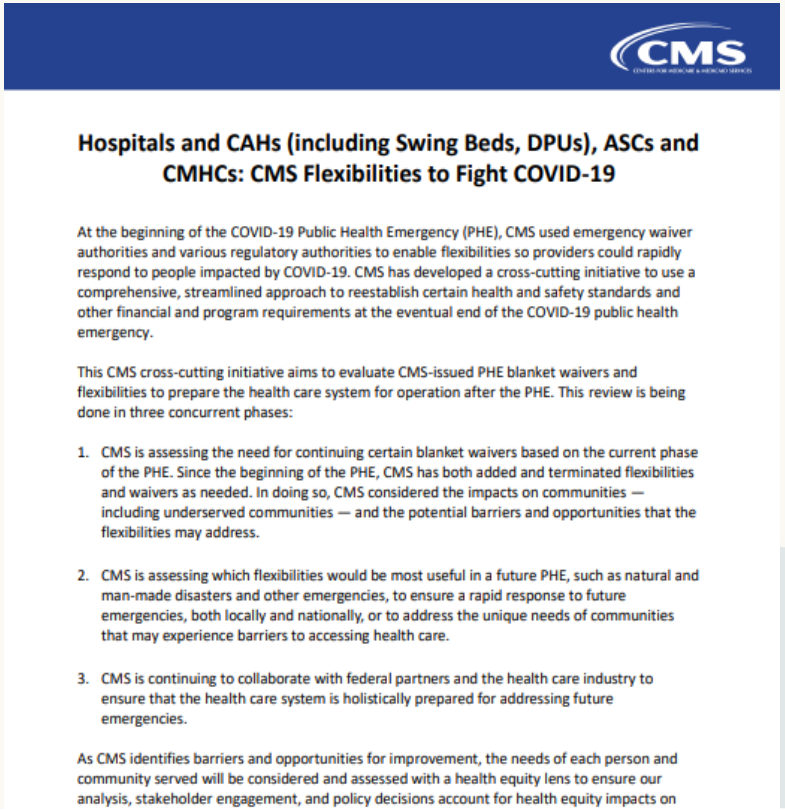
Read our provider-specific fact sheets for information about COVID-19 Public Health Emergency (PHE) waivers and flexibilities. These fact sheets

CMS FACT SHEET FOR HOSPITALS

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

At end of PHE, specified waivers will end, e.g.,

- ✓ Enhanced payment for COVID care
- ✓ Telehealth services provided in patient's home
- ✓ Hospitals without walls, use of provider-based depts, and other temporary expansion sites
- ✓ Clinical care requirements
- ✓ Physical environment and life safety regs
- ✓ CAH rural location, bed count, and length of stay
- ✓ Stark waivers for physician arrangements
- ✓ Etc., etc., etc.



CMS

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 has 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 aims to evaluate CMS-issued PHE blanket waivers and flexibilities to prepare the health care system for operation after the PHE. This review is being done in three concurrent phases:

1. CMS is assessing the need for continuing certain blanket 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 is assessing 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 emergencies.

As CMS identifies barriers and opportunities for improvement, the needs of each person and community served will be considered and assessed with a health equity lens to ensure our analysis, stakeholder engagement, and policy decisions account for health equity impacts on

CONTINUING WAIVERS?

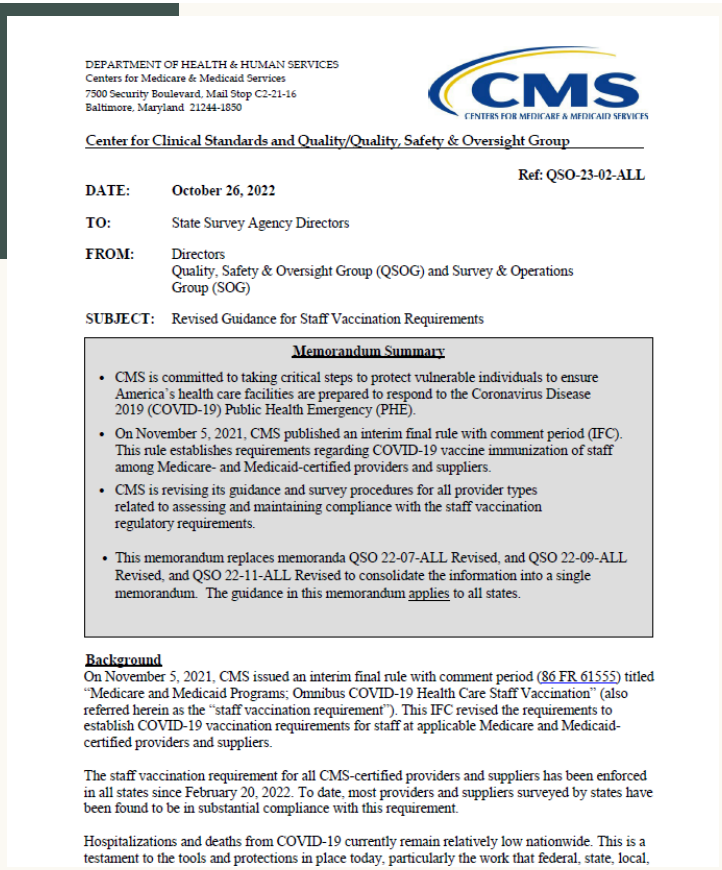
- Federal legislation has been proposed that would extend or make permanent some changes, e.g.,
  - Consolidated Appropriations Act of 2021 permanently expanded telebehavioral health services.
  - Consolidated Appropriations Act of 2022 gives 151-day extension after COVID-19 emergency ends for certain telehealth services.
- On 9/6/22, CMS issued Request for Information (RFI) concerning COVID waivers, including comment on which or whether waivers should become permanent.
- Stay tuned…

MANDATORY STAFF VACCINATION

On 10/26/22, CMS issued updated Guidance re Staff Vaccination for all Provider Types

- Reaffirms vaccination requirements for all providers.
- Condition-level violation = egregious non-compliance
  - E.g., more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required.
- Standard-level violation = other situations
  - E.g., less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

(QSO-23-02-ALL (Rev'd 10/26/22), Attachment D: Hospitals)



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-23-02-ALL

DATE: October 26, 2022

TO: State Survey Agency Directors

FROM: Directors
Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Revised Guidance for Staff Vaccination Requirements

Memorandum Summary

- CMS is committed to taking critical steps to protect vulnerable individuals to ensure America's health care facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On November 5, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes requirements regarding COVID-19 vaccine immunization of staff among Medicare- and Medicaid-certified providers and suppliers.
- CMS is revising its guidance and survey procedures for all provider types related to assessing and maintaining compliance with the staff vaccination regulatory requirements.
- This memorandum replaces memoranda QSO 22-07-ALL Revised, and QSO 22-09-ALL Revised, and QSO 22-11-ALL Revised to consolidate the information into a single memorandum. The guidance in this memorandum applies to all states.

Background

On November 5, 2021, CMS issued an interim final rule with comment period (86 FR 61555) titled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination" (also referred herein as the "staff vaccination requirement"). This IFC revised the requirements to establish COVID-19 vaccination requirements for staff at applicable Medicare and Medicaid-certified providers and suppliers.

The staff vaccination requirement for all CMS-certified providers and suppliers has been enforced in all states since February 20, 2022. To date, most providers and suppliers surveyed by states have been found to be in substantial compliance with this requirement.

Hospitalizations and deaths from COVID-19 currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local,

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TELEHEALTH

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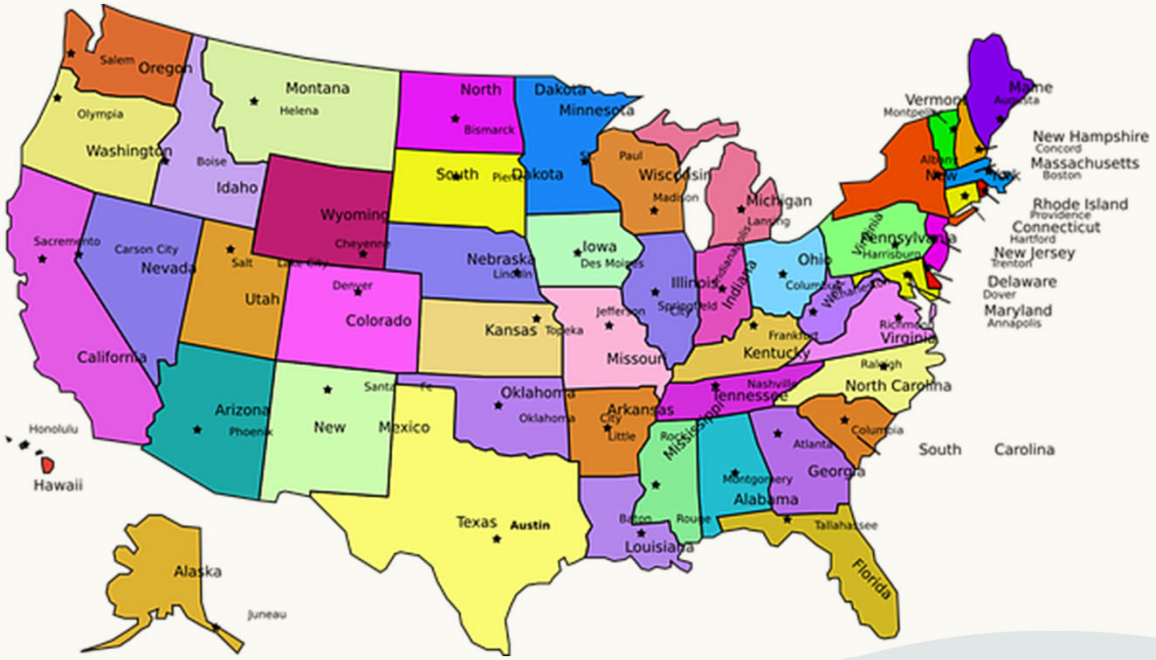
TELEHEALTH

- During pandemic, telehealth visits—
  - 840,000 in 2019
  - 52,700,000 in 2020
  - 63x increase

  (https://www.hhs.gov/about/news/2021/12/03/new-hhs-study-shows-63-fold-increase-in-medicare-telehealth-utilization-during-pandemic.html)
- Federal and state initiatives to retain or expand telehealth.
- Relaxed standards during PHE may end…

TELEHEALTH

- No coordinated national standard.
- Satisfy the laws and regs of each state in which you provide telehealth:
  - Where provider is located
  - Where patient is located.
- Regulations within each state may vary for different licensed providers.



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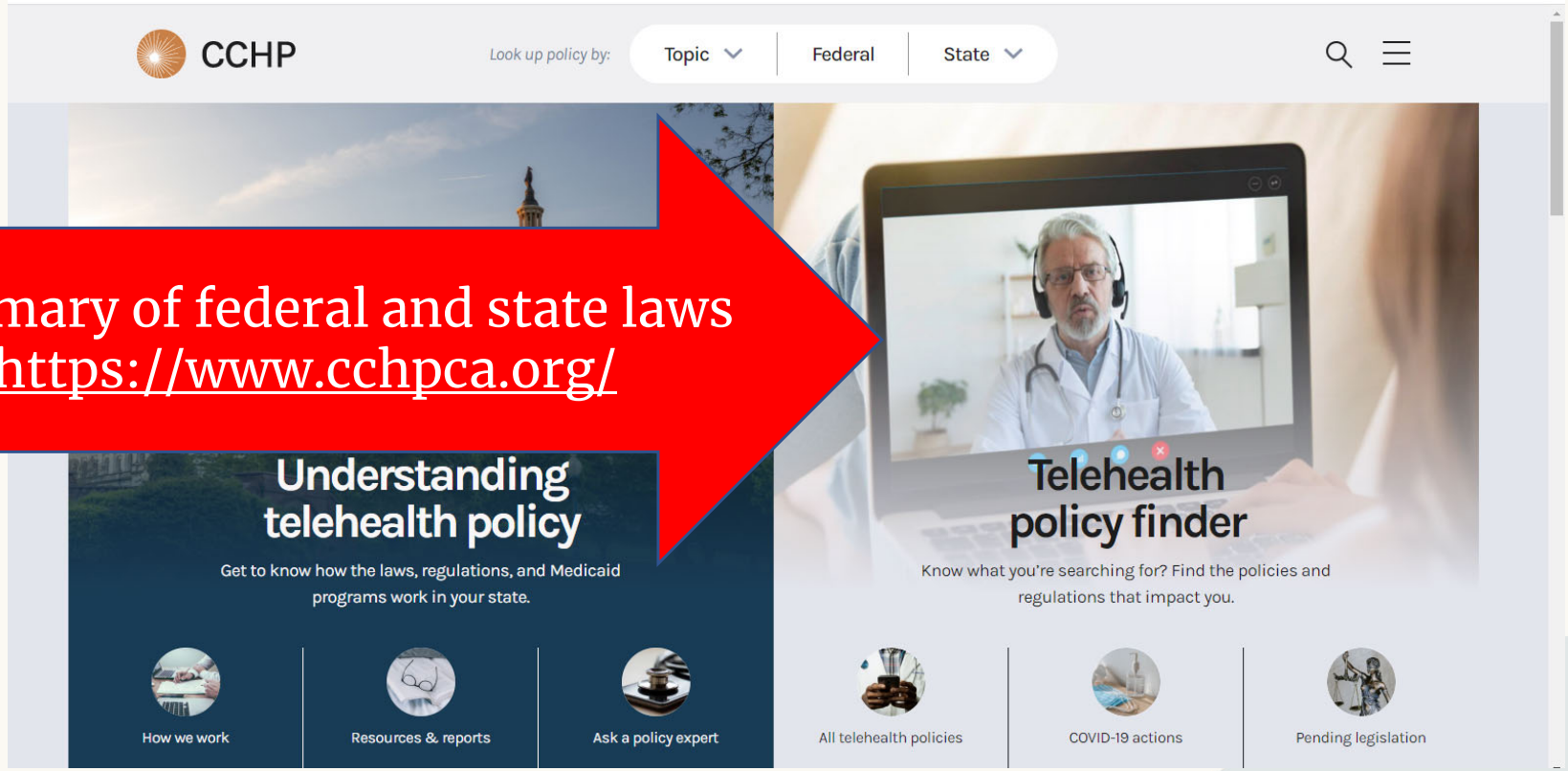
TELEHEALTH CONCERNS

- Licensure for telehealth
- DEA and state registration
- Credentialing providers at facility
- Establishing provider-patient relationship
- Permissible platforms and modalities
- Standard of care
- Informed consent
- Remote prescribing
- Terminating patient relationship and patient abandonment
- Scope of practice and supervision
- Corporate practice of medicine
- Medical records
- Reimbursement
- Privacy and security
- Malpractice standards and procedures
- Insurance coverage

CENTER FOR CONNECTED HEALTH POLICY



Summary of federal and state laws
https://www.cchpca.org/

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RYAN HAIGHT ONLINE PHARMACY CONSUMER PROTECTION ACT

- Providers may not prescribe controlled substances via telehealth without first performing an in-person medical evaluation of the patient.

