RECENT RULES AFFECTING PHYSICIAN PRACTICES

- **Vaccine Mandates**
- **No Surprise Billing**
- **Information Blocking**

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10-21

HOLLAND&HART LLP

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VACCINE MANDATES FOR HEALTHCARE WORKERS

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VACCINE MANDATES

Federal Mandates

- Healthcare workers
  - CMS rules
- Employers with more than 100 employees
  - OSHA rules
- Federal workers and contractors
  - Executive Order

Other Mandates

- State mandates
- Private employer mandates

➢ ***Providers may be subject to more than one mandate.***

THE WHITE HOUSE

Administration Priorities COVID Plan Briefing Room Español MENU

September 9, 2021

PATH OUT OF THE PANDEMIC

PRESIDENT BIDEN'S COVID-19 ACTION PLAN

Requiring All Employers with 100+ Employees to Ensure their Workers are Vaccinated or Tested Weekly

Requiring Vaccinations for all Federal Workers and for Millions of Contractors that Do Business with the Federal Government

Requiring COVID-19 Vaccinations for Over 17 Million Health Care Workers at Medicare and Medicaid Participating Hospitals and Other Health Care Settings

Calling on Large Entertainment Venues to Require Proof of Vaccination or Testing for Entry

Requiring Employers to Provide Paid Time Off to Get Vaccinated

HEALTHCARE VACCINE MANDATE: TO WHOM DOES IT APPLY?

Applies to:

- Hospitals
- Nursing facilities
- Ambulatory surgery centers (ASCs)
- Dialysis facilities
- Home health agencies
- Other participating "facilities"

<u>May</u> not apply to:

- Healthcare providers that are not associated with a participating "facility", e.g.,
  - Physician groups
  - Non-participating providers

(https://www.whitehouse.gov/covidplan/#vaccinate)

HEALTHCARE VACCINE MANDATE: TO WHOM DOES IT APPLY?

"[CMS]" is taking action to require COVID-19 vaccinations for workers in most health care settings that receive Medicare or Medicaid reimbursement, including but not limited to hospitals, dialysis facilities, ambulatory surgical settings, and home health agencies. This action builds on the vaccination requirement for nursing facilities recently announced by CMS…."

(White House Website, https://www.whitehouse.gov/covidplan/#vaccinate)

HEALTHCARE VACCINE MANDATE: TO WHOM DOES IT APPLY?

"My plan will extend the vaccination requirements that I previously issued in the healthcare field. Already, I've announced, we'll be requiring vaccinations that all nursing home workers who treat patients on Medicare and Medicaid.....

"Tonight, I'm using that same authority to expand that to cover those who work in hospitals, home healthcare facilities, or other medical facilities –- a total of 17 million healthcare workers.

"If you're seeking care at a health facility, you should be able to know that the people treating you are vaccinated. Simple. Straightforward. Period."

(Pres. Biden, 9/9/21, https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/)

HEALTHCARE VACCINE MANDATE: TO WHOM DOES IT APPLY?

- "The Biden-Harris Administration will require COVID-19 vaccination of staff within all Medicare and Medicaid-certified facilities… Facilities across the country should make efforts now to get health care staff vaccinated to make sure they are in compliance when the rule takes effect.
- "[E]mergency regulations requiring vaccinations for nursing home workers will be expanded to include hospitals, dialysis facilities, ambulatory surgical settings, and home health agencies, among others, as a condition for participating in the Medicare and Medicaid programs.
- "CMS will continue to work closely with all Medicare and Medicaid certified facilities to ensure these new requirements are met."

(https://www.cms.gov/newsroom/press-releases/biden-harris-administration-expand-vaccination-requirements-health-care-settings)

HEALTHCARE VACCINE MANDATE: TO WHOM DOES IT APPLY?

"Facilities" at https://www.cms.gov/Outreach-and-Education/Find-Your-Provider-Type/Facilities/Facilities-page

- Hospitals
- Critical Access Hospitals (CAHs)
- Inpatient Rehabilitation Facilities (IRFs)
- Ambulatory Surgical Centers (ASCs)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Federally Qualified Health Centers (FQHCs)
- Rural Health Clinics (RHCs)
- Long-term care facilities & Skilled Nursing Facilities (SNFs)
- Durable medical equipment suppliers (DMEs)
- Pharmacy
- Durable medical equipment, prosthetics, & orthotics (DMEPOS)
- Home Health Agencies (HHAs)
- Hospice
- Clinical labs
- Ambulance

HEALTHCARE VACCINE MANDATE: TO WHOM DOES IT APPLY?

