HEALTH INFO UPDATE: HIPAA, PART 2, AND INFO BLOCKING

KIM C. STANGER

(5-22)

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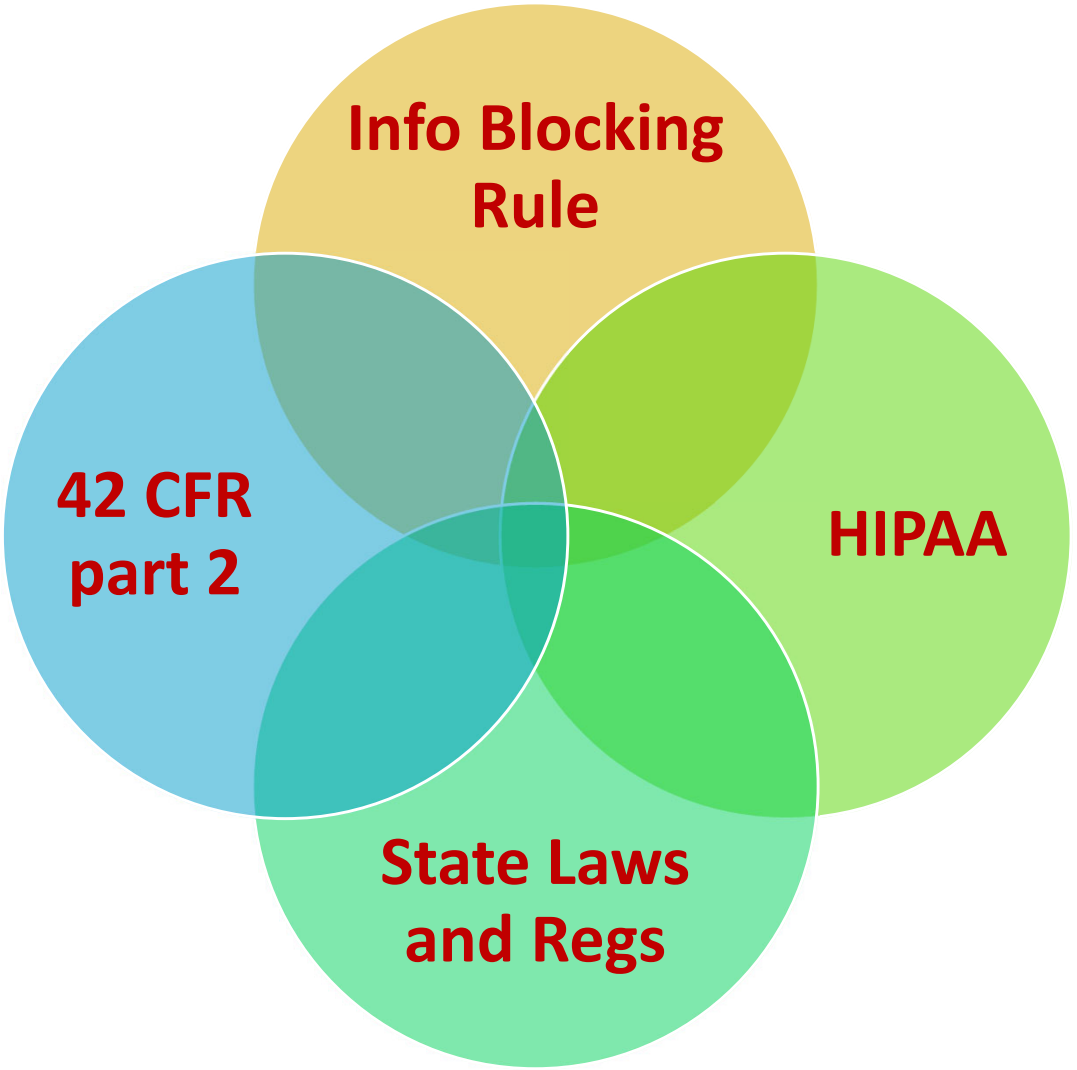
PRELIMINARIES

- This is an overview.
  - Check relevant regulations when applying.
  - Application may depend on circumstances.
  - Consider other potentially applicable regs.
- We're going to be moving fast…
- Won't cover all slides, but decided to leave slides in as a resource for you.
- If you did not receive the slides, contact cphippen@hollandhart.com.
- If you have questions:
  - Submit them using chat feature, or
  - E-mail me at kcstanger@hollandhart.com.

LAWS OVERLAP AND MAY CONFLICT



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COMPLY WITH MOST RESTRICTIVE LAW

42 CFR part 2

Info Blocking Rule

HIPAA

Other state or federal law

- Must generally comply with the most restrictive federal or state law, i.e.,
  - Law that gives greater protection to patient info, or
  - Law that gives greater control of their info to the patient.

HIPAA PRIVACY RULE, 45 CFR 164.500-.530

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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))

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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)

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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 % of penalties or settlement.
  - On 4/6/22, HHS issued request for information about issued notice soliciting input. (87 FR 19833)
- Must sanction employees who violate HIPAA.
- Possible lawsuits by affected individuals or others.
- State attorney general can bring lawsuit.
  - $25,000 fine per violation + fees and costs

HIPAA: AVOIDING CIVIL PENALTIES

You can likely avoid HIPAA civil penalties if you:

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

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

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ENTITIES SUBJECT TO HIPAA

- Covered entities
  - Health care providers who engage in certain electronic transactions.
    - Consider hybrid entities.
  - Health plans, including employee group health plans if:
    - 50 or more participants; or
    - Administered by third party (e.g., TPA or insurer).
  - Health care clearinghouses.
- Business associates of covered entities
  - Entities with whom you share PHI to perform services on your behalf.

PROTECTED HEALTH INFO

- Protected health info ("PHI") = info
  - Is created or received by a health care provider or health plan;
  - Relates to the past, present, or future physical or mental health; health care, or payment for health care to an individual; and
  - That either
    - Identifies the individual; or
    - With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(45 CFR 160.103)

NOT COVERED BY HIPAA

- Info after person has been dead for 50 years.
- Info maintained in capacity other than as provider.
  - e.g., as employment records
- "De-identified" info, i.e., remove certain identifiable info
  - Names
  - Dates
  - Telephone, fax, and e-mail
  - Social Security Number
  - Medical Record Number
  - Account numbers
  - Biometric identifiers
  - Full face photos and comparable images
  - Other unique identifying number, characteristic, or code

(45 CFR 160.103, 164.514)

Presume PHI protected by HIPAA

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USE AND DISCLOSURE RULES (45 CFR 164.502-.514)

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TREATMENT, PAYMENT OR OPERATIONS

- May use/disclose PHI without patient's authorization for your own treatment, payment, or health care operations (as defined in rules).
- May disclose PHI to another covered entity for other covered entity's treatment, payment, or certain healthcare operations if both have relationship with patient.
- Exceptions: need patient authorization if--
  - Psychotherapy notes.
  - Agree with patient not to use or disclose for treatment, payment or healthcare operations.
    - *Don't agree to limit such use or disclosure!*

(45 CFR 164.506. 164.508 and 164.522)

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PERSONS INVOLVED IN CARE

- May use or disclose PHI to family or others involved in patient's care or payment for care:
  - If patient present, may disclose if:
    - Patient agrees to disclosure or has chance to object and does not object, or
    - Reasonable to infer agreement from circumstances.
  - If patient unable to agree, may disclose if:
    - Patient has not objected; and
    - You determine it is in the best interest of patient.
  - Limit disclosure to scope of person's involvement.
- Applies to disclosures after the patient is deceased.

(45 CFR 164.510)

FACILITY DIRECTORY

- May disclose limited PHI for facility directory if:
  - Gave patient notice and patient does not object, and
  - Requestor asks for the person by name.
- If patient unable to agree or object, may use or disclose limited PHI for directory if:
  - Consistent with person's prior decisions, and
  - Determine that it is in patient's best interests
- Disclosure limited to:
  - Name
  - Location in facility
  - General condition
  - Religion, if disclosure to minister

(45 CFR 164.510)

EXCEPTIONS FOR PUBLIC HEALTH OR GOVERNMENT FUNCTIONS

- Another law requires disclosures
- Disclosures to prevent serious and imminent harm.
  - Proposed rule would make it easier to disclose.
- Public health activities
- Health oversight activities
- Judicial or administrative proceedings
  - Court order or warrant
  - Subpoenas
- Law enforcement
  - Must satisfy specific requirements
- Workers compensation

(45 CFR 164.512)

Ensure you comply with specific regulatory requirements

AUTHORIZATION

- Must obtain a valid written authorization to use or disclose protected PHI:
  - Psychotherapy notes.
  - Marketing
  - Sale of PHI
  - Research
  - For all other uses or disclosures unless a regulatory exception applies.
- Authorization may not be combined with other documents.
- Authorization must contain required elements and statements.

(45 CFR 164.508)

EMPLOYEE VACCINATIONS, TESTS, OR PHYSICALS; DRUG TESTS; IMES, ETC.

- HIPAA generally applies anytime you are rendering care as a healthcare provider, including:
  - Employee vaccinations or tests.
  - Employment physicals or drug screens.
  - Independent medical exams ("IMEs").
  - School physicals.
  - Others?
- Must have patient's authorization or HIPAA exception to use or disclose info, including use or disclosure for employment-related purposes.

(65 FR 82592 and 82640; 67 FR 53191-92)

➢ *Suggestions*
  - *Obtain authorization before providing service.*
  - *Provider may condition exam on authorization.*
  - *Employer may condition employment on authorization.*

MARKETING

- Generally need authorization for "marketing", i.e., communication about a product or service that encourages recipient to purchase or use product or service except:

Not defined as "Marketing"

  - To describe product or service provided by the covered entity,
  - For treatment or healthcare operations, or
  - For case management, care coordination, or to direct or recommend alternative treatment, therapies, providers, or setting,

  unless covered entity receives financial remuneration from third party for making the communication.

(45 CFR 164.501 and .508(a)(3))

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PERSONAL REPRESENTATIVES

- Under HIPAA, treat the personal rep as if they were the patient.
- Personal rep may exercise patient rights.
- Personal rep = persons with authority under state law to:
  - Make healthcare decisions for patient, or
  - Make decisions for deceased patient's estate.

(45 CFR 164.502(g))

- For example, in Idaho, personal reps =
  - Court appointed guardian
  - Agent in DPOA
  - Spouse
  - Adult child
  - Parent
  - Delegation of parental authority
  - Other appropriate relative
  - Any other person responsible for patient's care

(IC 39-4504)

➢ *Check your state law!*

PERSONAL REPRESENTATIVES

- Not required to treat personal rep as patient (i.e., not required to disclose PHI to them) if:
  - Minor has authority to consent to care.
  - Minor obtains care at the direction of a court or person appointed by the court.
  - Parent agrees that provider may have a confidential relationship.
  - Provider determines that treating personal representative as the patient is not in the best interest of patient, e.g., abuse.