(21 USC 829; 21 CFR 1306.09)

- During COVID-19 emergency, DEA-registered practitioners may prescribe controlled substances without prior in-person medical evaluation if evaluate patient through (i) telephone, or (ii) interactive audio-visual communication.

(https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf)

- Relaxed standards end with PHE.
- Beware similar state law requirements.

HIPAA SECURITY/PRIVACY

- Telehealth platforms and services must comply with HIPAA privacy and security rules (45 CFR part 164)
- During PHE, providers may use any non-public facing remote communication product event though it may not comply with security rule (e.g., FaceTime, Facebook Messenger, Google Hangouts, Zoom, Skype, etc.; NOT Facebook Live, TikTok, etc.).
  - Notify patients of privacy risks.
  - Enable encryption to extent able.

(OCR Notification, 85 FR 22024; *see also* FAQs at https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf)

- Relaxed standards end with public health emergency.

(https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html)

AUDIO-ONLY TELEHEALTH

- On 6/13/22, OCR issued Guidance re Audio-Only Telehealth
  - Must comply with HIPAA rules, e.g.,
    - Implement reasonable safeguards (e.g., use private setting; avoid overhearing).
    - Verify identity of individual.
    - Comply with security rule if applicable (not landline, but will apply to voice over internet protocol (VoIP), cellular messaging, record and store tech, etc.).
      - Risk analysis, encrypt ePHI, store and access ePHI, etc.
      - ➢ Note: this is change in OCR position re audio-only PHI.
    - Obtain BAAs if required (e.g., platforms that are not merely conduits for PHI).

(OCR Guidance re Audio-Only Telehealth, https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html)

DISCRIMINATION IN TELEHEALTH

- On 7/29/22, OCR and DOJ issued Guidance on Nondiscrimination in Telehealth (Section 504, ADA, Title VI, and Section 1557)

  Persons with Disabilities

  - Nondiscrimination
  - Reasonable modifications
  - Effective communication

  Limited English Proficiency

  - Meaningful access, e.g., language assistance services

(https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html)

- Proposed 1557 rule would add a provision expressly prohibiting discrimination in telehealth.

DISCRIMINATION IN TELEHEALTH

Per OCR/DOJ Guidance, examples of necessary accommodations might include:

- Intellectual disability:
  - Offer more time for patient and provide support person to assist during encounter.
- Deaf or hard of hearing:
  - Provide sign language interpreter during encounter.
  - Use platform that provides real-time captioning.
- Blind or visual disability.
  - Ensure recommendations are screen-reader capable.
  - Use video with audio descriptions.

(https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html)

DISCRIMINATION IN TELEHEALTH

Per OCR/DOJ Guidance, examples of necessary accommodations might include:

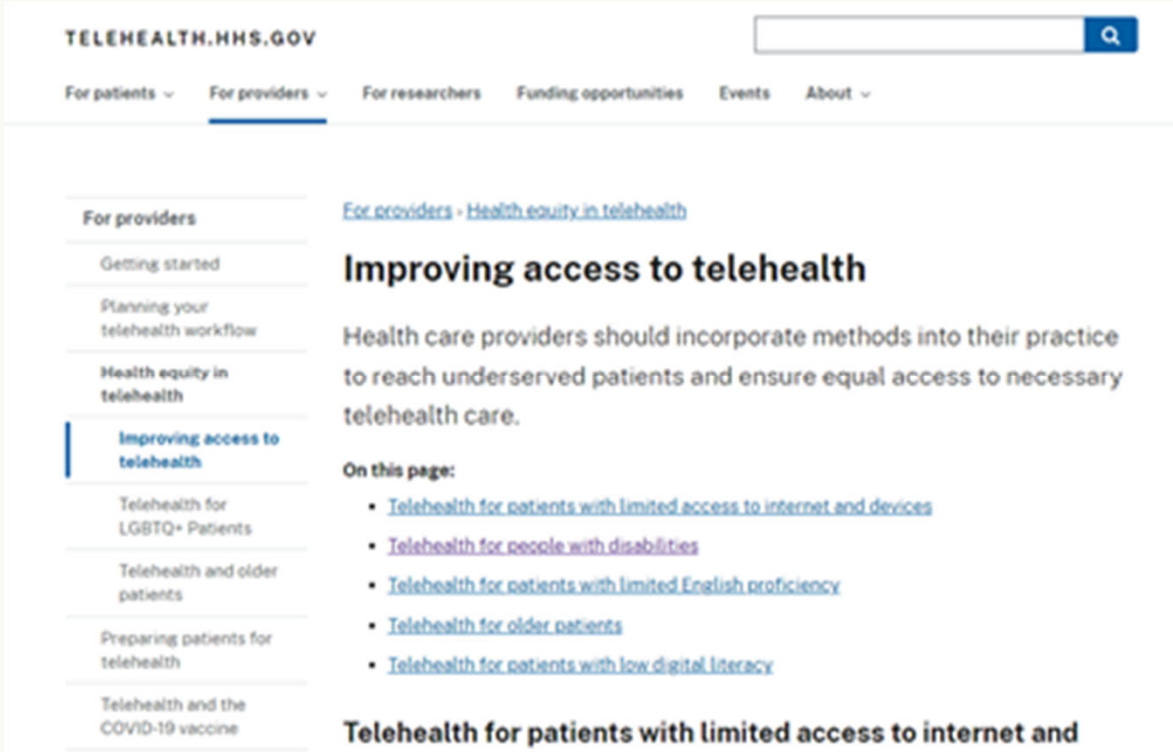
- Limited English proficiency
  - In e-mails or social media posts about telehealth opportunities, include short non-English statement that explains how LEP person may obtain info in their language.
  - Provide qualified language interpreter; don't rely on patient to bring their own interpreter.
  - Ensure telehealth platform may accommodate an interpreter or video remote interpreter.

(https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html)

TELEHEALTH.HHS.GOV

https://telehealth.hhs.gov/providers/health-equity-in-telehealth/improving-access-to-telehealth/#telehealth-for-people-with-disabilities

- Patient with limited access to internet devices.
- People with disabilities
- Patients with limited English proficiency
- Older patients
- Patients with low digital literacy



MEDICARE REIMBURSEMENT

- During COVID-19 emergency, any health care provider who is eligible to bill Medicare can bill for telehealth services regardless of where the patient or provider is located.
    - Originating/distant site limits waived.
    - Practitioner limits waived.
    - Expanded covered services.
  - Patients must verbally consent.
  - Certain services may be provided via audio-only telephones.
  - FQHCs and RHCs may be distant sites.

(https://telehealth.hhs.gov/providers/billing-and-reimbursement/)

- Relaxed standards mostly end with or within a few months after PHE

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

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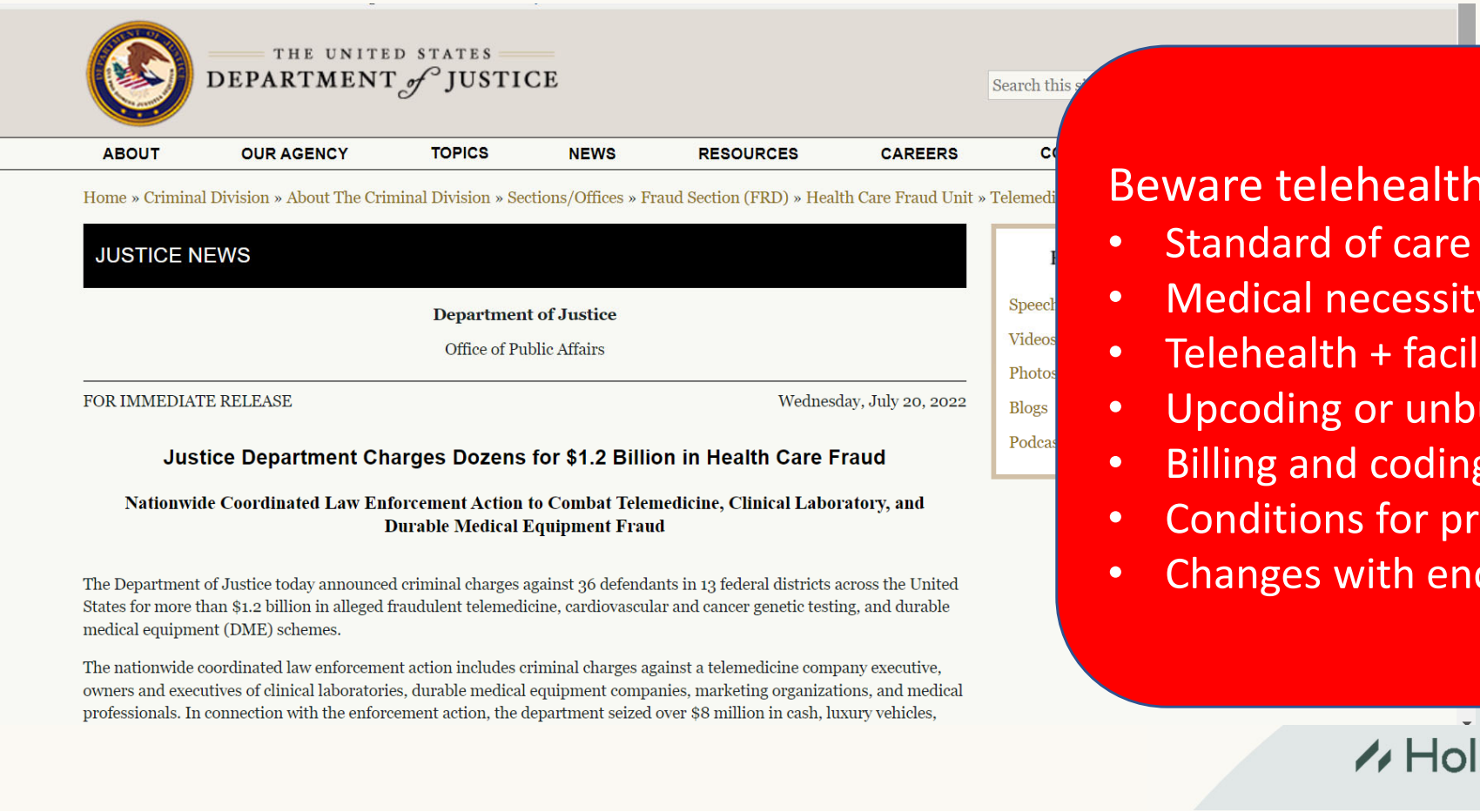
MEDICARE REIMBURSEMENT

- Consolidated Appropriations Act of 2021 permanently expanded telebehavioral health services.
- Consolidated Appropriations Act of 2022 gives 151-day extension after COVID-19 emergency ends for:
  - Originating site is anywhere the patient is located, including patient's home.
  - Expanded list of telehealth practitioners.
  - Coverage for audio-only telehealth.
  - In-person visit for telemental health.
  - FQHCs and RHCs may serve as distant site.
  - ➢ After 151 days, return to pre-COVID rules.
- Proposed legislation would extend waivers for 2 years.

DOJ TARGETING TELEHEALTH



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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Wednesday, July 20, 2022

Justice Department Charges Dozens for $1.2 Billion in Health Care Fraud

Nationwide Coordinated Law Enforcement Action to Combat Telemedicine, Clinical Laboratory, and Durable Medical Equipment Fraud

The Department of Justice today announced criminal charges against 36 defendants in 13 federal districts across the United States for more than $1.2 billion in alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and durable medical equipment (DME) schemes.