The mandate "will apply to nursing home staff as well as staff in hospitals and other CMS-regulated settings, including clinical staff, individuals providing services under arrangements, volunteers, and staff who are not involved in direct patient, resident, or client care. These requirements will apply to approximately 50,000 providers and cover a majority of health care workers across the country…."

(White House Website, https://www.whitehouse.gov/covidplan/#vaccinate)

HEALTHCARE VACCINE MANDATE: WHEN DOES IT TAKE EFFECT?

- "CMS is developing an Interim Final Rule with Comment Period that will be issued in October.
- "CMS expects certified Medicare and Medicaid facilities to act in the best interest of patients and staff by complying with new COVID-19 vaccination requirements. Health care workers employed in these facilities who are not currently vaccinated are urged to begin the process immediately. Facilities are urged to use all available resources to support employee vaccinations, including employee education and clinics, as they work to meet new federal requirements."

(https://www.cms.gov/newsroom/press-releases/biden-harris-administration-expand-vaccination-requirements-health-care-settings)

- CMS representative reportedly confirmed the rule would be subject to 60-day comment period before it takes effect.

HEALTHCARE VACCINE MANDATE: PENALTIES FOR VIOLATION?

- Don't know…
- Violation of Medicare conditions
  - Conditions of participation
  - Conditions of coverage
  - Medicare contracts
- Civil penalties?
- Program exclusion?

- Penalties likely imposed against facility/employer, not individuals.

HEALTHCARE VACCINE MANDATE: WILL THERE BE EXEMPTIONS?

- We don't know.
  - Unlike other mandates, the announcements concerning healthcare worker mandate does not refer to exemptions.
- Vaccine mandates typically contain exemptions for:
  - Medical conditions (e.g., allergic reactions to vaccines, treatment with monoclonal antibodies, history of multisystem inflammatory syndrome, pregnancy, etc.).
  - Sincerely held religious beliefs.
  - Others?
- Exemptions may be necessary to survive legal challenges.
  - Constitution
  - Religious Freedom Restoration Act of 1993
  - Others?

HEALTHCARE VACCINE MANDATE: WILL THERE BE ALTERNATIVES?

- We don't know.
  - Unlike the OSHA mandate, the announcements concerning healthcare worker mandate does not refer to alternatives.
- Other vaccine-related rules allow for alternatives to vaccination, e.g.,
  - Masking.
  - Weekly COVID-19 testing.
  - Isolation.
  - Others?

HEALTHCARE VACCINE MANDATE: WILL IT SURVIVE LEGAL CHALLENGE?

- Probably.
  - Supreme Court has upheld vaccine mandates. *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905).
  - Supremacy Clause of Constitution.
  - Tied to acceptance of Medicare/Medicaid dollars.
  - Providers may always choose forego participation in Medicare/Medicaid.
- So far, courts have upheld COVID-19 vaccine mandates, especially if they contain religious and medical exemptions.

HEALTHCARE VACCINE MANDATE: WHAT SHOULD YOU DO NOW?

- Don't count on an injunction or adverse court action.
- Watch for the CMS rules.
  - Likely will issue this month.
- Begin educating staff about your anticipated obligations.
- Review CDC Guidance for Workplace Vaccination Programs at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/essentialworker/workplace-vaccination-program.html.
- Review EEOC guidance concerning vaccines in the workplace, e.g., https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.
  - But new rules may affect this.
- Consider offering incentives for vaccinations or imposing penalties for failing to vaccinate.
  - Consider existing employee benefit plans.
- Begin planning for implementation.
- Beware privacy issues…

VACCINE INFORMATION: CONFIDENTIALITY

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HIPAA AND VACCINE INFORMATION

Patients

- No general HIPAA exception for COVID.
- To use or disclose PHI, need:
  - Patient authorization, or
  - HIPAA exception, e.g.,
    - Treat, pay, operation
    - Public health
    - Imminent threat
    - Law requires disclosure
    - OSHA surveillance
    - Others

Employees

- If obtained vaccine info solely as employer, HIPAA does not apply.
- If obtained vaccine info as either (i) a healthcare provider, or (ii) a health plan, HIPAA applies, i.e., need
  - Employee's authorization, or
  - HIPAA exception.