(45 CFR 164.502(g))

HTTPS://WWW.HHS.GOV/SITES/DEFAULT/FILES/PROVIDER_FFG.PDF

provider_ffg.pdf

https://www.hhs.gov/sites/default/files/provider_ffg.pdf

A HEALTH CARE PROVIDER'S GUIDE TO THE HIPAA PRIVACY RULE:

Communicating with a Patient's Family, Friends, or Others Involved in the Patient's Care

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

This guide explains when a health care provider is allowed to share a patient's health information with the patient's family members, friends, or others identified by the patient as involved in the patient's care under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. HIPAA is a Federal law that sets national standards for how health plans, health care clearinghouses, and most health care providers are to protect the privacy of a patient's health information.[1]

Even though HIPAA requires health care providers to protect patient privacy, providers are permitted, in most circumstances, to communicate with the patient's family, friends, or others involved in their care or payment for care. This guide is intended to clarify these HIPAA requirements so that health care providers do not unnecessarily withhold a patient's health information from these persons. This guide includes common questions and a table that summarizes the relevant requirements.[2]

COMMON QUESTIONS ABOUT HIPAA

1. **If the patient is present and has the capacity to make health care decisions, when does HIPAA allow a health care provider to discuss the patient's health information with the patient's family, friends, or others involved in the patient's care or payment for care?**

   If the patient is present and has the capacity to make health care decisions, a health care provider may discuss the patient's health information with a family member, friend, or other person if the patient agrees or, when given the opportunity, does not object. A health care provider also may share information with these persons if, using professional judgment, he or she decides that the patient does not object. In either case, the health care provider may share or discuss only the information that the person involved needs to know about the patient's care or payment for care.

   Here are some examples:

   - An emergency room doctor may discuss a patient's treatment in front of the patient's friend if the patient asks that her friend come into the treatment room.

BUSINESS ASSOCIATES

- May disclose PHI to business associates if have valid business associate agreement ("BAA").

(45 CFR 164.502)

- Failure to execute BAA = HIPAA violation
  - May subject you to HIPAA fines.
    - Recent settlement: gave records to storage company without BAA: $31,000 penalty.
  - Based on OCR settlements, may expose you to liability for business associate's misconduct.
    - Turned over x-rays to vendor; no BAA: $750,000.
    - Theft of business associate's laptop; no BAA: $1,550,000.

BUSINESS ASSOCIATES

- Business associates =
  - Entities that create, receive, maintain, or transmit PHI on behalf of a covered entity.
  - Covered entities acting as business associates.
  - Subcontractors of business associates.

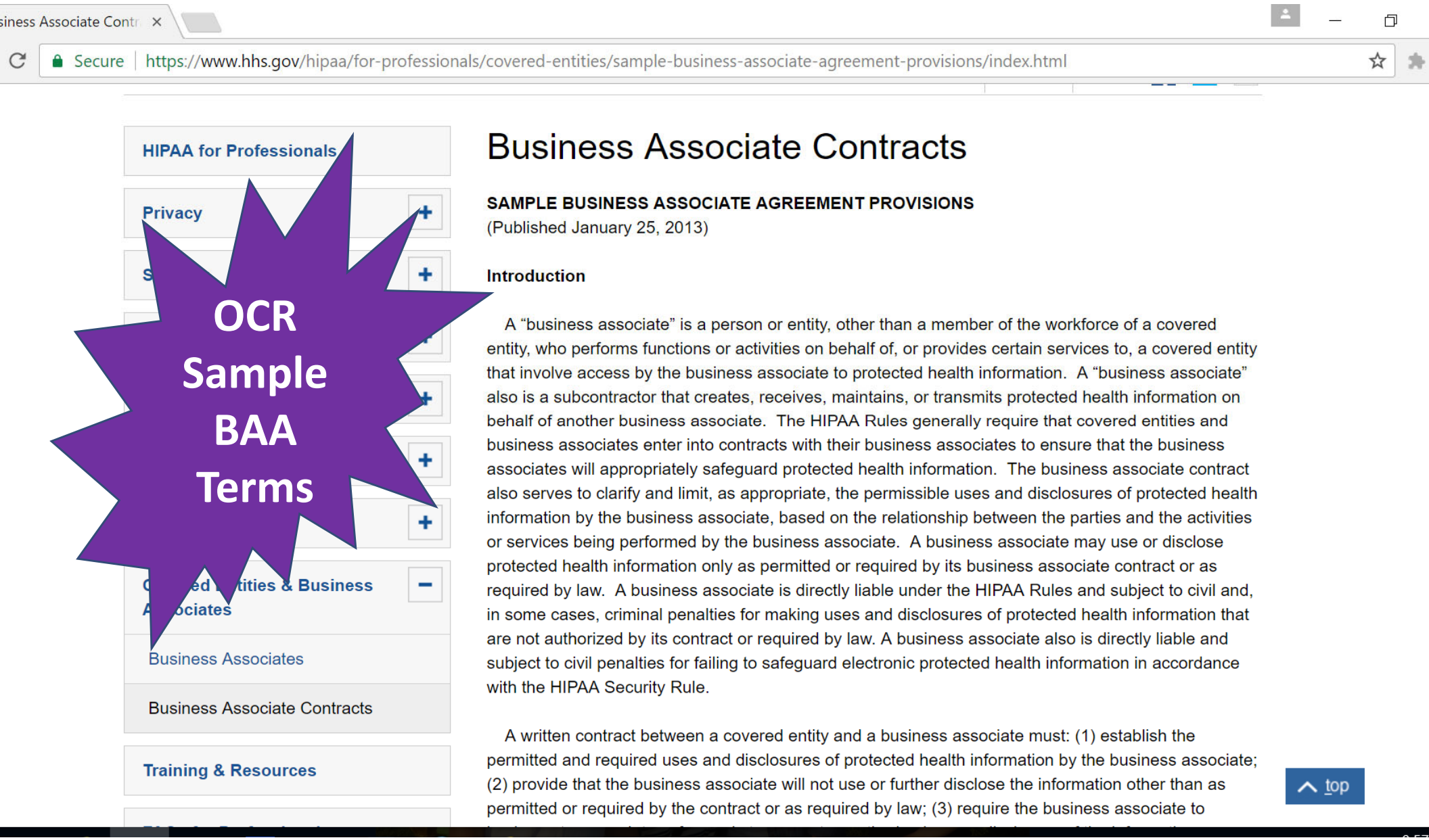
(45 CFR 160.103)

- BAAs must contain required terms and statements, e.g.,
  - Identify permissible uses
  - Pass limits to business associate and subcontractors

(45 CFR 164.314, 164.504(e))

➢ *Beware business associate's use of PHI for its own purposes.*

HTTPS://WWW.HHS.GOV/HIPAA/FOR-PROFESSIONALS/COVERED-ENTITIES/SAMPLE-BUSINESS-ASSOCIATE-AGREEMENT-PROVISIONS/INDEX.HTML



VERIFICATION

- Before disclosing PHI:
  - Verify the identity and authority of person requesting info if he/she is not known.
    - *E.g., ask for SSN or birthdate of patient, badge, credentials, etc.*
  - Obtain any documents, representations, or statements required to make disclosure.
    - *E.g., written satisfactory assurances for subpoena, representations from police that they need info for immediate identification purposes, etc.*

(45 CFR 164.514(f))

- Portals should include appropriate access controls.

(OCR *Guidance on Patient's Right to Access Their Information*)

MINIMUM NECESSARY STANDARD

- Cannot use or disclose more PHI than is reasonably necessary for intended purpose.
- Minimum necessary standard does not apply to disclosures to:
  - Patient.
  - Provider for treatment.
  - Per individual's authorization.
  - As required by law.
- Must adopt minimum necessary policies.
  - Identify those who have need to know.
  - Routine requests and routine disclosures.

(45 CFR 164.502 and .514)

PATIENT RIGHTS

- Notice of Privacy Practices
  - *Proposed rule would modify requirements to obtain acknowledgement of receipt.*
- Request restrictions on use or disclosure.
  - *Don't agree to restrictions.*
- Receive communications by alternative means.
- Access to info.
  - *OCR targeting access issues.*
  - *Consider effects of Info Blocking Rule.*
- Amendment of info.
- Accounting of disclosures of info.

(45 CFR 164.520 et. seq.)

PATIENT REQUESTS TO SEND PHI TO THIRD PARTY

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*)

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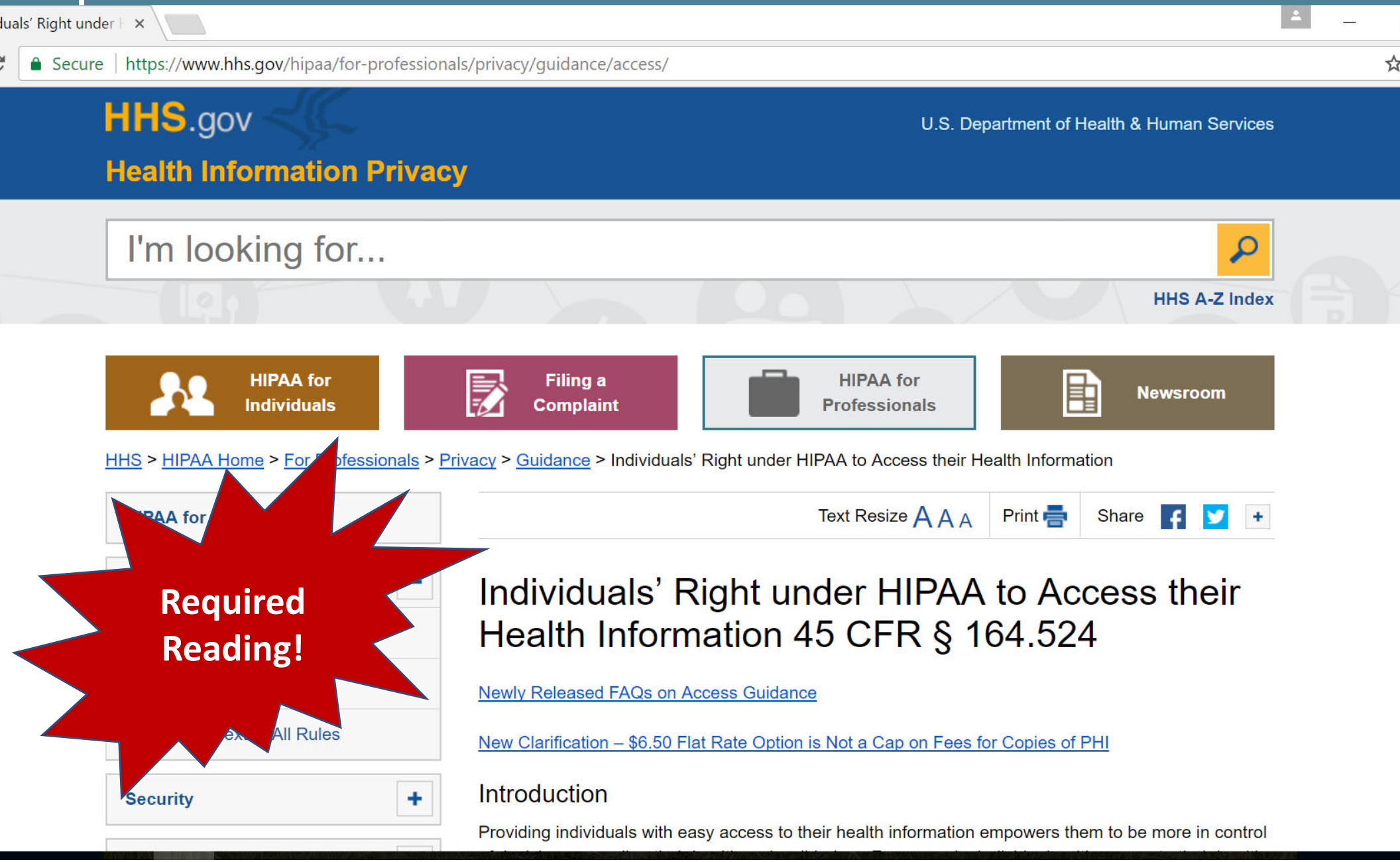