The nationwide coordinated law enforcement action includes criminal charges against a telemedicine company executive, owners and executives of clinical laboratories, durable medical equipment companies, marketing organizations, and medical professionals. In connection with the enforcement action, the department seized over $8 million in cash, luxury vehicles,

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Beware telehealth claims:

- Standard of care
- Medical necessity
- Telehealth + facility fee
- Upcoding or unbundling
- Billing and coding
- Conditions for proper billing
- Changes with end of PHE

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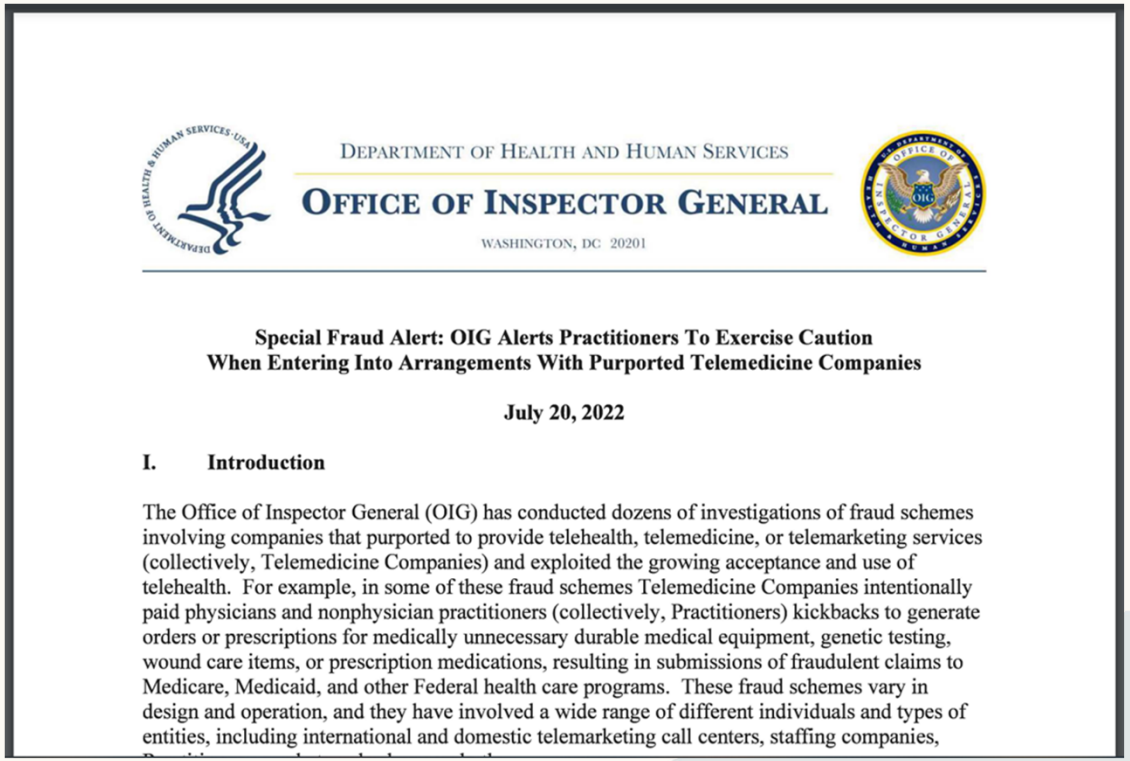
OIG SPECIAL FRAUD ALERT

Key concerns:

- Telehealth company recruits patients.
- Services not medically necessary.
- Provider has little to no interaction with patient.
- Provider paid based on volume or value of services ordered.
- No follow up with patients.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

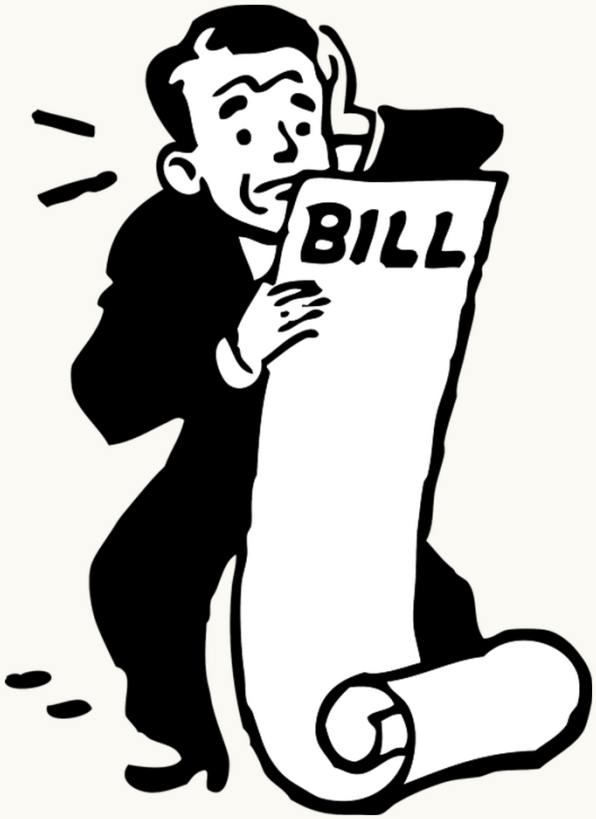
Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies

July 20, 2022

I. Introduction

The Office of Inspector General (OIG) has conducted dozens of investigations of fraud schemes involving companies that purported to provide telehealth, telemedicine, or telemarketing services (collectively, Telemedicine Companies) and exploited the growing acceptance and use of telehealth. For example, in some of these fraud schemes Telemedicine Companies intentionally paid physicians and nonphysician practitioners (collectively, Practitioners) kickbacks to generate orders or prescriptions for medically unnecessary durable medical equipment, genetic testing, wound care items, or prescription medications, resulting in submissions of fraudulent claims to Medicare, Medicaid, and other Federal health care programs. These fraud schemes vary in design and operation, and they have involved a wide range of different individuals and types of entities, including international and domestic telemarketing call centers, staffing companies,

NO SURPRISE BILLING RULES (45 CFR PART 149)



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NO SURPRISE BILLING RULES

INSURED PATIENTS

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

(45 CFR 149.410-.450)

SELF-PAY PATIENTS

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

(45 CFR 149.610-.620)

NSBR 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

(No Surprise Act § 2799D; 45 CFR 150.513; 86 FR 51730)

POST REQUIRED NOTICES

All Providers and Facilities

(for Uninsured/Self-Pay Patients)

- Post HHS notice, "Right to Receive a GFE of Expected Charges".
  - Website
  - Office where services rendered
  - Onsite where service scheduled or questions about items or services occur
- Provide Good Faith Estimate if required.

(45 CFR 149.610(b), (e))

You have the right to receive a "Good Faith Estimate" explaining how much your health care will cost

Under the law, health care providers need to give **patients who don't have certain types of health care coverage or who are not using certain types of health care coverage** an estimate of their bill for health care items and services before those items or services are provided.

- You have the right to receive a Good Faith Estimate for the total expected cost of any health care items or services upon request or when scheduling such items or services. This includes related costs like medical tests, prescription drugs, equipment, and hospital fees.
- If you schedule a health care item or service at least 3 business days in advance, make sure your health care provider or facility gives you a Good Faith Estimate in writing within 1 business day after scheduling. If you schedule a health care item or service at least 10 business days in advance, make sure your health care provider or facility gives you a Good Faith Estimate in writing within 3 business days after scheduling. You can also ask any health care provider or facility for a Good Faith Estimate before you schedule an item or service. If you do, make sure the health care provider or facility gives you a Good Faith Estimate in writing within 3 business days after you ask.
- If you receive a bill that is at least $400 more for any provider or facility than your Good Faith Estimate from that provider or facility, you can dispute the bill.

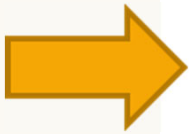
https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10791

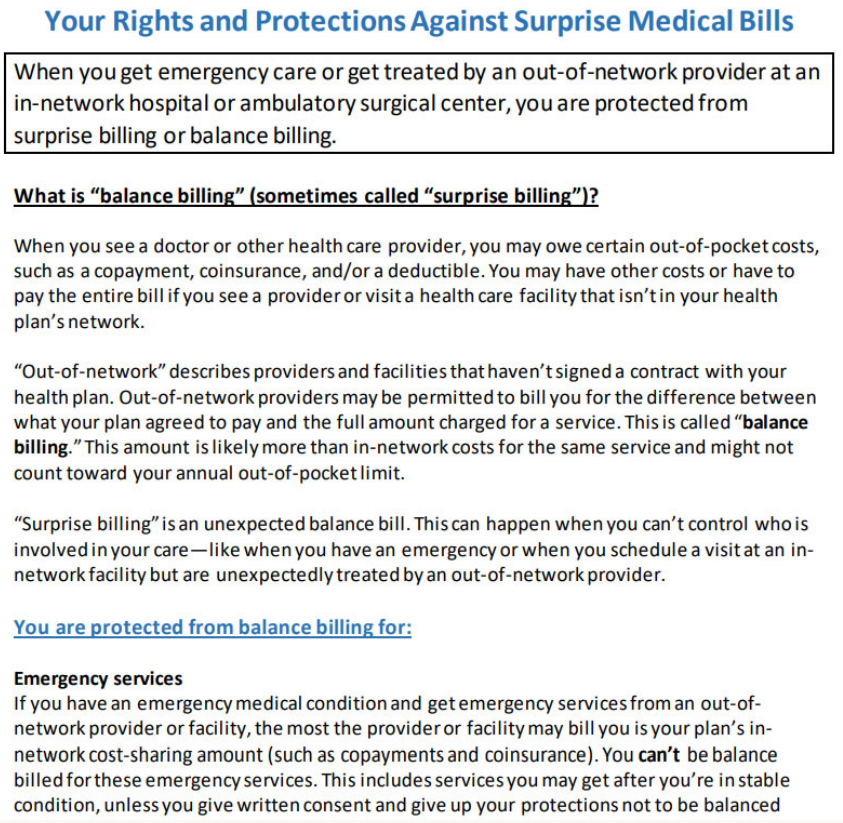
POST REQUIRED NOTICES

Hospitals, EDs, Freestanding EDs, ASCs, Outpatient Depts w/ Emergency Services <u>(for Insured Patients)</u>

- Post HHS notice, "Your Rights and Protections Against Surprise Medical Bills".
  - Website
  - Prominent sign in facility.
- Provide copy of notice to patients if required.

(45 CFR 149.430(a), (c))





Your Rights and Protections Against Surprise Medical Bills

When you get emergency care or get treated by an out-of-network provider at an in-network hospital or ambulatory surgical center, you are protected from surprise billing or balance billing.

What is "balance billing" (sometimes called "surprise billing")?

When you see a doctor or other health care provider, you may owe certain out-of-pocket costs, such as a copayment, coinsurance, and/or a deductible. You may have other costs or have to pay the entire bill if you see a provider or visit a health care facility that isn't in your health plan's network.

"Out-of-network" describes providers and facilities that haven't signed a contract with your health plan. Out-of-network providers may be permitted to bill you for the difference between what your plan agreed to pay and the full amount charged for a service. This is called "**balance billing**." This amount is likely more than in-network costs for the same service and might not count toward your annual out-of-pocket limit.

"Surprise billing" is an unexpected balance bill. This can happen when you can't control who is involved in your care—like when you have an emergency or when you schedule a visit at an in-network facility but are unexpectedly treated by an out-of-network provider.

You are protected from balance billing for:

Emergency services
If you have an emergency medical condition and get emergency services from an out-of-network provider or facility, the most the provider or facility may bill you is your plan's in-network cost-sharing amount (such as copayments and coinsurance). You **can't** be balance billed for these emergency services. This includes services you may get after you're in stable condition, unless you give written consent and give up your protections not to be balanced

https://www.cms.gov/files/document/model-disclosure-notice-patient-protections-against-surprise-billing-providers-facilities-health.pdf

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OON DISPUTE WITH PAYOR: IDR PROCESS

If dispute payor's payment to OON provider:

- 30 days to attempt agreement during open negotiation period.
- 4 days to request IDR.
- Parties select certified IDR entity or else HHS will appoint IDR entity.
- Payer and OON provider/facility submit their proposals.
  - On 8/26/22, HHS issued revised final rule on 8/26/22 (87 FR 52618)
    - Removed presumption in favor of "qualified payment amount" (QPA).
    - Payor must submit additional info if downcode.
- IDR entity determines which proposal is reasonable.
- Loser pays administrative costs.

(45 CFR 149.510(b)-(d))

OON DISPUTE WITH PAYOR: IDR PROCESS

As clarified in the final IDR rule, IDR entity may consider:

- QPA
- Training, experience, and quality and outcomes measurements of the provider.
- Patient acuity and complexity
- Good in entering or declining to enter network agreements.
- Market share.
- Teaching status, case mix and scope of services offered.
- Other appropriate and permissible info.

IDR entity may not consider (i.e., info not permitted):

- Usual and customary charges.
- Amount that would have been billed if balance billing provisions did not apply.
- Payment rates for public payors.