EMPLOYER ACTING AS PROVIDER OR EMPLOYER?

"[A] covered entity must remain cognizant of its dual roles as an employer and as a health care provider [or] health plan .... Individually identifiable health information created, received, or maintained by a covered entity in its health care capacity is [PHI]. It does not matter if the individual is a member of the covered entity's workforce or not. Thus, the medical record of a hospital employee who is receiving treatment at the hospital is protected health, information and is covered by [HIPAA], just as the medical record of any other patient of that hospital is protected health information and covered by the Rule. The hospital may use that information only as permitted by the Privacy Rule, and in most cases will need the employee's authorization to access or use the medical information for employment purposes."

(67 FR 53191)

EMPLOYER ACTING AS PROVIDER OR EMPLOYER?

"For example,

- "drug screening test results will be [PHI] when the provider administers the test to the employee, but will not be [PHI] when, pursuant to the employee's authorization, the test results are provided to the provider acting as employer and placed in the employee's employment record.
- "fitness for duty exam will be [PHI] when the provider administers the test to one of its employees, but will not be [PHI] when the results of the fitness for duty exam are turned over to the provider as employer pursuant to the employee's authorization."

(67 FR 53191)

HOSPITAL ACCESSING EMPLOYEE'S VACCINATION INFO

- Generally need patient's HIPAA-compliant authorization.
- Potentially relevant HIPAA exceptions:
  - Treatment, payment or healthcare operations (e.g., qualifications of members, compliance, etc.?).
  - For public health activities.
  - To family, friends and others involved in patient's care.
  - To avert serious and imminent threat of harm.
  - Required by law.
  - To public health agency.
  - Employer's medical surveillance of workplace if certain conditions met, including surveillance required by OSHA and written notice to employee.

(https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-covid-19-vaccination-workplace/index.html)

ASKING EMPLOYEES ABOUT VACCINATION STATUS

"If my employer requires proof of my COVID-19 vaccination status, does that violate my rights under HIPAA?

"In general, the HIPAA Rules do not apply to employers or employment records. HIPAA only applies to HIPAA covered entities – health care providers, health plans, and health care clearinghouses – and, to some extent, to their business associates. If an employer asks an employee to provide proof that they have been vaccinated, that is not a HIPAA violation, and employees may decide whether to provide that information to their employer."

(https://www.hhs.gov/answers/if-my-employer-requires-proof-of-my-covid-19-vaccination-status/index.html)

REQUIRING EMPLOYEES TO DISCLOSE VACCINATION STATUS

"Does the HIPAA Privacy Rule prohibit a covered entity or business associate from requiring its workforce members to disclose to their employers or other parties whether the workforce members have received a COVID-19 vaccine?

"No. The Privacy Rule does not apply to employment records, including employment records held by covered entities … acting in their capacity as employers. Thus, the Privacy Rule generally does not regulate what information can be requested from employees as part of the terms and conditions of employment that a covered entity … may impose on its workforce, such as the ability of a covered entity … to require its workforce members to provide documentation of their vaccination against COVID-19 or to disclose whether they have been vaccinated to their employer, other workforce members, patients, or members of the public.

(https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-covid-19-vaccination-workplace/index.html)

REQUIRING EMPLOYEES TO DISCLOSE VACCINATION STATUS

"For example, the Privacy Rule **does not prohibit** a covered entity … from requiring or requesting each workforce member to:

- "Provide documentation of their COVID-19 … vaccination to their current or prospective employer.
- "Sign a HIPAA authorization for a covered health care provider to disclose the workforce member's COVID-19 … vaccination record to their employer.

…

- "Disclose whether they have received a COVID-19 vaccine in response to queries from current or prospective patients."

(https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-covid-19-vaccination-workplace/index.html)

REQUIRING EMPLOYEES TO DISCLOSE VACCINATION STATUS

- But beware other laws (e.g., ADA, GINA, FMLA, state laws).
- "Other federal or state laws address whether an employer may require a workforce member to obtain any vaccinations as a condition of employment and provide documentation or other confirmation of vaccination. These laws also address how employers must treat medical information that they obtain from employees. For example, documentation or other confirmation of vaccination must be kept confidential and stored separately from the employee's personnel files under Title I of the Americans with Disabilities Act (ADA)."