ADMINISTRATIVE REQUIREMENTS

- Designate HIPAA privacy and security officers.
- Implement policies and safeguards.
- Train workforce and document training.
- Respond to complaints.
- Mitigate violations.
- Maintain documents required by HIPAA for 6 years.
  - *E.g., NPP, authorizations, designations, notices, etc.*
  - *<u>Not</u> medical records.*

(45 CFR 164.530)

HIPAA: PROPOSED RULES

- On 1/21/21, HHS proposed significant changes to HIPAA.
  - Strengthened individual's right of access.
    - Allows individuals to take notes or use other personal devices to view and capture images of PHI.
    - Must respond 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.*

HIPAA SECURITY RULE, 45 CFR 164.300-.318

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HIPAA SECURITY RULE

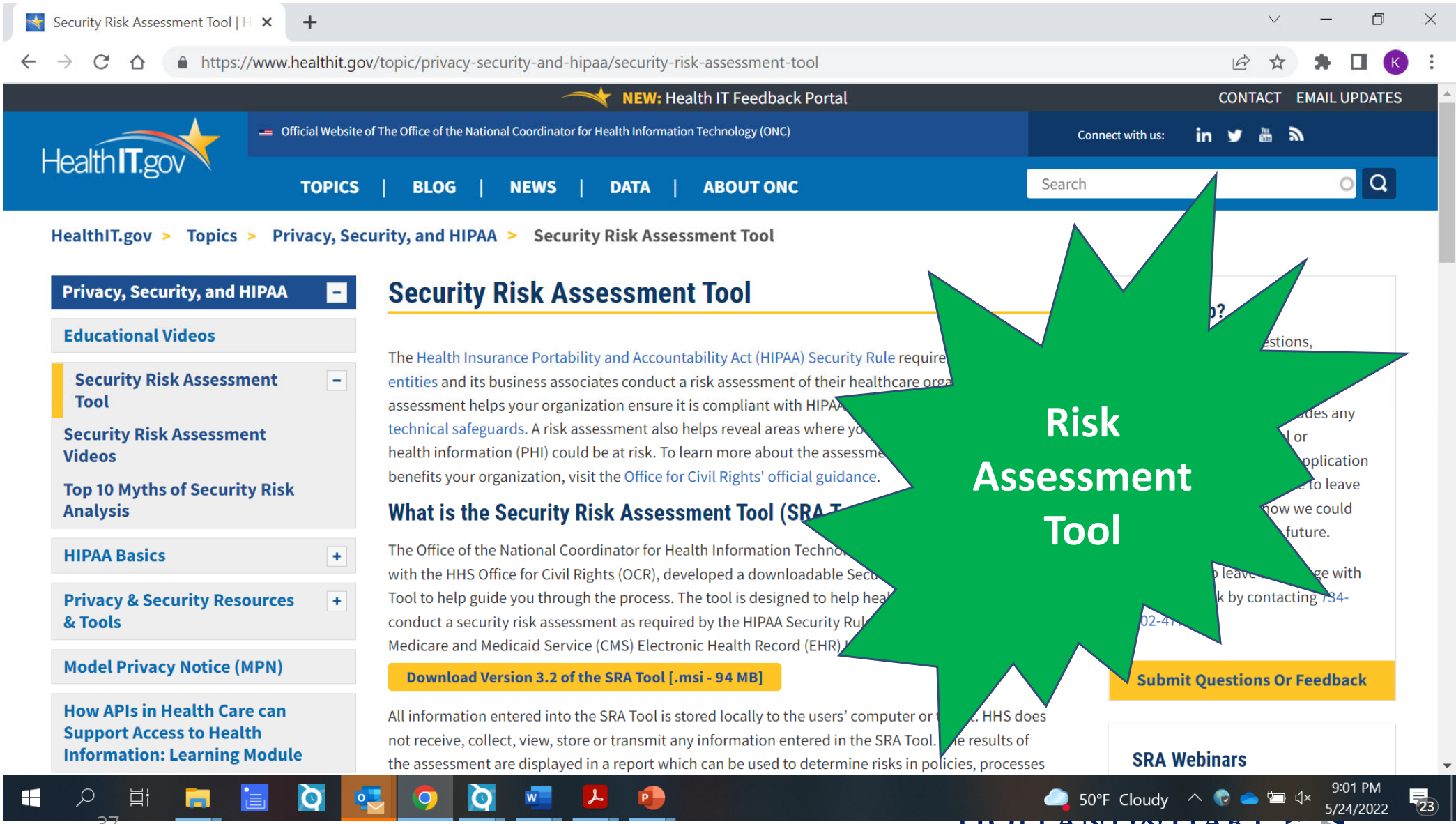
- Risk assessment
- Implement safeguards.
  - Administrative
  - Technical, including encryption
  - Physical
- Execute business associate agreements.

(45 CFR 164.300 et seq.)

Protect ePHI:

- Confidentiality
- Integrity
- Availability

HTTPS://WWW.HEALTHIT.GOV/TOPIC/PRIVACY-SECURITY-AND-HIPAA/SECURITY-RISK-ASSESSMENT-TOOL



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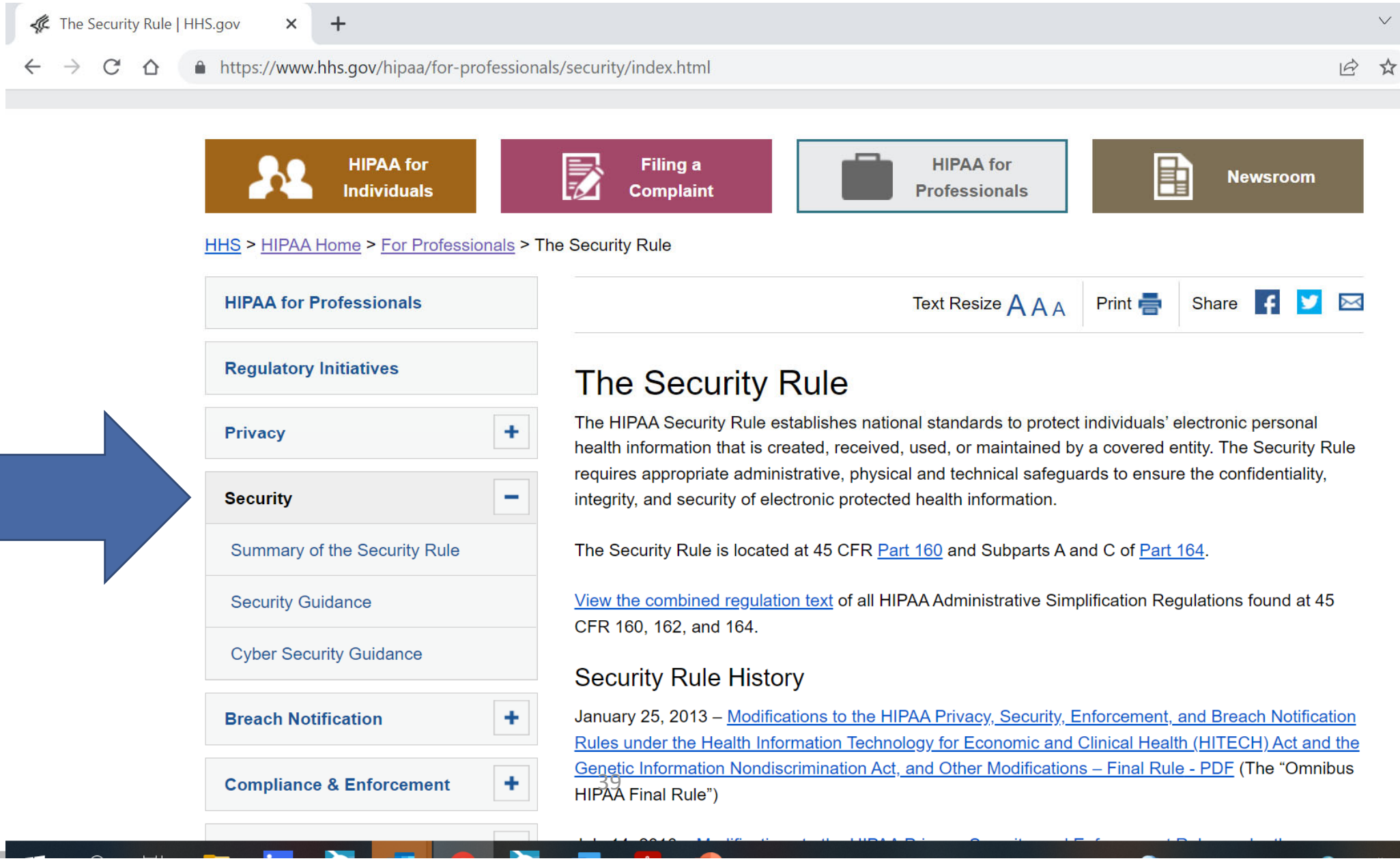


ENCRYPTION

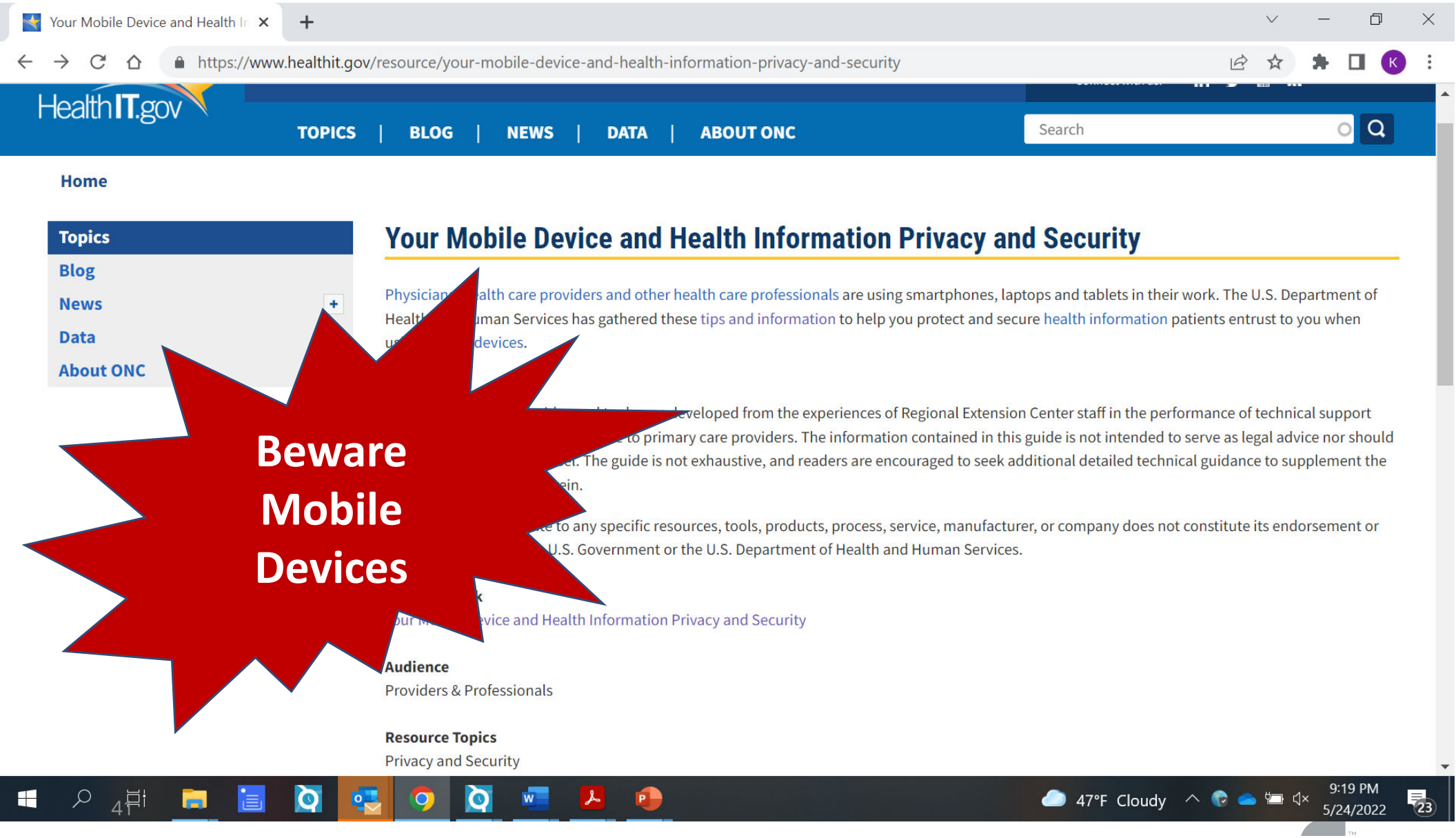
- Encryption is an addressable standard per 45 CFR 164.312:

  (e)(1) *Standard: Transmission security.* Implement technical security measures to guard against unauthorized access to [ePHI] that is being transmitted over an electronic communications network.