(45 CFR 149.510(b)-(d); 87 FR 52618)

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OON BALANCE BILLING PATIENT

- Limits patient's cost sharing amounts based on the "recognized amount", i.e., lesser of QPA or actual billed charges.
- May not balance bill patient for difference unless:
  - Rendered certain non-emergency, post-stabilization, non-ancillary services.
  - Give patient required written notice and good faith estimate at least 72 hours before date of service if possible, or if not, at least 3 hours before service.
    - Forms available at https://www.cms.gov/files/document/standard-notice-consent-forms-nonparticipating-providers-emergency-facilities-regarding-consumer.pdf
  - Obtain patient's valid signed written consent before service provided.
  - Notify insurer of patient's consent.
  - Maintain notice and consent for 7 years.

(45 CFR 149.410-.420)

UNINSURED/SELF-PAY PATIENTS

- Determine if person is uninsured/self-pay.
  - No insurance or govt programs, or
  - Will not submit claim to payer.
- Inform person of right to obtain good faith estimate (GFE) of charges.
- Give GFE if:
  - Person asks about cost;
    - HHS: ask about cost = request for GFE.
  - Person requests GFE; or
  - Person schedules services at least 3 days in advance.

(45 CFR 149.610)

- Do <u>not</u> need to give GFE if services are not scheduled in advance (e.g., urgent care, emergency care) unless patient asks about fees in advance.

(86 FR 56015-17)

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GOOD FAITH ESTIMATE

- ~~Contact co-provider within one business day to obtain fees and include in GFE.~~
  - On 12/2/22, HHS extended deadline for co-providers pending further rulemaking. (https://www.cms.gov/files/document/good-faith-estimate-uninsured-self-pay-part-3.pdf)
- Provide GFE to patient.
  - If primary service scheduled at least 3 business days in advance: not later than 1 business day after scheduling.
  - If primary service scheduled at least 10 business days in advance: not later than 3 business days after scheduling.
  - If requested by patient: not later than 3 business days after request.
  - If estimate changes: provide new estimate not later than 1 business day before item or service provided.
- May provide one GFE for recurring charges if conditions satisfied.

(45 CFR 149.610)

ACTUAL BILL > GOOD FAITH ESTIMATE: PPDR PROCESS

- If total billed charges for the listed provider/facility are "substantially in excess" of the total charges on GFE (i.e., at least $400 more than expected charges), patient may initiate the patient-provider dispute resolution (PPDR) process.

(45 CFR 149.620(b))

ACTUAL BILL > GOOD FAITH ESTIMATE: PPDR PROCESS

- Within 120 days of receipt of bill, patient must submit request and $25 fee to HHS.
- Notice sent to provider.
- Provider must not send bill to collections, pursue collection efforts, charge late fees, or engage in retribution during the PPDR process.
- Within 10 days of appointment of PPDR, provider must submit good faith estimate and other relevant information.
- PPDR considers whether services were medically necessary and unforeseen circumstances not reasonably anticipated when good faith estimate prepared.
- PPDR will look to median payment amount for same or similar provider in same geographic area.

(45 CFR 149.620)

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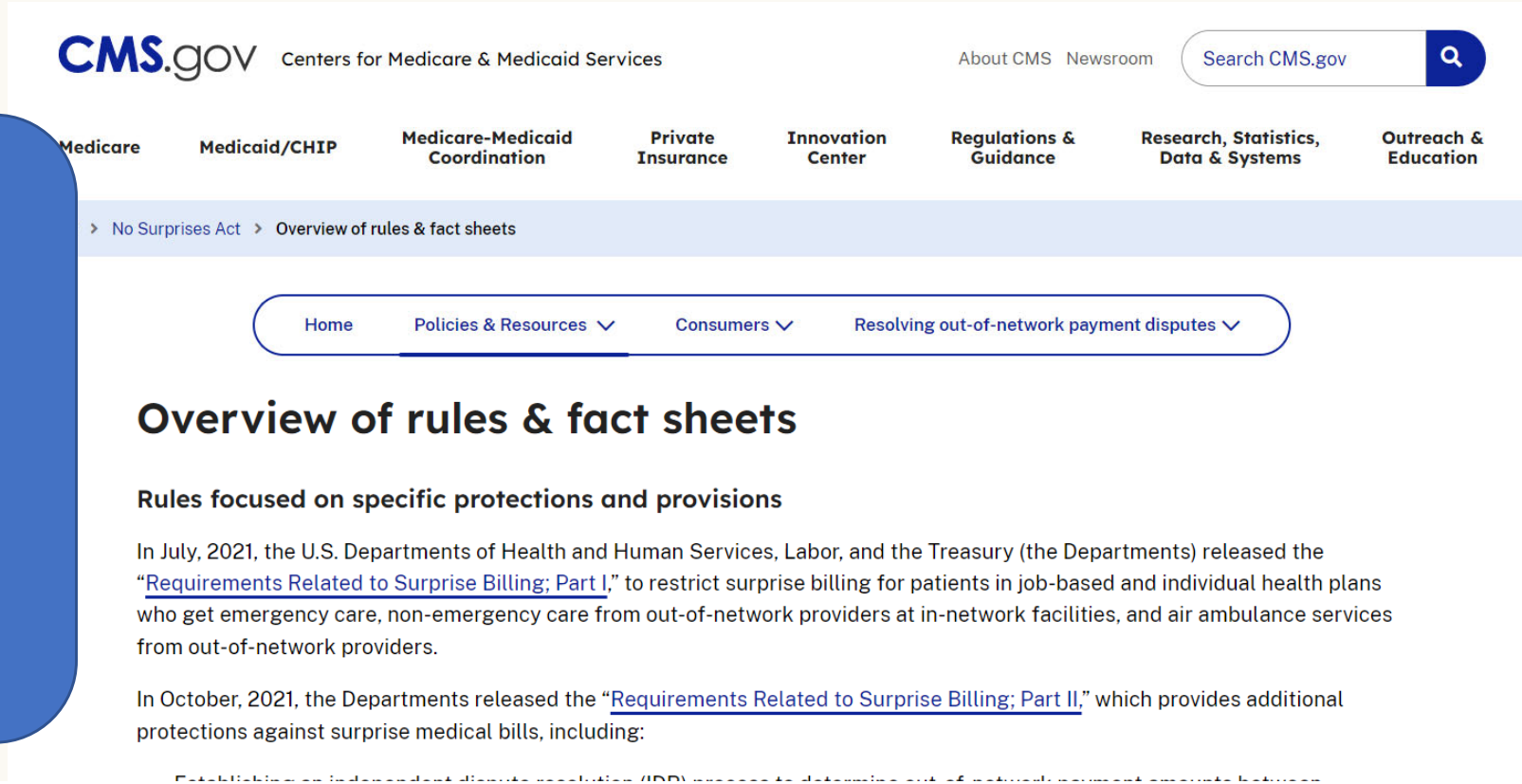
NSBR RESOURCES

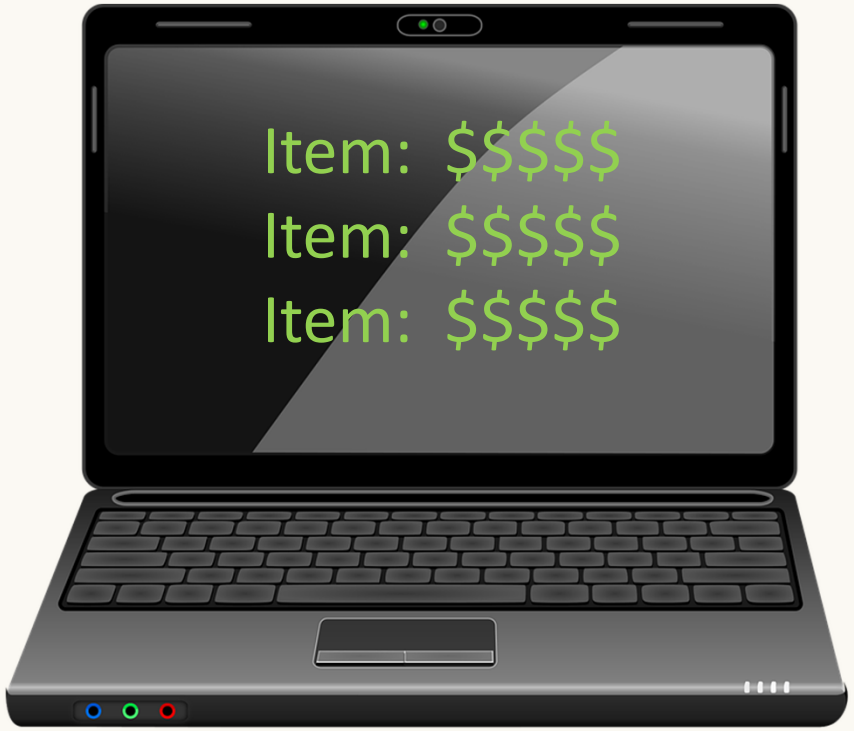
- https://www.cms.gov/nosurprises/policies-and-resources/overview-of-rules-fact-sheets

- Forms
- Training
- Fact Sheets
- FAQs
- Technical Guidance

➢ *Check for updates.*



HOSPITAL PRICE TRANSPARENCY (45 CFR 180)



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HOSPITAL PRICE TRANSPARENCY

Effective 1/1/21:

- Hospital must publish list of the hospital's "standard charges".
  - Gross charge on hospital's chargemaster absent discounts.
  - Discounted cash price for cash pay patients.
  - Payer-specific negotiated charge.
  - De-identified minimum negotiated charge with third-party payer.
  - De-identified maximum negotiated charge with third-party payer.
- Includes employed provider charges; not non-employed providers.

(45 CFR 180.50)

HOSPITAL PRICE TRANSPARENCY

- "Standard charges" must be published through:
  - Machine readable file for all items and services provided by the hospital; and
  - Either:
    - Consumer-friendly list of 300 "shoppable services" and ancillary services, or
    - Internet-based price estimator tool that gives consumers real-time estimates of expected costs.
- Must be available on the internet through hospital's website.
- Must update at least annually.

(45 CFR 180.40, 180-.60)

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PRICE TRANSPARENCY ENFORCEMENT

- CMS to monitor compliance through:
  - Complaints
  - Audits
  - Others

(45 CFR 180.70)

- Penalties
  - Written warning, corrective action plan, fines
  - Increased penalties effective 1/1/22:
    - Small hospitals (≤30 beds)
      - Maximum of $300 per day
    - Large hospitals (>30 beds)
      - Minimum of $10 per bed per day, and
      - Maximum of $5,500 per day.
    - Range of $109,500 to $2,007,500 per year
  - Post penalty on CMS website

(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)

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PRICE TRANSPARENCY ENFORCEMENT

- CMS auditing websites
- As of 6/22, has issued 352 warning letters

Enforcement Actions

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

Date Action Taken	Hospital Name	CMP Amount	Effective Date
2022-06-07 (PDF)	Northside Hospital Atlanta	$883,180.00	2021-09-02
2022-06-07 (PDF)	Northside Hospital Cherokee	$214,320.00	2021-09-09

In both cases,
- CMS sent warning letter and CAP
- Hospital failed to cure or respond with CAP

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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

HIPAA AND PATIENT CONFIDENTIALITY (45 CFR 164)

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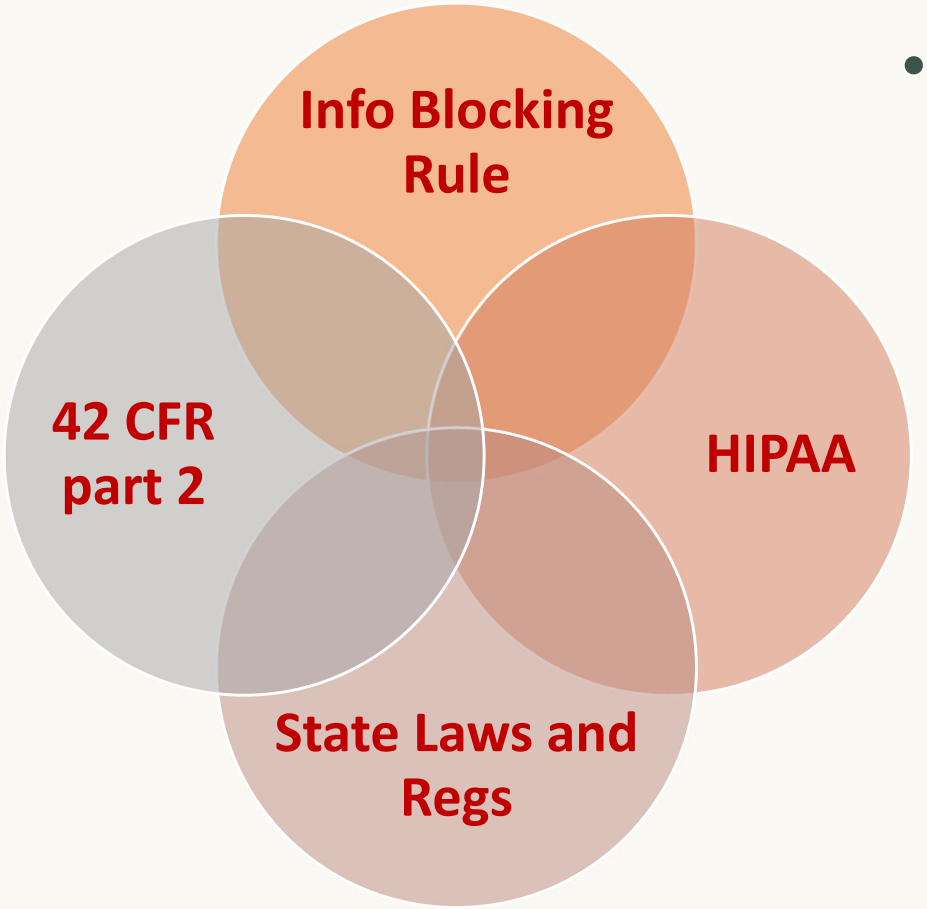
LAWS OVERLAP AND DIFFER



- Comply with the most restrictive, i.e.,
  - Gives greatest protection to protected health info (PHI), or
  - Gives patient most rights to control her/his PHI.