(https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-covid-19-vaccination-workplace/index.html)

HTTPS://WWW.EEOC.GOV/WYSK/WHAT-YOU-SHOULD-KNOW-ABOUT-COVID-19-AND-ADA-REHABILITATION-ACT-AND-OTHER-EEO-LAWS

What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws

Technical Assistance Questions and Answers - Updated on May 28, 2021.

INTRODUCTION

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- *All EEOC materials related to COVID-19 are collected at*

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ADA AND EMPLOYEE CONFIDENTIALITY

Under ADA:

- Employer may follow current CDC and local health dept guidelines in responding to COVID, including requiring vaccinations subject to reasonable accommodation for:
  - Sincerely held religious believes.
  - Disability.
- Employer may ask whether employee has been tested for COVID, is vaccinated, or is experiencing symptoms.
  - Not a disability-related question.
  - Do not ask follow up questions.

(29 CFR 1630.14; EEOC Guidance (5/21))

ADA AND EMPLOYEE CONFIDENTIALITY

Under ADA:

- Employer must keep employee health info confidential, including vaccination status.
  - Store separately from medical file.
  - May disclose to supervisors or managers to allow necessary accommodations.
  - May require those who are not vaccinated to wear a mask subject to reasonable accommodation.

(29 CFR 1630.14; EEOC Guidance (5/21))

  - Maybe allow employee to display something confirming that they may work without a mask but do not require notice of vaccination status.
  - Maybe allow voluntary vaccination stickers.

➢ *Check local laws.*

OSHA AND PATIENT CONFIDENTIALITY

Under the OSHA ETS

- Detailed guidance for healthcare workers, including PPE.
- If employer learns employee is COVID positive, employer must within 24 hours:
  - Notify other employees who were not wearing PPE that employee was in close contact with someone with COVID and date of contact.
  - Notify others in well-defined portion (e.g. a particular floor).
  - Do not included infected employee's name, contact info, or occupation.
- Must maintain COVID log.

(OSHA ETS 1910.502(I)(3) (6/21/21))

NO SURPRISE BILLING RULES

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NO SURPRISES ACT AND NO SURPRISE BILLING RULES

- No Surprises Act (12/27/20)
- Part I Rule (7/13/21)
  - Limits amounts an out of network ("OON") provider may bill patient and payer for:
    - Emergency services at emergency facility,
    - Non-emergency services by an out-of-network ("OON") provider at an in-network facility.
- Part 2 Rule (9/30/21)
  - Requires providers to give good faith estimate of charges to self-pay patients.
  - Establishes IDR process for disputes between providers, payers, and self-pay patients.
- Effective 1/1/22

PENALTIES

- HHS may impose a $10,000 civil penalty against facilities and providers for violations.
- HHS shall waive the penalty if:
  - The facility or provider did not know and should not have reasonably known its actions violated the rule, and
  - The facility or provider, within 30 days of violation:
    - Withdraws the bill that violated the rule, and
    - Reimburses the health plan, insurer, or patient as applicable in an amount equal to the difference between the amount billed and the amount allowed to be billed plus interest at a rate determined by HHS.