  (2)(ii) *Encryption (Addressable).* Implement a mechanism to encrypt electronic protected health information whenever deemed appropriate.

- ePHI that is properly encrypted is "secured".
  - *Not subject to breach reporting.*
- OCR presumes that loss of unencrypted laptop, USB, mobile device is breach.
  - *But see HHS v. M.D. Anderson (5th Cir. 2021)*

HTTPS://WWW.HEALTHIT.GOV/RESOURCE/YOUR-MOBILE-DEVICE-AND-HEALTH-INFORMATION-PRIVACY-AND-SECURITY



COMMUNICATING BY E-MAIL OR TEXT

- General rule: must be secure, i.e., encrypted.
  - To patients: may communicate via unsecure e-mail or text if warned patient and they choose to receive unsecure.

(45 CFR 164.522(b); 78 FR 5634)

  - To providers, staff or other third parties: must use secure platform.

(45 CFR 164.312; CMS letter dated 12/28/17)

  - Orders: Medicare Conditions of Participation and Conditions for Coverage generally prohibit texting orders.

(CMS letter dated 12/28/17)

CYBERSECURITY: SECURITY RULE IN ACTION…

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...

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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.

CYBERSECURITY

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

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

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

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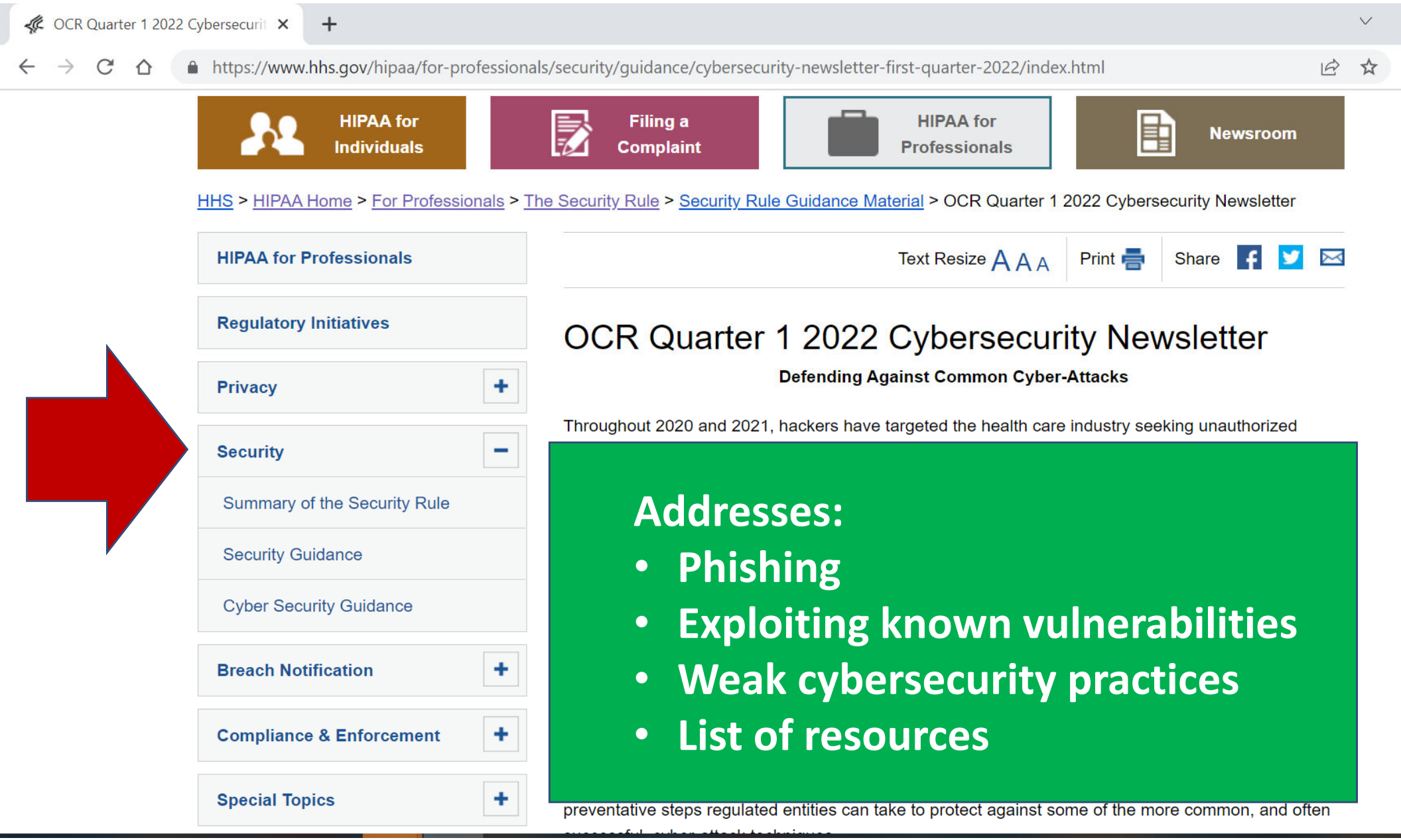

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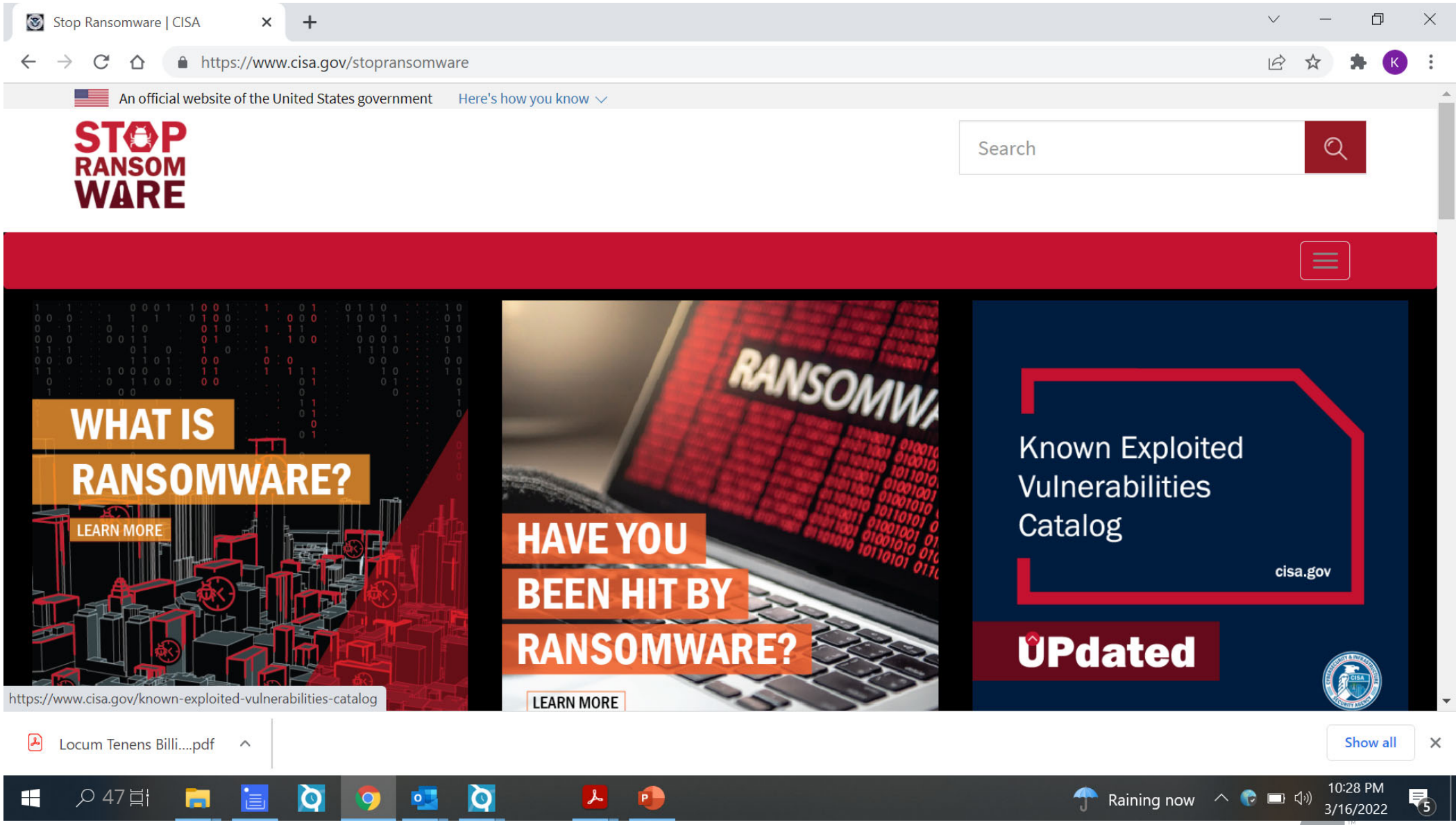
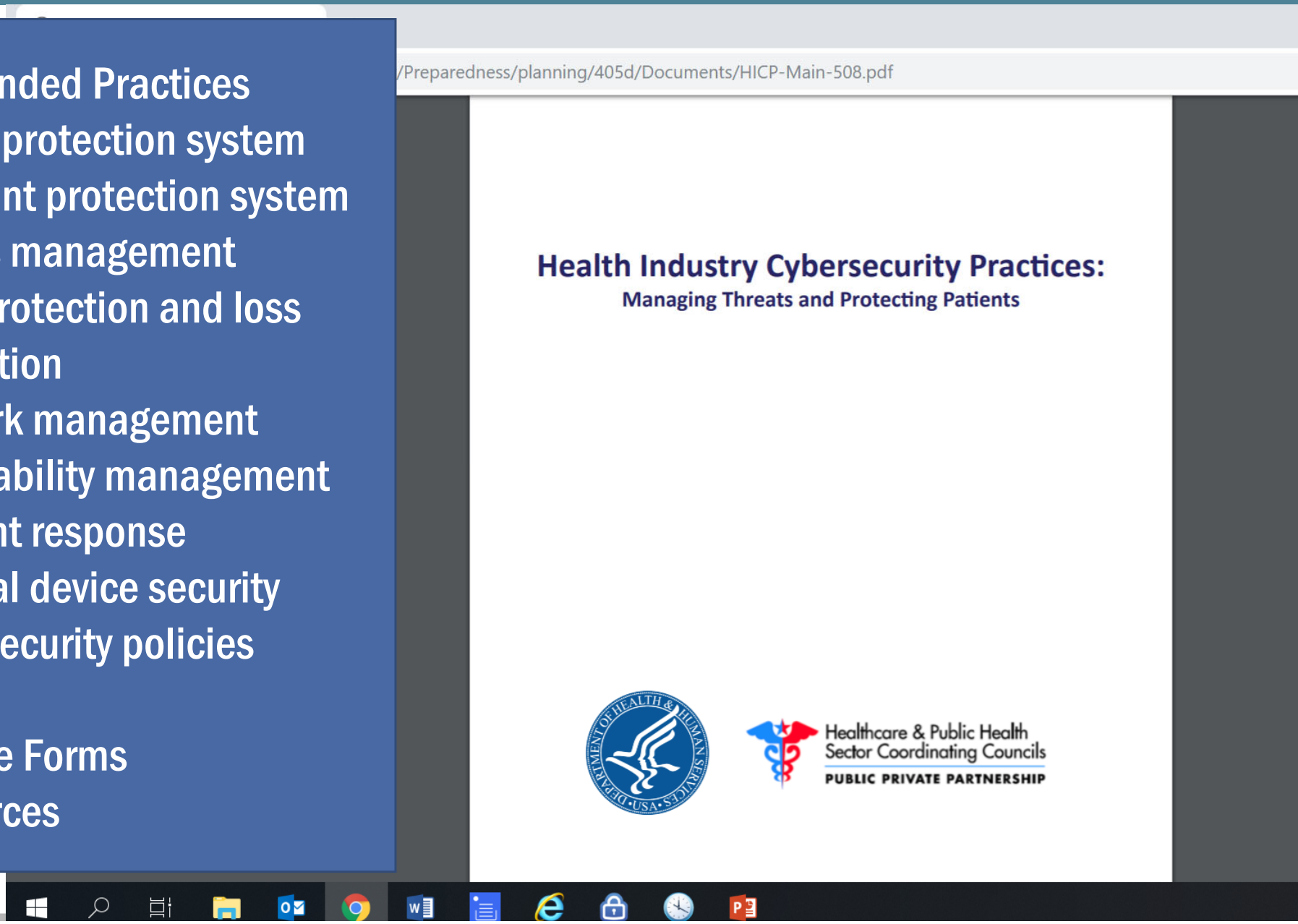