SUD RECORDS: CARES ACT § 3221 (3/27/20)

- Allows disclosure of SUD info for treatment, payment or healthcare operations if obtain initial consent.
- May share de-identified info with public health authority
- Limits use of SUD info in criminal, civil and administrative proceedings.
- Replaces criminal penalties with HIPAA penalties.
- Prohibits discrimination against persons based on SUD info.
- Requires breach notification for improper disclosure of SUD info.
- Requires HHS to promulgate regulations applicable to uses or disclosures of SUD info after 3/27/21.
- Requires HHS to update HIPAA notice of privacy practices rules.

(CARES Act 3221, amending 42 USC 290dd)

42 CFR PART 2 PROPOSED RULE (11/28/22)

Implements CARES Act § 3221

- Permits use and disclosure of Part 2 records based on a single patient consent given once for all future uses and disclosures for treatment, payment, and health care operations.
- Permits redisclosure of Part 2 records as permitted by HIPAA, with certain exceptions.
- Affirms patient rights to obtain accounting of disclosures and request restrictions on certain disclosures of Part 2 records per HIPAA.
- Expands prohibitions on the use and disclosure of Part 2 records in civil, criminal, administrative, and legislative proceedings.
- Applies HIPAA breach notification requirements to Part 2 breaches.
- Updates HIPAA Notice of Privacy Practices requirements re Part 2 records.
- Applies HIPAA civil and criminal penalties to Part 2 violations.

(87 FR 74216; see also HHS Fact Sheet, https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/hipaa-part-2/index.html)

HIPAA CIVIL PENALTIES

Conduct	Penalty
Did not know and should not have known of violation	• $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	• $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	• $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	• $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)

HIPAA ENFORCEMENT

- In future, individuals may recover portion of penalties or settlement.
  - On 4/6/22, HHS issued request for information soliciting input. (87 FR 19833)
- Must self-report breaches of unsecured protected health info
  - To affected individuals.
  - To HHS.
  - To media if breach involves > 500 persons.
- State attorney general can bring lawsuit.
  - $25,000 fine per violation + fees and costs
- Criminal penalties for unauthorized access or use. (42 USC 1320d-6)
  - $50,000 to $250,000 fine
  - 1 to 10 years in prison

AVOIDING HIPAA PENALTIES

You can likely avoid HIPAA civil penalties if you:

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

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

(See https://www.hollandhart.com/hipaa-checklist-covered-entities)

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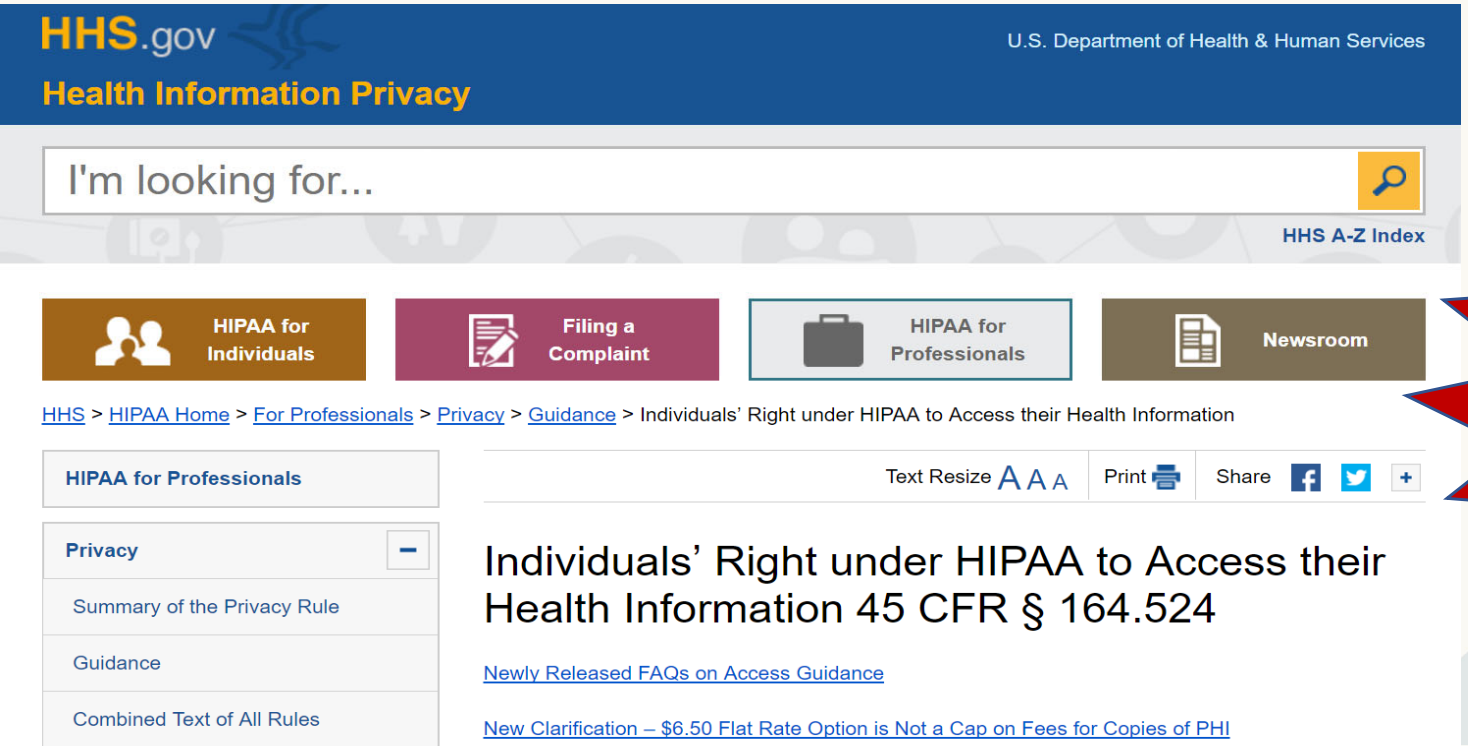
COMMON HIPAA PROBLEMS

- Security rule compliance (see discussion below)
- Encryption of devices.
  - OCR: Loss or theft of unencrypted device with PHI is presumptive breach.
    - MD Anderson fined $4.3 million.
  - 5th Circuit: Loss or theft of unencrypted device not necessarily a breach.
    - ALJ decision vacated and remanded.

    (*Univ. of Tex. M.D. Anderson Cancer Center v. HHS*, 985 F.3d 472 (5th Cir. 2021)
- Sending PHI through unsecured platform.
  - To patients: patient may consent to use of unencrypted communication.
  - To others: generally requires encryption.
- Patient's right of access
  - OCR Right of Access Initiative has resulted in 41 settlements

HIPAA RIGHT OF ACCESS

https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html#:~:text=With%20limited%20exceptions%2C%20the%20HIPAA,care%20providers%20and%20health%20plans



Required Reading!

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HIPAA RIGHT OF ACCESS

On January 23, 2020, *Ciox* court modified OCR rules for disclosures per patient's request to send PHI to third party.

ePHI IN EHR	OTHER PHI
Must send ePHI maintained in EHR to third party identified by patient.	Not required to send to third party per patient's request.
Part of patient's right to access, i.e., must respond within 30 days.	N/A
Not limited to reasonable cost-based fee (patient rate)	Not limited to reasonable cost-based fee (patient rate)

(45 CFR 164.524; OCR *Guide to Patient Access*)

HIPAA PROPOSED RULE (1/21/21)

- Strengthens individual's right of access.
  - Allows individuals to take notes or use other personal devices to view and capture images of PHI.
  - Must respond 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 (NPP).
- Modifies content of NPP.

(86 FR 6446)

➢ *No final rule yet.*

OCR GUIDANCE RE REPRODUCTIVE RIGHTS

- On 6/29/22, OCR issued post-*Dobbs* guidance on disclosing PHI relating to reproductive rights.
  - HIPAA prohibits disclosures without patient's authorization unless exception applies.
  - Potential exceptions might include the following; however, HIPAA does not require disclosures in these situations:
    - Disclosures required by law
    - Disclosures for law enforcement purposes.
    - Disclosures to avert serious and imminent threat of harm.
  - But other laws might require disclosures…

(https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/phi-reproductive-health/index.html)

OCR GUIDANCE RE ONLINE TRACKING

- On 12/1/22, OCR issued Guidance re Online Tracking Technologies
  - Tracking technologies may collect and analyze info about how users interact with websites and apps.
  - Covered entities and business associates "are not permitted to use tracking technologies in a manner that would result in impermissible disclosures of PHI to tracking technology vendors or any other violations of the HIPAA Rules."
    - May use for treatment, payment and healthcare operations.
    - May only use minimum necessary for permitted purpose.
    - May not use for marketing, vendor's own research or use, etc., without patient's HIPAA-compliant authorization.
    - Must have BAA with vendor for permissible uses of PHI.

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

HIPAA SECURITY RULE

- Risk assessment
  - In 6/22, OCR and ONC released updated security risk assessment tool (version 3.3 (7/22)), available at https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool
  - OCR and ONC have training videos available.
  - Review and update on regular basis.
- Implement safeguards.
  - Administrative
  - Physical
  - Technical, including encryption
- Execute BAAs.

(45 CFR 164.301 et seq.)

Protect ePHI:

- Confidentiality
- Integrity
- Availability

HIPAA SECURITY RULE

- In 1/21, HITECH Act amendments required OCR to take into consideration an entity's compliance with recognized security practices (RSPs) when considering HIPAA penalties.
- On 10/31/22, OCR posted a video addressing RSPs available at https://www.youtube.com/watch?v=e2wG7jUiRjE:
  - Compliance with RSPs is not a safe harbor but is a factor OCR considers when determining penalties.
  - RSPs =
    - NIST Framework
    - HICP technical volumes
    - Other

RSP Resources

- Public Law 116-321:
  - https://www.congress.gov/116/plaws/publ321/PLAW-116publ321.pdf
- HHS Resources on Section 405(d) of the Cybersecurity Act of 2015:
  - Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients (HICP)
    - https://405d.hhs.gov/Documents/HICP-Main-508.pdf
    - https://405d.hhs.gov/Documents/tech-vol1-508.pdf
    - https://405d.hhs.gov/Documents/tech-vol2-508.pdf
- NIST Cybersecurity Framework:
  - https://www.nist.gov/cyberframework
- NIST Online Informative References (OLIR):
  - https://csrc.nist.gov/projects/olir

OCR RESOURCES

Connect with Us

Office for Civil Rights
U.S. Department of Health and Human Services

www.hhs.gov/hipaa

Join our Privacy and Security listservs at
https://www.hhs.gov/hipaa/for-professionals/list-serve/