HTTPS://WWW.PHE.GOV/PREPAREDNESS/PLANNING/405D/DOCUMENTS/HICP-MAIN-508.PDF

Recommended Practices

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

- Sample Forms
- Resources



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HIPAA BREACH NOTIFICATION RULE, 45 CFR 164.400-.420

BREACH NOTIFICATION

- If there is "breach" of "unsecured PHI",
  - Covered entity must notify:
    - Each individual whose unsecured PHI has been or reasonably believed to have been accessed, acquired, used, or disclosed.
    - HHS.
    - Local media, if breach involves > 500 persons in a state.
  - Business associate must notify covered entity.

(45 CFR 164.400 et seq.)

"BREACH" OF UNSECURED PHI

- Acquisition, access, use or disclosure of PHI in violation of privacy rule is presumed to be a breach unless the covered entity or business associate demonstrates that there is a low probability that the info has been compromised based on a risk assessment of the following factors:
  - nature and extent of PHI involved;
  - unauthorized person who used or received the PHI;
  - whether PHI was actually acquired or viewed; and
  - extent to which the risk to the PHI has been mitigated,

  unless an exception applies.

(45 CFR 164.402)

NOT A "BREACH" OF UNSECURED PHI

- Loss of "secured" data, e.g., properly encrypted.
- Incidental disclosure, i.e., disclosure that is incidental to permissible disclosure so long as covered entity implemented reasonable safeguards. (45 CFR 164.502(a)(1)(iii))
- "Breach" defined to exclude:
  - Unintentional acquisition, access or use by workforce member if made in good faith, within scope of authority, and PHI not further disclosed in violation of privacy rule.
  - Inadvertent disclosure by authorized person to another authorized person at same covered entity, and PHI not further used or disclosed in violation of privacy rule.
  - Disclosure of PHI where covered entity has good faith belief that unauthorized person receiving info would not reasonably be able to retain info.

(45 CFR 164.402)

NOTICE TO INDIVIDUAL

- Without unreasonable delay but no more than 60 days of discovery.
  - When known by anyone other than person who committed breach.
- Written notice to individual.
  - By mail.
  - Must contain elements, including:
    - Description of breach
    - Actions taken in response
    - Suggested action individual should take to protect themselves.

(45 CFR 164.404(d))

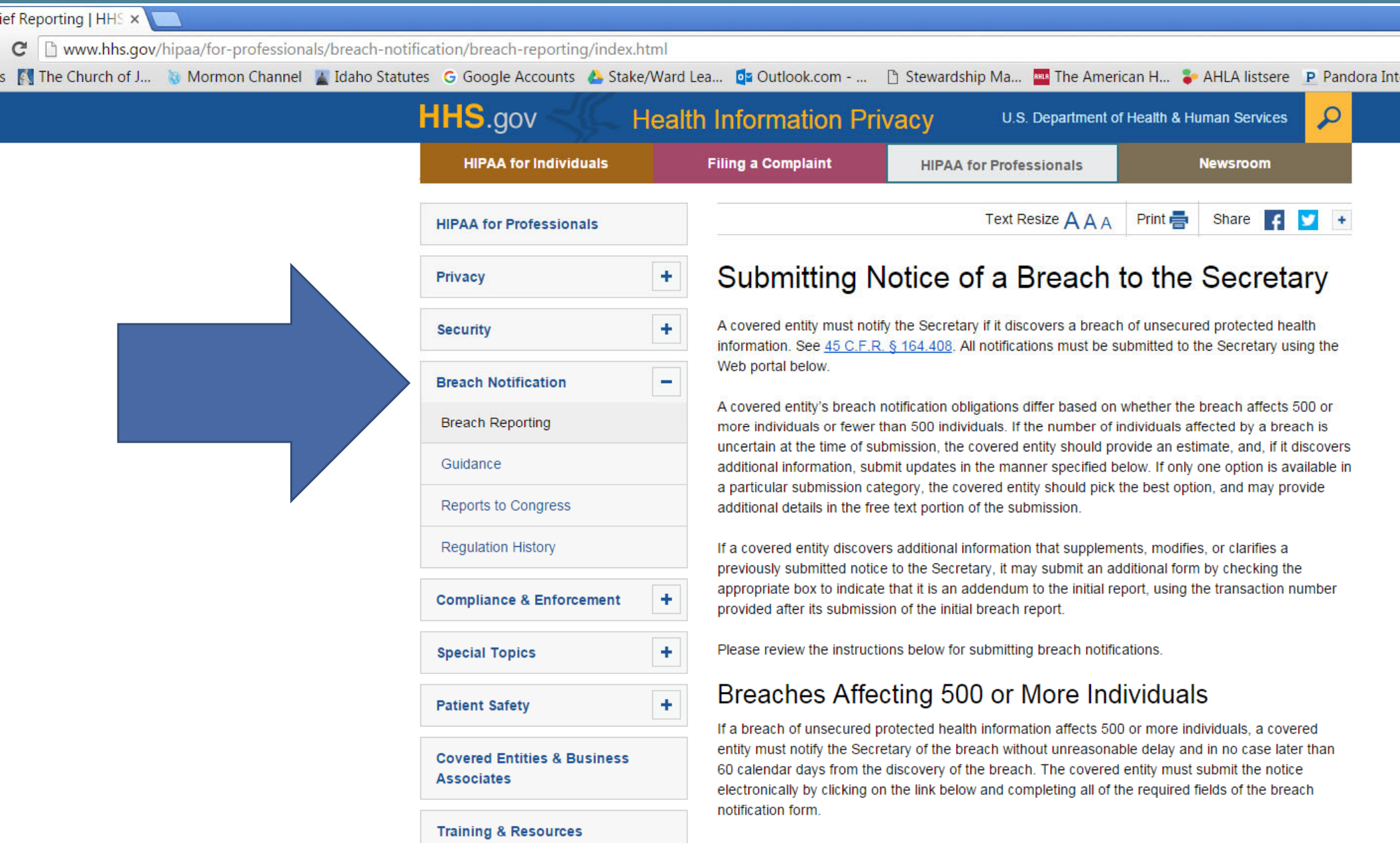
NOTICE TO HHS

- If breach involves fewer than 500 persons:
  - Submit to HHS annually within 60 days after end of calendar year in which breach was discovered (i.e., by March 1).
- If breach involves 500 or more persons:
  - Notify HHS contemporaneously with notice to individual or next of kin, i.e., without unreasonable delay but within 60 days.

(45 CFR 164.408)

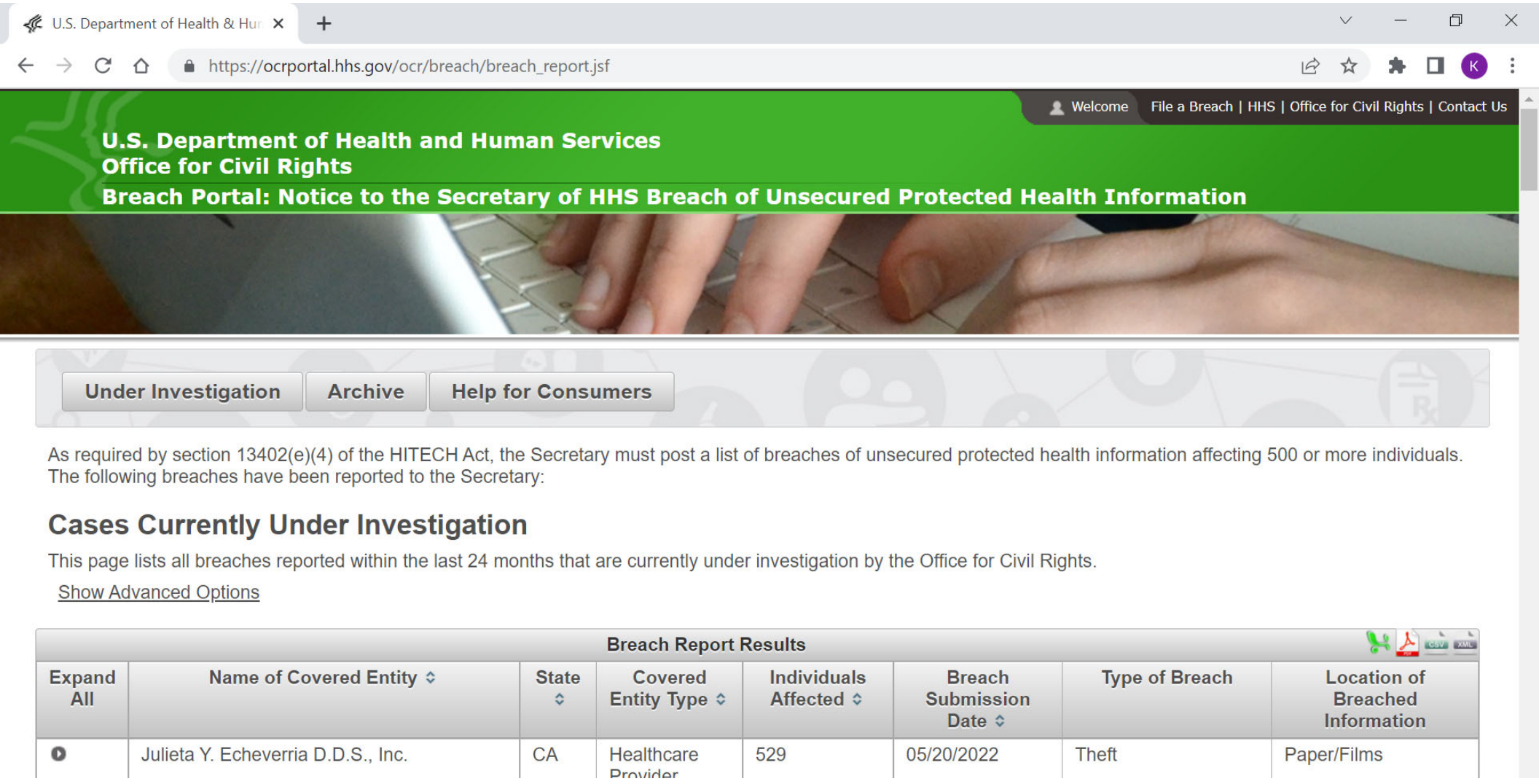
- Submit report at http://www.hhs.gov/hipaa/for-professionals/breach-notification/breach-reporting/index.html.

HTTPS://WWW.HHS.GOV/HIPAA/FOR-PROFESSIONALS/BREACH-NOTIFICATION/BREACH-REPORTING/INDEX.HTML



HHS "WALL OF SHAME"

- HHS posts list of those with breaches involving more than 500 at https://ocrportal.hhs.gov/ocr/breach/breach_report.jsfpersons



NOTICE TO MEDIA

- If breach involves unsecured PHI of more than 500 residents in a state, covered entity must notify prominent media outlets serving that state (e.g., issue press release).
  - Without unreasonable delay but no more than 60 days from discovery of breach.
  - Include same content as notice to individual.

(45 CFR 164.406)

➢ *Don't include PHI in your notice to media!*

NOTICE BY BUSINESS ASSOCIATE

- Business associate must notify covered entity of breach of unsecured PHI:
  - Without unreasonable delay but no more than 60 days from discovery.
  - Notice shall include to extent possible:
    - Identification of individuals affected, and
    - Other info to enable covered entity to provide required notice to individual.

(45 CFR 164.410)

➢ *Ensure BAA requires prompt notice of breach, e.g., within 5 business days.*

STATE BREACH REPORTING STATUTES

For example:

- Statute requires commercial entities to immediately investigate and notify subject persons if there is a
  - Breach of computer system
  - Resulting in illegal acquisition
  - Of certain unencrypted computerized personal info
    - Name + certain other identifiers (e.g., SSN, driver's license, credit card number + PIN or password, etc.)
  - Actual or reasonably likely misuse of personal info
- $25,000 fine if fail to notify persons.
- Compliance with HIPAA may satisfy Idaho statute.

(IC 28-51-104)

INFORMATION BLOCKING RULE, 45 CFR 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 RULE: 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.

INFO BLOCKING: EXAMPLES

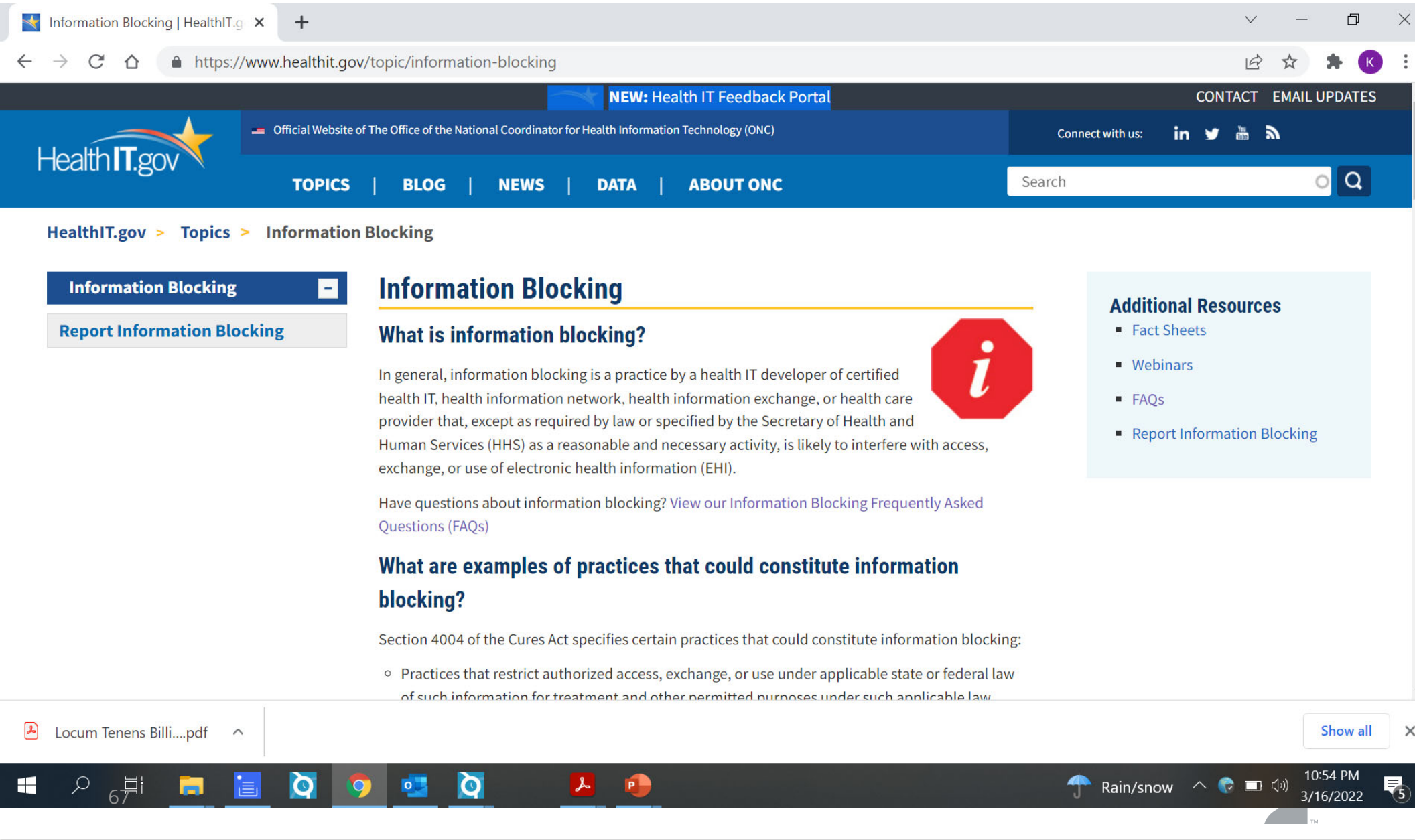
- Refusing to timely respond to requests.
- Charging excessive fees.
- Imposing unreasonable administrative hurdles.
- Imposing unreasonable contract terms, e.g., EHR agreements, BAAs, etc.
- Implementing health IT in nonstandard ways that increase the burden.
- Others?

NOT INFO BLOCKING

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

INFO BLOCKING EXCEPTIONS

HTTPS://WWW.HEALTHIT.GOV/TOPIC/INFORMATION-BLOCKING



TIME FOR RESPONDING TO PATIENT REQUESTS

"Q: 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 [IBR] do[es] 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/curesrule/resources/information-blocking-faqs).

TIME FOR RESPONDING TO PATIENT REQUESTS

"Q: When would a delay in fulfilling a request for access [to] EHI be considered an interference under the [IBR]?

"A determination as to whether a delay would be an interference … would require a fact-based, case-by-case assessment of the circumstances….

"Likely to be an Interference: … if a health care provider established [a] policy that … 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…. [I]t also would likely be considered an interference

- where a delay in providing access … 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/curesrule/resources/information-blocking-faqs).

TIME FOR RESPONDING TO PATIENT REQUESTS

- **"Q: 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….

(https://www.healthit.gov/curesrule/resources/information-blocking-faqs)

INFO BLOCKING RULE AND HIPAA

If HIPAA allows access or disclosure:

- IBR prohibits info blocking.
- IBR may require provider to allow access or disclosure even if HIPAA does not require it, e.g.,
  - Treatment, payment, operations.
  - Authorization.
- IBR may require quicker response than HIPAA.
  - > 30 days.

If HIPAA or other law prohibits disclosure:

- Not info blocking if conditions for access or disclosure are not satisfied, e.g.,
  - Patient consent.
  - Patient authorization.
  - Confirmation that HIPAA exception allows disclosure.

42 CFR PART 2

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SUBSTANCE USE DISORDER RECORDS

- 42 USC 290dd
- CARES Act 3221
- Confidentiality of Substance Use Disorder Patient Records, 42 CFR part 2
- HIPAA privacy and security regulations, 45 CFR part 164
- Other federal and state laws, e.g.
  - Information Blocking Rule
  - State laws re access or disclosure of SUD records

CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS, 42 CFR PART 2

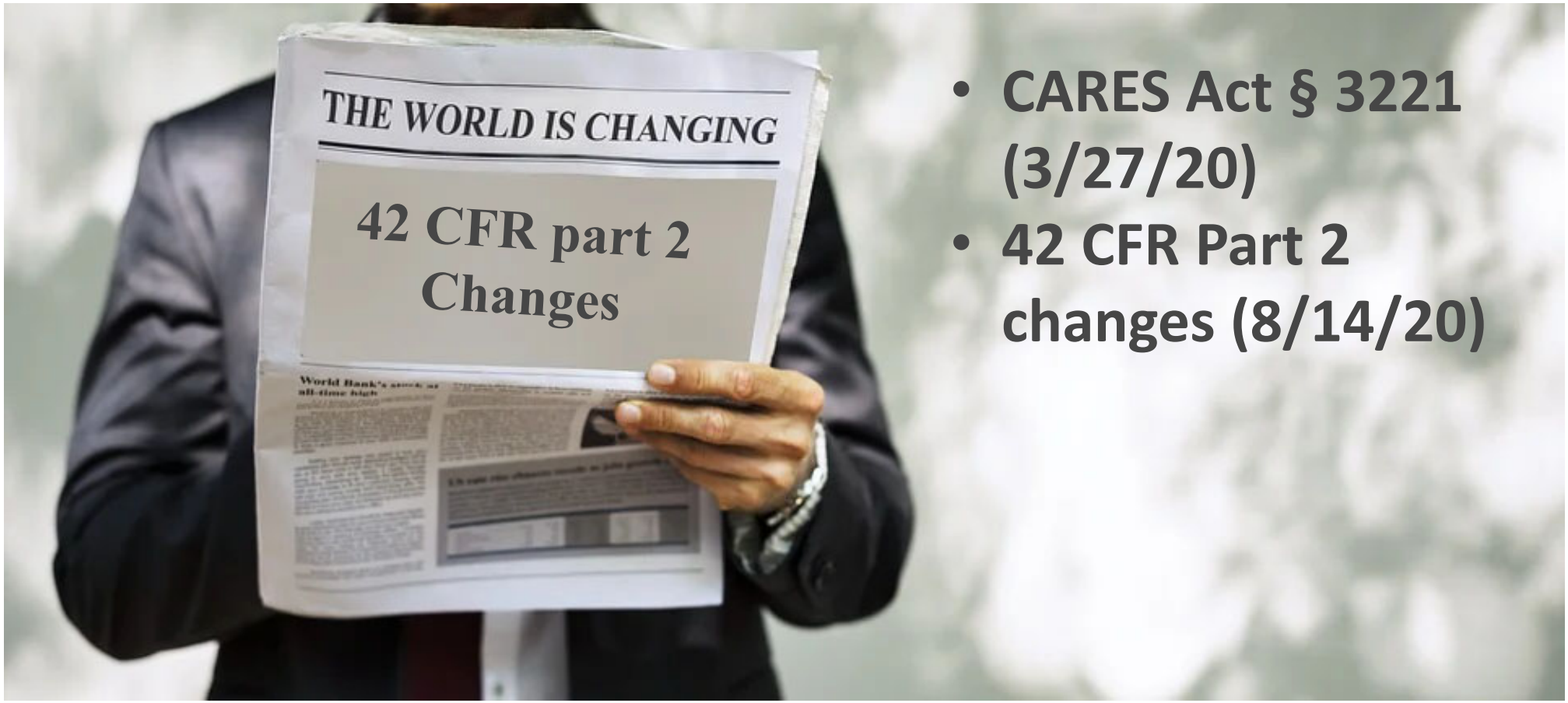
Purpose

- To encourage persons to obtain treatment for a substance use disorder ("SUD") by limiting disclosure of info relating to their treatment.