@HHSOCR

CYBERSECURITY

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CYBERSECURITY

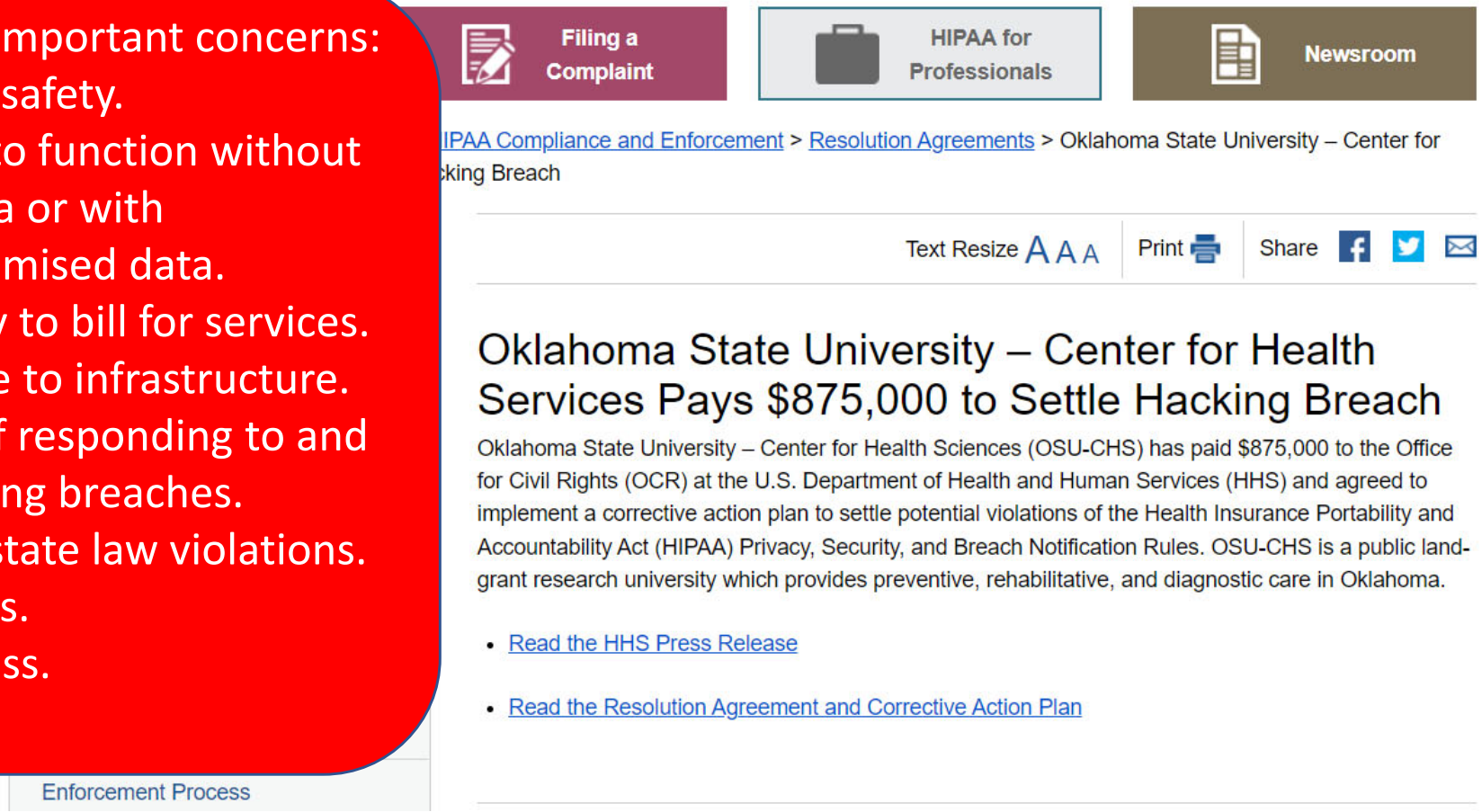
"Cybersecurity incidents and data breaches continue to increase… A 2022 cybersecurity firm report noted a 42% increase in cyber-attacks for the first half of 2022 compared to 2021, and a 69% increase in cyber-attacks targeting the health care sector. The number of data breaches occurring in the health care sector also continue to rise…. Seventy-four percent (74%) of the breaches [involving more than 500 persons] reported to OCR in 2021 involved hacking/IT incidents. In the health care sector, hacking is now the greatest threat to the privacy and security of PHI."

(OCR October 2022 Cybersecurity Newsletter (10/25/22), available at https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity-newsletter-october-2022/index.html)

CYBERSECURITY

But more important concerns:

- Patient safety.
- Ability to function without out data or with compromised data.
- Inability to bill for services.
- Damage to infrastructure.
- Costs of responding to and mitigating breaches.
- FTC or state law violations.
- Lawsuits.
- Bad press.



OCR CYBERSECURITY NOTICE

https://www.hhs.gov/blog/2022/02/28/improving-cybersecurity-posture-healthcare-2022.html

HHS.gov U.S. Department of Health & Human Services

I'm looking for...

A-Z Index

About HHS | Programs & Services | Grants & Contracts | Laws & Regulations

Home > Blog > Improving the Cybersecurity Posture of Healthcare in 2022

Categories

- Coronavirus (8)
- Fraud (1)
- Global Health (1)
- Grants and Contracts (1)
- Health Data (1)
- Health IT (3)
- HIPAA (1)
- Holidays and Observances (2)
- Prevention and Wellness (3)
- Public Health and Safety (4)

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Improving the Cybersecurity Posture of Healthcare in 2022

February 28, 2022 | *By: Lisa Pino, Director for Office for Civil Rights (OCR)*

Summary: Encourages HIPAA covered entities and business associates to strengthen their cyber posture in 2022.

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OCR CYBERSECURITY NOTICE

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

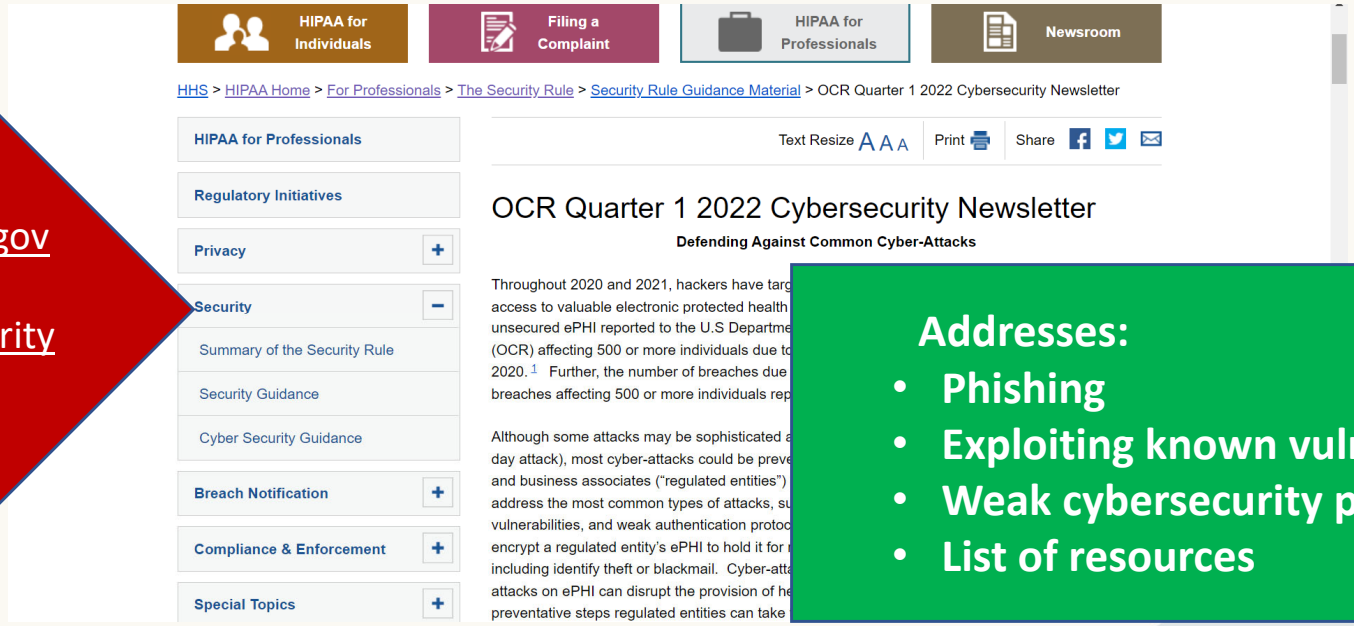
- "Maintaining offline, encrypted backups of data and regularly test your backups;
- "Conducting regular scans to identify and address vulnerabilities, especially those on internet-facing devices, to limit the attack surface;
- "Regular patches and updates of software and Operating Systems; and
- "Training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

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

CYBERSECURITY RESOURCES

https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity-newsletter-first-quarter-2022/index.html

https://www.hhs.gov/hipaa/for-professionals/security/index.html



Addresses:

- **Phishing**
- **Exploiting known vulnerabilities**
- **Weak cybersecurity practices**
- **List of resources**

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CYBERSECURITY RESOURCES

- https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity-newsletter-october-2022/index.html

https://www.hhs.gov/hipaa/for-professionals/security/index.html

Addresses:

- Cybersecurity incident response
- Recommended procedures
- Resources

DATA PRIVACY LAWS

- Watch for data privacy developments.
  - Several federal bills have been proposed.
  - Cyber Incident Reporting Critical Infrastructure Act of 2022 (CIRCIA) regulations are pending.
    - Will require reports of cybersecurity breaches.
- Beware state privacy laws.
  - See https://www.ncsl.org/research/telecommunications-and-information-technology/security-breach-notification-laws.aspx

INFORMATION BLOCKING RULE (45 CFR PART 171)

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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 PENALTIES

DEVELOPERS, HIN, HIE

- Complaints to ONC
  - https://www.healthit.gov/topic/information-blocking.
- ONC investigations
- Proposed rule:
  - Civil monetary penalties of up to $1,000,000 per violation

(85 FR 22979 (4/24/2020); proposed 42 CFR 1003.1420)

HEALTHCARE PROVIDERS

- "Appropriate disincentives to be established by HHS."
- Waiting for rule.

ELECTRONIC HEALTH INFO

- *Electronic health info* (EHI) = electronic PHI as defined in HIPAA to the extent it would be included in a designated record set under HIPAA, i.e.,
  - Medical records and billing records;
  - Enrollment, payment, claims adjudication, and case or medical management record systems; and
  - Records used to make decisions about individuals.
- Does not include
  - Psychotherapy notes as defined by HIPAA; or
  - Info compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

(45 CFR 171.102; see also 45 CFR 164.501)

- Prior to 10/6/22, IBR limited to United States Core Data for Interoperability (USCDI)
- Effective 10/6/22, IBR applies to all EHI.

INFO BLOCKING EXAMPLES

- Delaying a response to a request for access.
- Charging excessive fees to access.
- Imposing unreasonable administrative hurdles.
- Imposing unreasonable contract terms affecting access, e.g., EHR agreements, BAAs, etc.
- Implementing health IT in nonstandard ways that increase the burden.
- Others?

NOT INFO BLOCKING

- Blocking action is required by law.
  - HIPAA, 42 CFR part 2, state privacy laws, etc.
  - Laws require conditions before disclosure (e.g., patient consent) if conditions are not satisfied.
- Blocking action is reasonable under the circumstances.
- Blocking action fits within regulatory exception.

NOT INFO BLOCKING

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INFO BLOCKING EXAMPLES

Are actors (for example, health care providers) expected to release test results to patients through a patient portal or application programming interface (API) as soon as the results are available to the ordering clinician?

While the information blocking regulations do not require actors to proactively make electronic health information (EHI) available, once a request to access, exchange or use EHI is made actors must timely respond to the request (for example, from a patient for their test results). Delays or other unnecessary impediments could implicate the information blocking provisions.

In practice, this could mean a patient would be able to access EHI such as test results in parallel to the availability of the test results to the ordering clinician.

(https://www.healthit.gov/faqs)

INFO BLOCKING EXAMPLES

When would a delay in fulfilling a request for access … be considered an interference?…

If the delay is necessary to enable the access … it is **unlikely** to be considered an interference … (85 FR 25813). For example, if the release of EHI is delayed in order to ensure that the release complies with state law … (see also 85 FR 25813). …

It would **likely** be considered an interference … if a health care provider established an organizational policy that, for example, imposed delays on the release of lab results for any period of time in order to allow an ordering clinician to review the results or in order to personally inform the patient of the results before a patient can electronically access such results (see also 85 FR 25842)….

To further illustrate, it also would likely be considered an interference:

- where a delay in providing access, exchange, or use occurs after a patient logs in to a patient portal to access EHI that a health care provider has (including, for example, lab results) and such EHI is not available—for any period of time—through the portal.
- where a delay occurs in providing a patient's EHI via an API to an app that the patient has authorized to receive their EHI.

(https://www.healthit.gov/faqs)

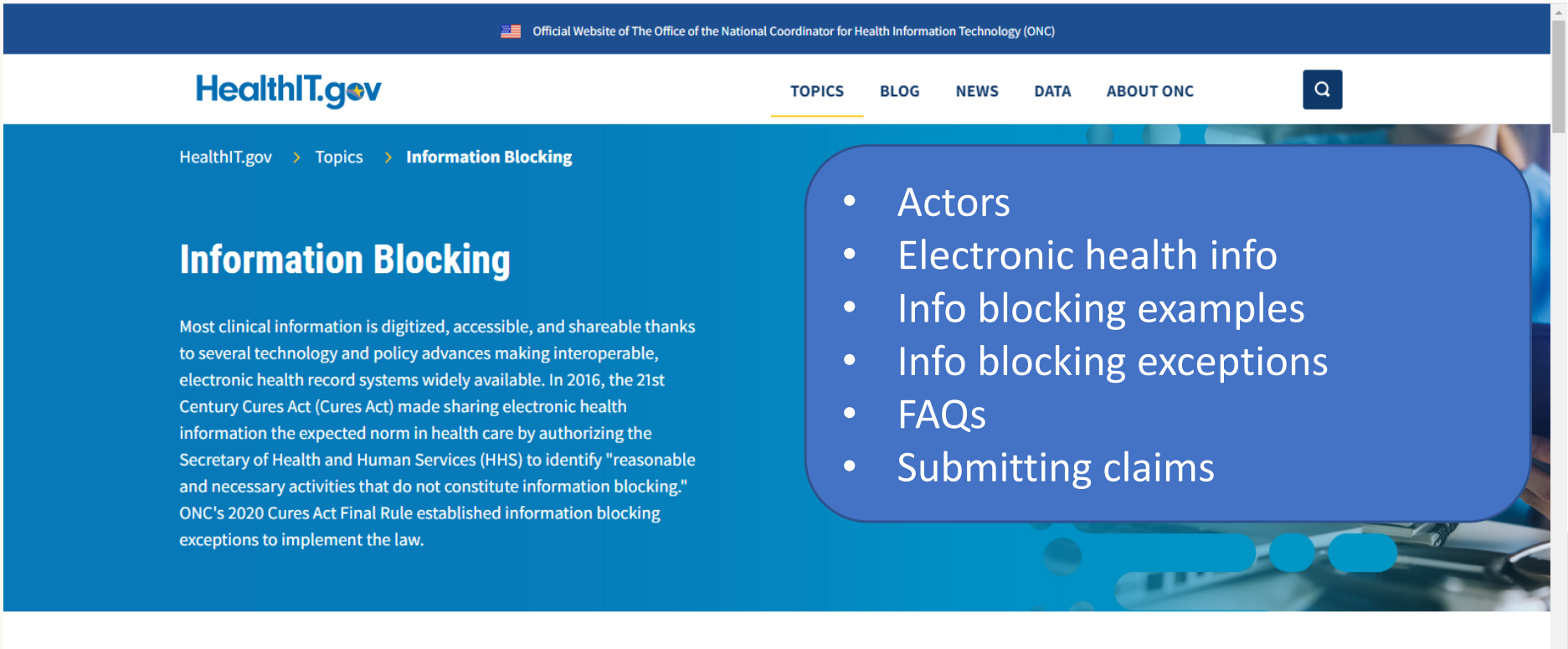
INFO BLOCKING EXAMPLES

When a state or federal law or regulation, such as the HIPAA Privacy Rule, requires EHI be released by no later than a certain date after a request is made, is it safe to assume that any practices that result in the requested EHI's release within that other required timeframe will never be considered information blocking?

No. The information blocking regulations … have their own standalone provisions …. If an actor who could more promptly fulfill requests for legally permissible access, exchange, or use of EHI chooses instead to engage in a practice that delays fulfilling those requests, that practice could constitute an interference under the information blocking regulation, even if requests affected by the practice are fulfilled within a time period specified by a different applicable law.

(https://www.healthit.gov/faqs)

IBR RESOURCES



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

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FRAUD AND ABUSE ISSUES

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FALSE CLAIMS ACT

- Cannot knowingly submit a false claim for payment to the federal govt.
- Must report and repay an overpayment within the later of 60 days or date cost report is due.

(31 USC 3729; 42 USC 1320a-7a(a); 42 CFR 1003.200)

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)

➢ *Subject to qui tam claims*

ANTI-KICKBACK STATUTE

- 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*, 760 F.2d 68 (3rd Cir. 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 False Claims Act violation*

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

ELIMINATING KICKBACK IN RECOVERY ACT (EKRA)

- Cannot solicit, receive, pay or offer any remuneration in return for referring a patient to a laboratory, recovery homes or clinical treatment facility unless arrangement fits within statutory or regulatory exception.

(18 USC 220(a))

Penalties

- $200,000 criminal fine
- 10 years in prison

(18 USC 220(a))

- *Beware if you operate or deal with a lab.*
- *Applies to private or public payors.*
- *Exceptions more restrictive than Stark or AKS.*

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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 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 False Claims Act violation*

➢ *Likely Anti-Kickback Statute violation*

CIVIL MONETARY PENALTIES LAW

Prohibits certain specified conduct, e.g.:

- Submitting false claims, misrepresenting facts relevant to services, or engaging in other fraudulent practices.
- Violating Anti-Kickback Statute or Stark law.
- Failing to report and repay an overpayment.
- Failing to grant timely access.
- Offering inducements to program beneficiaries.
- Hospitals offering inducements to physicians to limit medically necessary services.
- Submitting claims for services ordered by, or contracting with, an excluded entity.

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

PROBLEM PATIENT ARRANGEMENT

- Gifts or rewards to patients.
- "Refer a friend" programs.
- Free or discounted items to patients (e.g., free equipment, supplies, services).
- Free meals, rooms, transportation.
- Health fairs and free screenings.
- Waiver of copays or deductibles or "insurance only" billing.
- Writing off bills.
- Prompt pay discounts.
- Paying premiums.
- Anything else of value for labs or items or services payable federal healthcare programs.

➢ *Watch your marketing department…*

- Check for relevant:
  - AKS safe harbors
  - EKRA exceptions
  - CMPL definitions or exceptions
  - Advisory Opinions
  - State laws or regulations

PROBLEM PROVIDER ARRANGEMENT

- Arrangements under PHI Stark waivers once PHE ends.
- Gifts or perks to referring providers.
- Professional courtesy programs.
- Free or discounted items, space, or support to referring providers.
- Provider arrangements that vary with volume or value of referrals, e.g., share of profits, pools, comp for services performed by others, etc.
  - Physicians: cannot vary with volume or value of referrals for DHS
  - Non-physicians: may* be able to pay employees based on referrals.
- Compensation that is more/less than FMV or is not commercially reasonable.
- Physician contracts with directed referrals + compensation changed retroactively.
- Groups that don't satisfy the "group practice" requirements.
- Referrals to entities that are owned by the referring provider.
- Favorable investment or joint venture opportunities.

"NEW" STARK DEFENSES

- No DHS or federal program referrals (411.351)
- Inpatient services if does not affect IPPS rate (411.351)
- No remuneration, e.g., facility and physician bill separately.
- Payments by a physician (411.357(i))
- Remuneration <$5000/year to a physician (411.357(z))
- Fair market value (411.357(l))
- Prospective amendments to comp (411.354(d))
- Settlement of bona fide dispute (411.357(f))
- Indirect arrangement if comp does not vary by referrals (411.357(c))
- Contemporaneous documents = contract (411.354(e))
- Reconciling discrepancies w/in 90 days after termination (411.353(h)

But beware…

- Anti-Kickback Statute even if Stark is satisfied.
- EKRA if labs are involved.
- State laws.
- Private payer agreements.

PRIVATE PAYER CONCERNS

- Breach of third-party payer agreement.
  - Waive or discount copays.
  - Failure to repay
- Insurance fraud.
  - Misrepresent services, cost, or preconditions of services.
- Travel Act.
  - Based on violation of state bribery or similar statutes.
- Consumer protection statutes.
  - Violation of law may form predicate for consumer protection law.
- Other?

(See https://www.hollandhart.com/fraud-and-abuse-in-private-payor-situations)

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FRAUD AND ABUSE TO DO LIST

- ✓Ensure your provider compensation structures satisfy laws and regulations.
- ✓Evaluate provider's ownership interest in entities to which they refer.
- ✓Review arrangements with referral sources.
- ✓Review billing and collection policies, including discounts or write offs.
- ✓Review marketing plans, especially inducements to patients.
- ✓Review professional courtesy policies.
- ✓Review billing practices.
- ✓Review, implement, and/or update compliance program.
- ✓Report and repay timely if required.

CRITICAL ACCESS HOSPITAL STATUS (42 CFR 485)

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CAH REQUIREMENTS

- Located in a rural area (i.e., outside a metropolitan statistical area) or an area that is treated as rural.
- Satisfy one of the following:
  - Designated by state as a "necessary provider" prior to January 1, 2006; or
  - More than 35-miles drive from nearest hospital or CAH; or
  - More than 15-mile drive without primary roads to another hospital or CAH; or
  - More than 15-mile drive through mountainous terrain.
- No more than 25 inpatient beds and/or swing-beds.
- Annual average length of stay of 96 hours or less per inpatient.
- Emergency care services provided 24/7/365.
- Complies with COPs, 42 CFR 485.601 *et seq.*

(42 CFR 485.601 *et seq.*; SOM Ch. 2 at 2254D)

CAH REQUIREMENTS

- CAH waivers will terminate at the end of the PHE:
  - Location in a rural area or treated as rural.
  - 35/15-mile proximity to other hospitals or CAHs.
  - Off-campus and co-location requirements.
  - 25 bed limit
  - 96-hour length of stay

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

PROPOSED CAH RULE (6/6/22)

- Reaffirms that CAHs must maintain location requirements.
- New process for evaluating CAH status:
  - CMS would use geocoding to identify hospitals/CAHs within 50-mile radius.
  - CAHs with no new hospitals within 50 miles would be recertified.
  - CAHs with new hospitals within 50 miles will receive additional review "focus[ing] primarily on expanded healthcare capacity and access to care within the 35-mile radius of the CAH being examined and less on the actual roadway designations used in making the calculations."
  - "CAHs that do not meet the regulatory distance and location requirements at the time of review … may face enforcement actions."

(87 FR 40373)

PROPOSED CAH RULE (6/22/22)

- "Primary roads" =
  - A numbered Federal highway, including interstates, intrastates, expressways, or any other numbered Federal highway; or
  - A numbered State highway with 2 or more lanes each way.
  - ~~A road shown on a map prepared in accordance with the U.S. Geological Survey's Federal Geographic Data Committee (FGDC) Digital Cartographic Standard for Geologic Map Symbolization as a "primary highway, divided by median strip.~~
- CMS soliciting comment on whether "primary road" should include only those Federal highways with 2+ lanes in either direction as is required for state highways.

(87 FR 40373 *et seq.*)

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CAH RISKS

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

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

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PROPOSED CAH RULE (6/22/22)

Proposed additional CAH Conditions of Participation:

- Notice of patient rights
- Grievance process
- Informed consent and advance directives
- Care in safe and private setting
- Confidentiality of and access to patient records
- Restraints and seclusion
  - Use of restraints or seclusion
  - Staff training
  - Death reporting
- Patient visitation rights

(87 FR 40374-76, 40401-03)

Parallels COPs for hospitals

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PROPOSED CAH RULE (6/22/22)

Creates new options for CAHs in a multi-facility system to address:

- Staffing and staff responsibilities
- Infection prevention and control
- Quality assessment and performance improvement programs

(87 FR 40374-76, 40403-04)

CO-LOCATION AND SPACE-SHARING ARRANGEMENTS

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CO-LOCATION AND SPACE SHARING

Risks include:

- Medicare COPs
  (42 CFR parts 482 and 485)
- Provider-Based Status Rules
  - PBD must be under control of hospital.
  - PBD held out to public as part of hospital.

  (42 CFR 413.65)
- State licensing standards
- Stark and Anti-Kickback Concerns
  - Use of space, equipment, personnel = remuneration depending on who bills for it.
  - Consider applicable safe harbors, e.g., lease, time share, payments by a physician, limited remuneration to physician, fair market value, personal services, etc.

  (42 CFR 411.357 and 1001.952)

CO-LOCATION AND SPACE SHARING

- CMS Co-Location Guidance (rev'd 11/21) provides less prescriptive, more general guidance for compliance with COPs.
  - Addresses space, patient rights, infection controls, contracted or shared services, staffing, emergency services, etc.
  - No discussion of timeshares or leases.
  - Defines "healthcare providers" to exclude CAHs and physician offices.

(CMS, *Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities*, S&C QSO-19-13-Hospital (Rev'd 11/12/21), available at https://www.cms.gov/files/document/qso-19-13-hospital-revised.pdf)

HOSPITAL CREDENTIALING

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HOSPITAL CREDENTIALING BY PROXY

- Hospital and CAH Conditions of Participation (CoP) allow hospitals to rely on credentialing done by remote hospital/entity for telehealth providers if:
  - Hospital bylaws allow it.
  - Have written credentialing agreement with distant site with required terms.
  - Distant site complies with CoP standards.
  - Practitioner privileged at distant site.
  - Practitioner licensed in state where services provided.
  - Hospital reviews practitioner's performance and provides results to distant site.

(42 CFR 482.12 and .22, 485.616 and .635)

- Requirements vary depending on whether parties are a CAH, hospital, or other distant site entity.
- Requirements relaxed during COVID, but will resume.
- Beware state law requirements.

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JOINT COMMISSION GUIDANCE RE REAPPOINTMENTS

- On 11/23/22, Joint Commission changed reappointment period for licensed practitioners from 2 years to 3 years.
  - Effective immediately.
  - Applies to hospitals and CAHs, ambulatory health care, behavioral health care and human services, nursing care centers, and office-based surgery.

(https://www.jointcommission.org/standards/prepublication-standards/revisions-related-to-licensed-practitioner-evaluation-time-frames/)

- But beware:
  - State laws and regulations.
  - Other accreditation organizations.

NON-DISCRIMINATION RULES (45 CFR 92)

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ENFORCEMENT

Discrimination statutes

- Section 1557 of the ADA
- Section 504 of the Rehabilitation Act
- Title VI of the Civil Rights Act
- Age Discrimination Act
- State laws

Enforcement

- OCR investigation
- DOJ lawsuit
- Private lawsuit
  - Damages
  - Plaintiffs cannot recover emotional distress damages. (*Cummings v. Premier Rehab Keller*, 142 SCt 1562 (2022))

HISTORY OF 1557 DISCRIMINATION RULES

- 2016: Obama Administration promulgated Section 1557 of the ACA.
  - Prohibits discrimination by healthcare providers receiving federal financial aid, including discrimination based on, e.g., disability, limited English proficiency, sex, including sexual orientation, gender identity, termination of pregnancy, etc.
- 2016: Federal court enjoined 557 Rules relating to gender identity and termination of pregnancy. (*Franciscan Alliance v. Burwell*, 227 F. Supp.3d 660 (ND Tex. 2016))
- 2020: Trump Administration scaled back Section 1557 Rules.
  - Limited scope of application.
  - Eliminated grievance process, nondiscrimination coordinator, and notices.
  - Sex discrimination excludes sexual orientation, gender identity, sex stereotyping, and termination of pregnancy.
- 2020: Supreme Court held sex discrimination includes sexual orientation and gender identity. (*Bostock v. Clayton County*, 130 SCt 1731 (2020))

PROPOSED 1557 RULE (8/4/22)

Biden Administration proposed new 1557 Rules.