Requirements

- In general, part 2 programs may not disclose any info that would identify a person as having, or having had, or being referred to a substance use disorder unless the person provides written consent or an exception applies.
- Certain entities to whom program discloses info must comply with part 2.

42 CFR PART 2 UPDATE



- CARES Act § 3221 (3/27/20)
- 42 CFR Part 2 changes (8/14/20)

CARES ACT § 3221

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

(CARES Act 3221, amending 42 USC 290dd)

REVISED 42 CFR PART 2 REGS (EFFECTIVE 8/14/20)

- ***SAMHSA has not issued regs to implement Cares Act CARES Act § 3221.***

- SAMSHA did issue regs to implement rules proposed in 2019 to facilitate coordinated care.
  - Limits application to non-part 2 providers who record oral info or segregate part 2 records.
  - Consent requirements relaxed.
  - Easier to disclose to central registries and prescription drug monitoring programs.
  - Exception for medical emergencies expanded.
  - Modifies rules for research disclosures.
  - Modifies rules for audit disclosures.

(85 FR 42986 (7/15/20))

APPLICABILITY: 42 CFR PART 2

- Generally prohibits use or disclosure of records without patient consent if:
  - Record identifies a patient as having, having had, or referred for a substance use disorder ("SUD"); and
  - SUD record is created, obtained, or maintained by a federally assisted drug or alcohol abuse program.

(42 CFR 2.12(a))

- "SUD" = cluster of cognitive, behavioral and physiological symptoms indicating that the patient continues using substance despite significant substance-related problems such as impaired control, social impairment, risky use, tolerance and withdrawal.

(42 CFR 2.11)

APPLICABILITY: "FEDERALLY ASSISTED" PROGRAM

- "Federally assisted" =
  - Carried out under license or authorization granted by U.S. department or agency (e.g., participating in Medicare, DEA registration, etc.);
  - Supported by funds provided by a U.S. department or agency (e.g., receiving federal financial assistance, Medicaid, grants, etc.);
  - Program is tax-exempt or claims tax deductions relating to program; or
  - Conducted directly or by contract or otherwise by any dept or agency of the United States (but see rules re VA or armed forces).

(42 CFR 2.12(b))

- Not purely private pay programs.
  - *But HIPAA may still apply.*

APPLICABILITY: FEDERALLY ASSISTED "PROGRAM"

- "Program" =
  - Individual or entity (other than general medical facility*) that holds itself out as providing and provides SUD diagnosis, treatment or referral.
  - Identified unit in a general medical facility* that holds itself out as providing and provides SUD diagnosis, treatment or referral.
  - Medical personnel in a general medical facility* whose primary function is providing SUD diagnosis, treatment or referral and who are identified as such providers.

(42 CFR 2.11; 2.12(e))

* "General medical facilities" = hospitals, trauma centers, FQHCs, maybe primary care practice, etc.

(SAMHSA FAQ 10, https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs)

APPLICABILITY: FEDERALLY ASSISTED "PROGRAM"

Individual or Entity; <u>Not</u> General Medical Facility	**General Medical Facility**	
	Identified Unit	Medical Personnel or Staff
1. Holds itself out as providing SUD diagnosis, treatment, or referral for treatment, *and* 2. Provides SUD diagnosis, treatment, or referral for treatment	1. Holds itself out as providing SUD diagnosis, treatment, or referral for treatment, *and* 2. Provides SUD diagnosis, treatment, or referral for treatment	1. Primary function is to provide SUD diagnosis, treatment or referral for treatment, *and* 2. Identified as such providers

APPLICABILITY: FEDERALLY ASSISTED "PROGRAM"

- "Hold self out" = activity that would lead one to reasonably conclude that the individual or entity provides SUD diagnosis, treatment, or referral for treatment, e.g., through advertising or marketing.

(42 CFR 2.11; 2.12(e))

- May include state licensing procedures, advertising or posting notices, certifications in addiction medicine, listings in registries, internet statements, consultation activities for non-"program" practitioners, info presented to patients or families, etc.

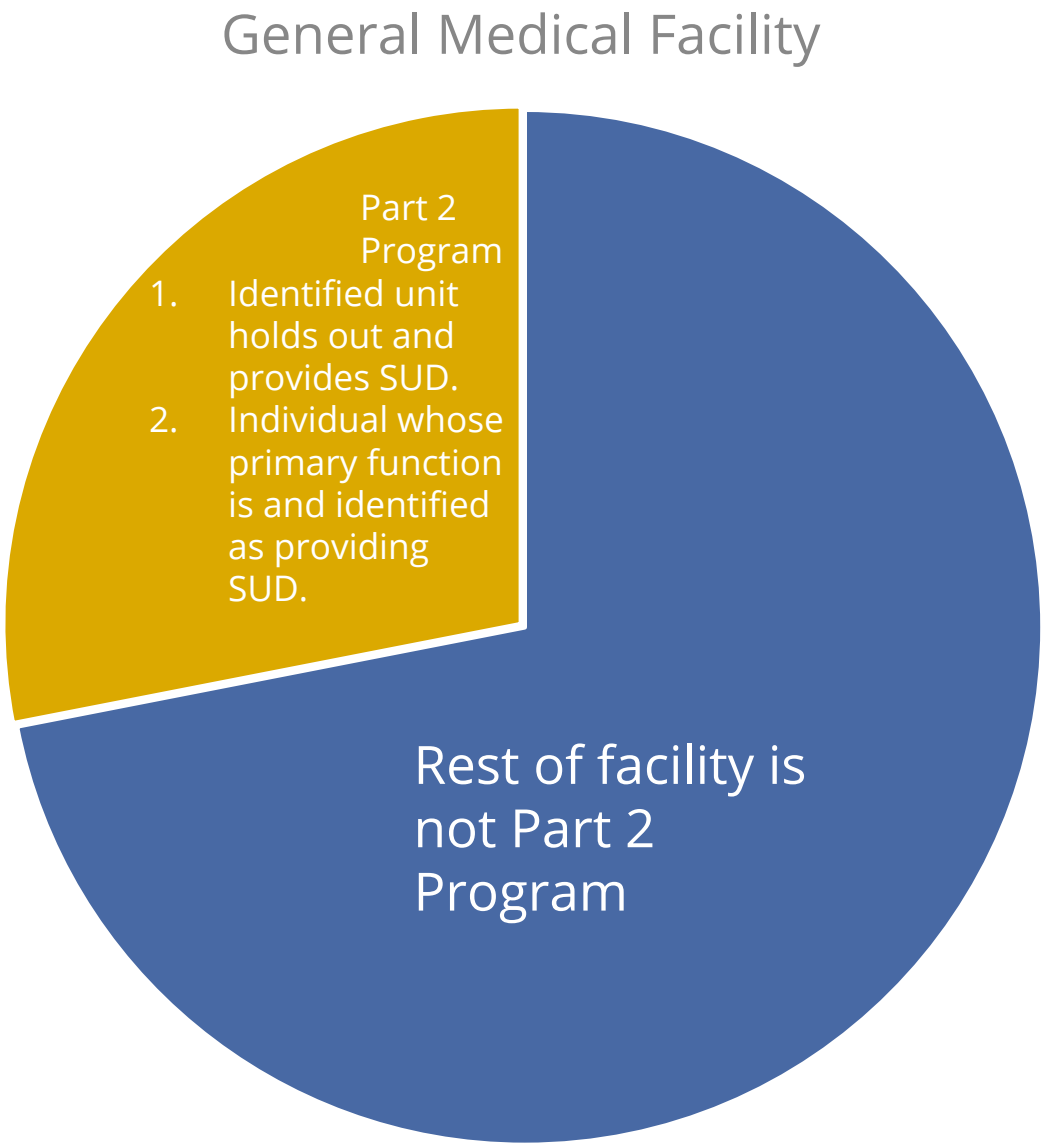
(SAMHSA FAQ 10, at https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs)

APPLICABILITY: FEDERALLY ASSISTED "PROGRAM"

- Part 2 program is not:
  - Emergency room personnel who treat overdose.
  - Providers who prescribe controlled substances to treat SUD but who do not hold themselves out as providing SUD treatment.

(SAMHSA FAQ 10, at https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs)

APPLICABILITY: FEDERALLY ASSISTED PROGRAM



- Only the SUD unit/provider is the "program".
- Program must comply with part 2 in disclosing SUD info outside the program, e.g.,
  - Per consent
  - To administrative control
  - To QSO
  - Other exception
- Program must have administrative controls in place to share SUD info.

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ENTITIES THAT MUST MAINTAIN CONFIDENTIALITY

- Prohibition against disclosure applies to:
  - Part 2 program.
  - Entities having direct administrative control over the part 2 program.
  - "Lawful holders", e.g., persons who appropriately:
    - Receive SUD info from a part 2 program, and
    - Receive required notice prohibiting redisclosure.

(42 CFR 2.12(d)(2), as amended)

DISCLOSURE OF SUD INFO

With patient's written consent

- For treatment, payment or healthcare operations.
- For other purposes specified in consent.
- Consent must contain required elements.
- Must include notice prohibiting redisclosure.

(CARES Act 3221; 42 CFR 2.31-2.33)

➢ *Compare HIPAA.*

Without patient's written consent

- Within part 2 program if need to know.
- To those with administrative control over program.
- Qualified Service Organization ("QSO") if have QSOA agreement ("QSOA")
- Medical emergency.
- Report to law enforcement if crime on premises or threat against program personnel.
- Report child abuse.
- Research subject to conditions.
- Audits and investigations subject to conditions.
- Per compliant order + subpoena.

NOTICE OF REDISCLOSURE

- If disclose with written consent, must include one of these notices with the SUD records produced:
  - "This record which has been disclosed to you is protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of this record unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or, is otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see §2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§2.12(c)(5) and 2.65."

  or

  - "42 CFR part 2 prohibits unauthorized disclosure of these records."

(42 CFR 2.32, as amended)

LIMITS ON DISCLOSURE

- Any disclosure of SUD records must be limited to that info which is necessary to carry out the purpose of the disclosure.