- Expands to healthcare programs receiving federal financial assistance, including Medicare Part B recipients and others.
- Sex discrimination includes sex stereotyping, sex characteristics, sexual orientation, gender identity and pregnancy-related conditions, including abortion.
- Give "primary consideration" to patient's requested accommodation.
- Prohibits discrimination in telehealth services.
- Post and provide notices:
  - Nondiscrimination, and
  - Availability of language assistance.
- Require 1557 coordinator, grievance process.
- Train staff re 1557 requirements.
- Refines process for claiming conscience and religious objections.

(87 FR 47824)

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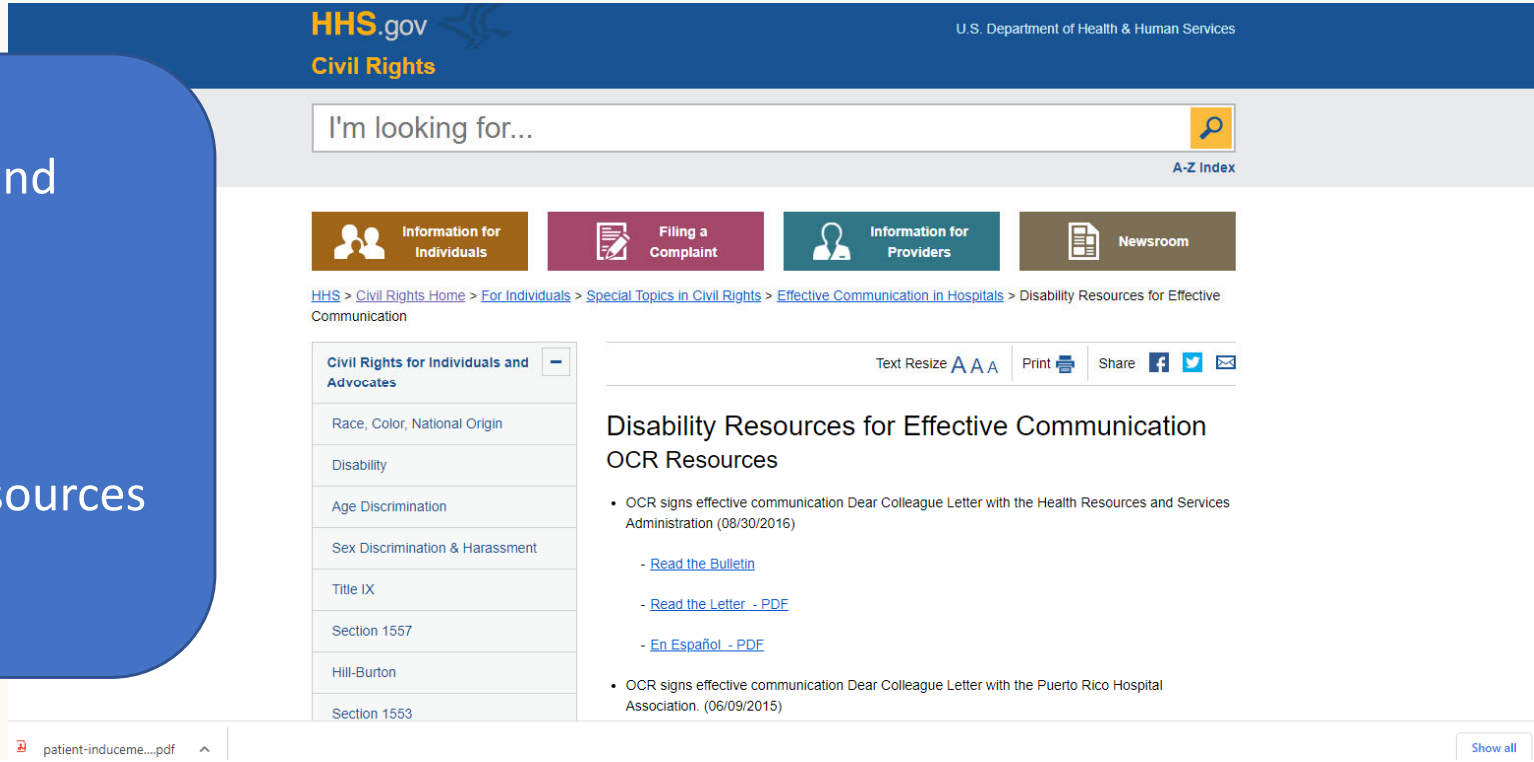
OCR DISABILITY RESOURCES

- 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



OCR GUIDANCE RE GENDER AFFIRMING CARE

- On 3/2/22, OCR issued Guidance on Gender Affirming Care.
  - Restricting an individual's ability to receive, or limiting a health provider's ability to provide, gender affirming care based on an individual's sex assigned at birth or gender identity likely violates Section 1557.
  - Gender dysphoria may qualify as a disability under the Americans with Disabilities Act (ADA).
  - Preventing qualified individuals from receiving gender affirming care based on their gender dysphoria, gender dysphoria diagnosis, or perceived gender dysphoria may violate Section 504 and Title II of the ADA.

(https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/phi-reproductive-health/index.html)

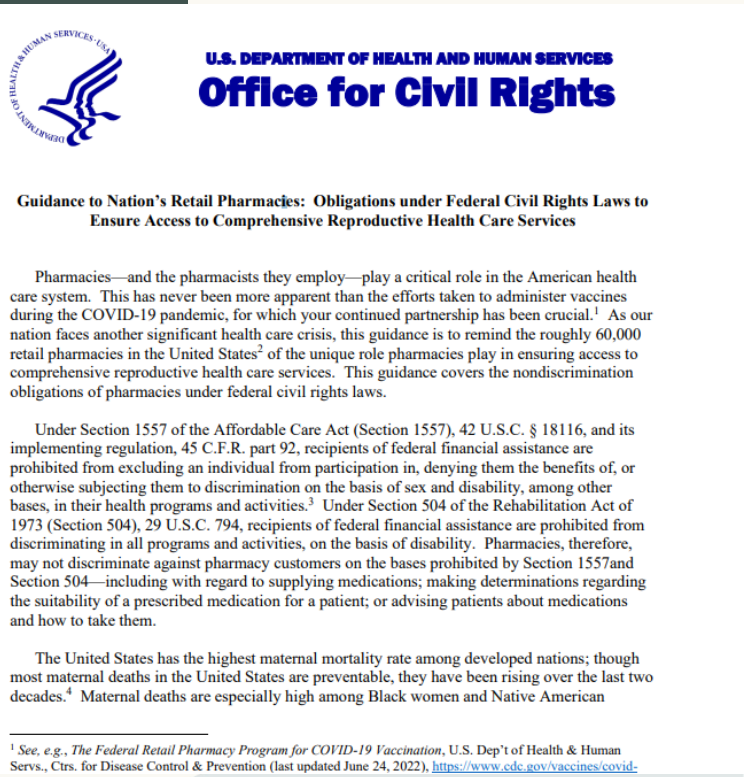
- On 10/1/22, ND Tex issued judgment vacating the OCR guidance as arbitrary, capricious, and violated Administrative Procedure Act.

(*Texas v. EEOC* (ND Tex. 10/1/22))

OCR GUIDANCE TO PHARMACIES

- On 7/13/22, OCR issued Guidance to Pharmacies re Obligations to Ensure Access to Comprehensive Reproductive Health Care Services
- Discrimination may include:
  - Failing to stock or make available contraceptives.
  - Failing to fill prescriptions for drugs which may be used for abortion in addition to other uses.
  - Failing to fill prescriptions that which may cause abortion as side effect.
  - Failing to fill prescription to end ectopic pregnancy.

(https://www.hhs.gov/sites/default/files/pharmacies-guidance.pdf)



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services

Pharmacies—and the pharmacists they employ—play a critical role in the American health care system. This has never been more apparent than the efforts taken to administer vaccines during the COVID-19 pandemic, for which your continued partnership has been crucial.[1] As our nation faces another significant health care crisis, this guidance is to remind the roughly 60,000 retail pharmacies in the United States[2] of the unique role pharmacies play in ensuring access to comprehensive reproductive health care services. This guidance covers the nondiscrimination obligations of pharmacies under federal civil rights laws.

Under Section 1557 of the Affordable Care Act (Section 1557), 42 U.S.C. § 18116, and its implementing regulation, 45 C.F.R. part 92, recipients of federal financial assistance are prohibited from excluding an individual from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex and disability, among other bases, in their health programs and activities.[3] Under Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794, recipients of federal financial assistance are prohibited from discriminating in all programs and activities, on the basis of disability. Pharmacies, therefore, may not discriminate against pharmacy customers on the bases prohibited by Section 1557and Section 504—including with regard to supplying medications; making determinations regarding the suitability of a prescribed medication for a patient; or advising patients about medications and how to take them.

The United States has the highest maternal mortality rate among developed nations; though most maternal deaths in the United States are preventable, they have been rising over the last two decades.[4] Maternal deaths are especially high among Black women and Native American

[1] *See, e.g.*, *The Federal Retail Pharmacy Program for COVID-19 Vaccination*, U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control & Prevention (last updated June 24, 2022), https://www.cdc.gov/vaccines/covid-

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REPRODUCTIVE RIGHTS.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/)

ADDITIONAL RESOURCES

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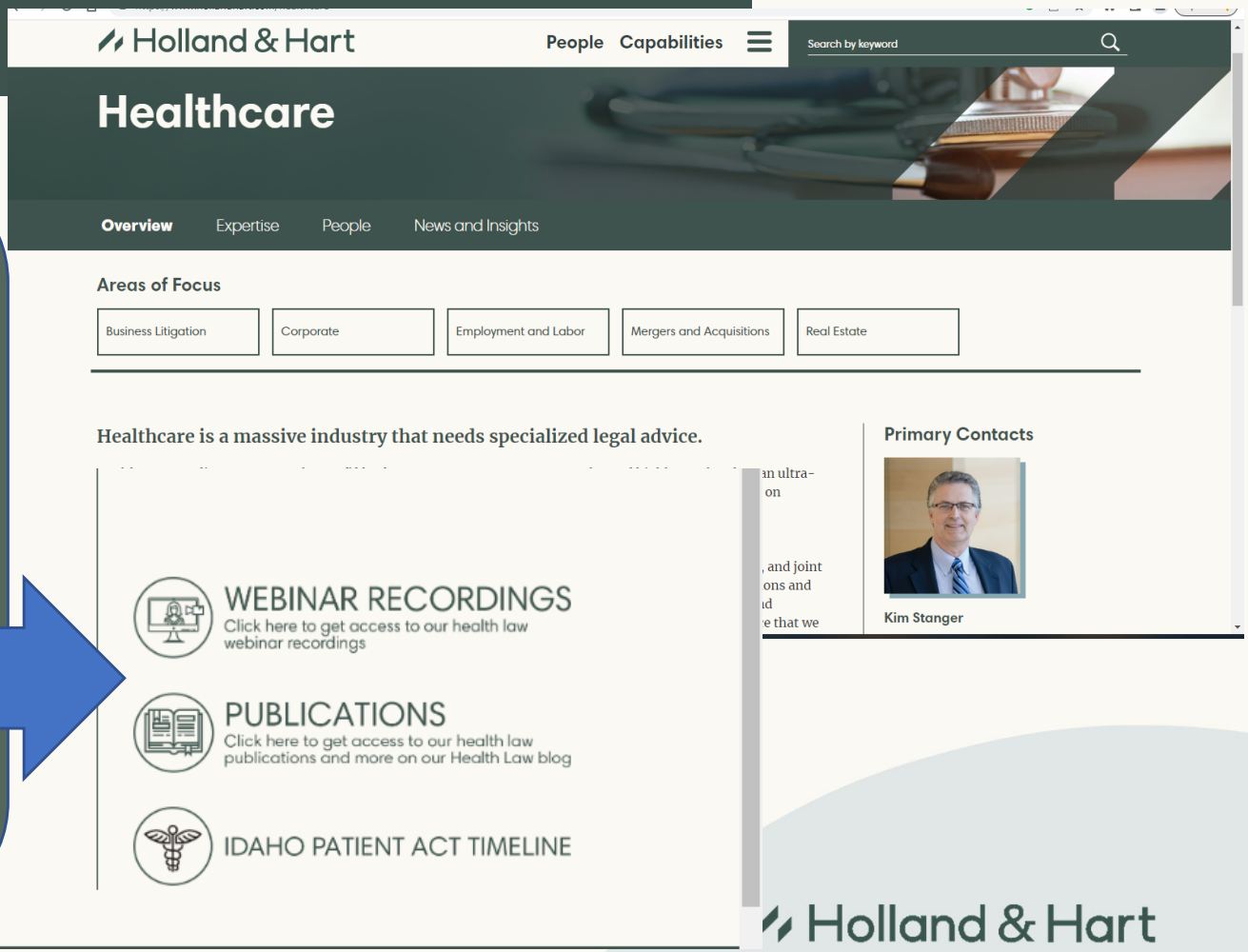
HTTPS://WWW.HOLLANDHART.COM/HEALTHCARE

Free content:

- Recorded webinars
- Client alerts
- White papers
- Other



Questions?

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