(42 CFR 2.13(a))

➢ *Similar to HIPAA "minimum necessary" standard.*

LAWFUL HOLDERS AND AGREEMENTS

- If patient gives written consent to disclosures for payment or healthcare operations, recipient ("lawful holder") may further disclose to contractors, subs and legal representatives to carry out such purposes if:
  - Have written contract or other legal instrument by which contractor is bound by part 2.
  - Furnish notice of redisclosure.
  - Require recipient to implement appropriate safeguards to protect info.
  - Require recipient to report unauthorized uses, disclosures, or breaches.
  - Lawful holder discloses only minimum necessary.
  - Recipient may only further disclose to contracted entity to help them fulfill purposes of disclosure by lawful holder.

(42 CFR 2.33(b)-(c))

LAWFUL HOLDERS: DISCLOSURE FOR PAYMENT OR OPERATIONS

- Billing, claims, collections, etc.
- Clinical professional support, e.g., QA, utilization review, etc.)
- Patient safety activities
- Peer review, training, assessments, etc.
- Accreditation, certification, licensing, credentialing, etc.
- Underwriting, enrollment, premium rating, etc.
- Third party liability coverage.
- Address fraud, waste, abuse.
- Medical review, legal, auditing.
- Business planning, development
- Business management and general administrative duties.
- Customer service.
- Resolution of internal grievances.
- Sale, transfer, merger, dissolution.
- Determine eligibility of coverage, claims adjudication, subrogation.
- Review of medical necessity, coverage.
- Care coordination and/or case management.
- Others.

(42 CFR 2.33(b), as amended)

SUBPOENAS AND ORDERS

May disclose SUD info if have:

- Subpoena + court order authorizing disclosure.
  - Protect life or serious bodily injury.
  - Extremely serious crime committed by patient.
  - Criminal prosecution.
  - Investigate part 2 program.
- Regulations have specific process for obtaining order, including notice to holder of record.

(42 CFR 2.61-2.67)

➢ *May need to seek compliant order for certain disclosures.*

➢ *Must challenge non-compliant subpoena or order.*

NOTICE OF CONFIDENTIALITY PROTECTIONS

- Upon admission (or if patient lacks capacity at the time as soon as patient gains capacity) program must:
  - Communicate federal laws and regulations protecting SUD info.
  - Give patient written summary of laws and regulations, including:
  - Describe limited situations in which part 2 program may acknowledge that patient is present or disclose SUD.
  - State that violation of law is a crime + contact info for reports.
  - State that info related to patients' commission of crime on the part 2 premises or against part 2 personnel is not protected.
  - State that reports of child abuse and neglect are not protected.
  - Cite federal laws and regulations.

(42 CFR 2.22)

PATIENT ACCESS TO RECORDS

- May provide a patient with a copy of or access to the patient's own records.
- No written consent is required to disclose the patient's info to the patient.

(42 CFR 2.23)

But remember:

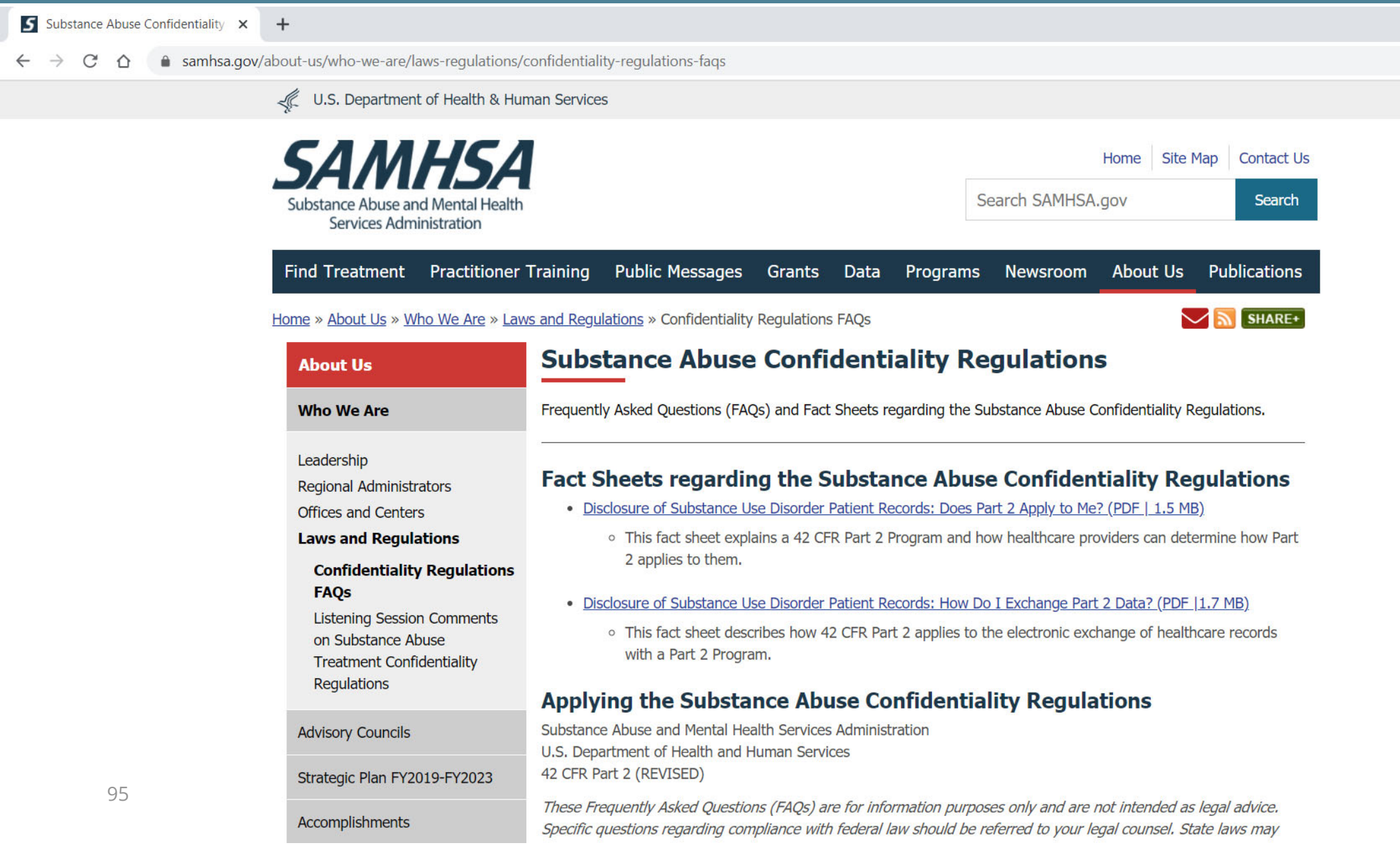
- HIPAA generally requires "covered entities" to allow patient access to protected health info in a designated set unless exceptions satisfied. (45 CFR 164.524)
- Information Blocking Rule prohibits "actors" from blocking access to electronic health info unless exceptions satisfied. (45 CFR part 171)

SECURITY

- Part 2 programs and lawful holders must have formal policies and procedures to reasonably protect against unauthorized use or disclosure of SUD info or threats to security of SUD info.
- Policies and procedures must address:
  - Transfer and removing records.
  - Destroying records, including sanitizing media.
  - Maintaining records in secure room, locked file cabinet, safe, or similar container or storage facility when not in use.
  - Using and accessing workstations, secure rooms, locked file cabinets, safes, or similar containers or storage facilities.
  - De-identification of records.

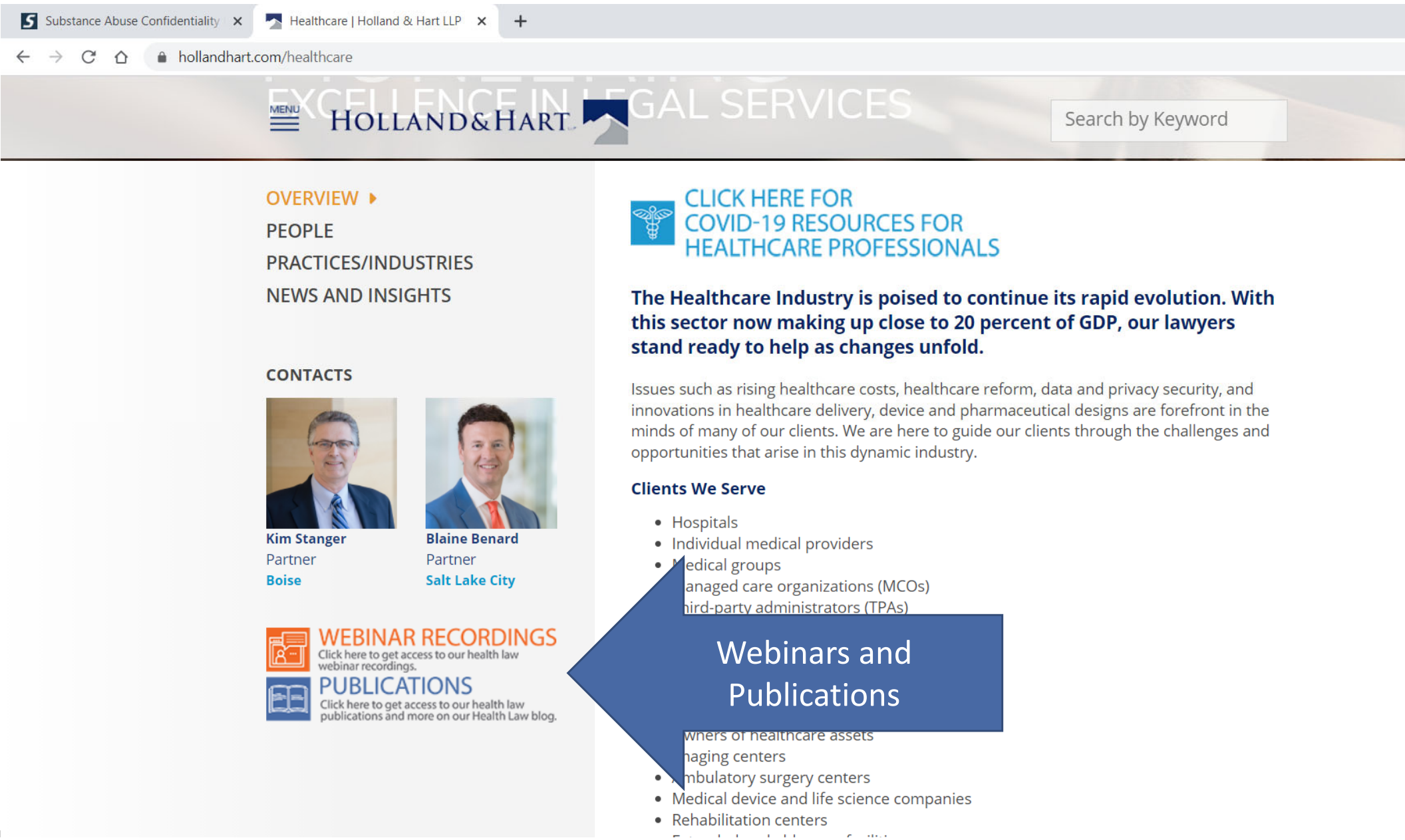
(42 CFR 2.16)

WWW.SAMHSA.GOV/ABOUT-US/WHO-WE-ARE/LAWS-REGULATIONS/CONFIDENTIALITY-REGULATIONS-FAQS



ADDITIONAL RESOURCES

WWW.HOLLANDHART.COM/HEALTHCARE



QUESTIONS?

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