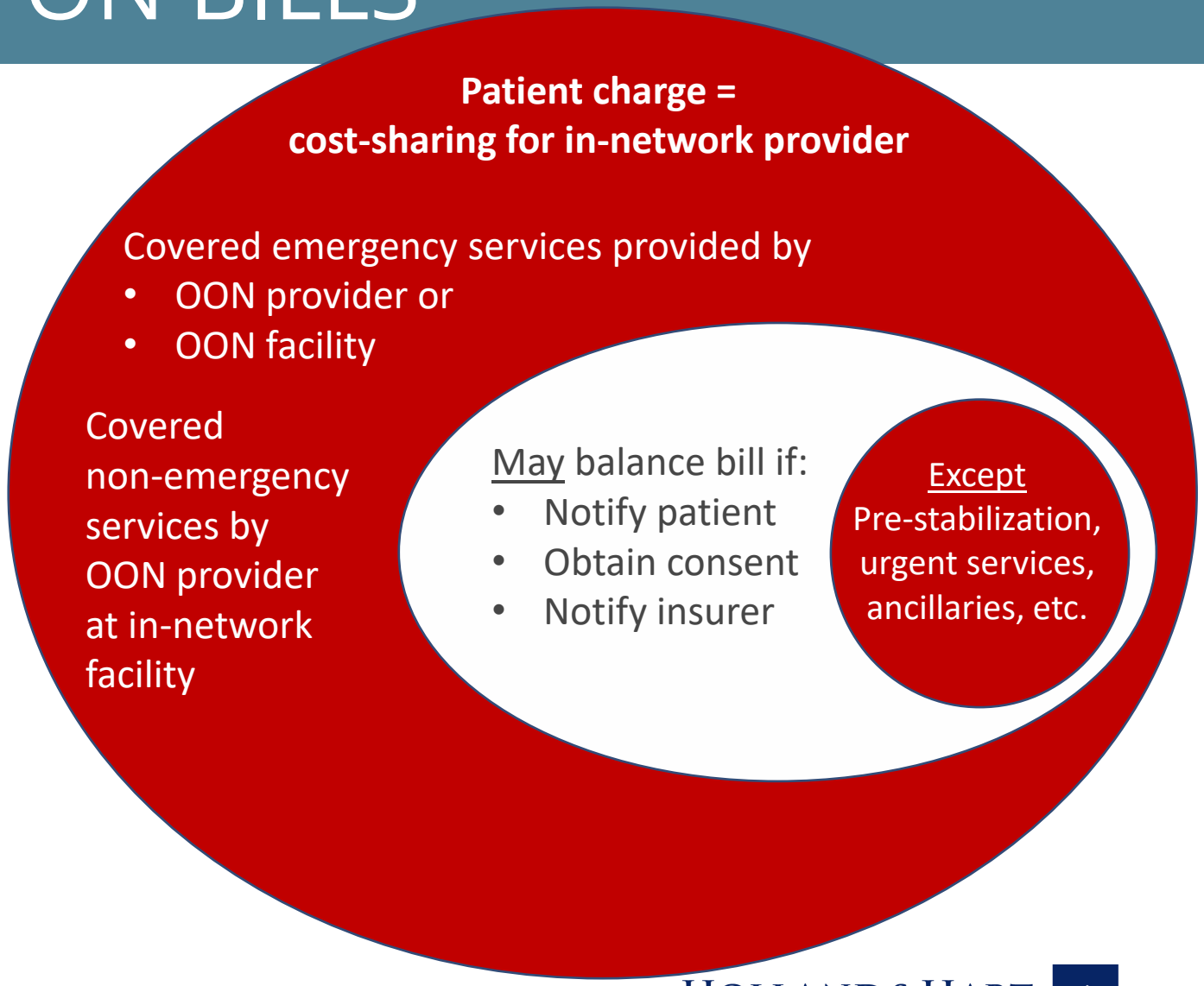
(No Surprise Act § 2799D(b)(1), (4); 86 FR 36905)

➢ *Watch for future rule*

INSURED PATIENTS: LIMITS ON BILLS

Limits on surprise bills do <u>not</u> apply to:

- In-network providers/facilities.
- Self-pay patients.
- Health reimburse arrangements, retiree-only plans, short-term limited duration plans.
- Items or services <u>not</u> covered by health plan.
- Items or services that are <u>not</u> provided at or in connection with a visit to a "facility."



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INSURED PATIENTS: LIMITS ON COST-SHARING

- Only applies to OON providers or facilities when:
  - Emergency services are provided by a OON provider or OON emergency facility.
    - *Facility = emergency dept of hospital or independent freestanding emergency dept as licensed by state (may include urgent care center) (86 FR 36879)*
  - Non-emergency services are provided by a OON provider at an in-network health care facility.
    - *Facility = hospital, hospital outpatient dept, CAH, or ASC that has a contract with a health plan covering the services provided, including single case agreements. (86 FR 36882).*
  - Air ambulance services are furnished by an OON provider of air ambulance services.

(86 FR 36904)

INSURED PATIENTS: LIMITS ON COST-SHARING

- Patient's cost-sharing for out-of-network services is no higher than in-network level.
  - E.g., if patient's cost-sharing amount for in-network services is 20%, then patient's cost-sharing amount for out-of-network service is 20%.
- The amount to which cost-sharing applies (i.e., the "recognized amount") is determined in descending order of following:
  - Amount determined by applicable All-Payer Model Agreement under the SSA; or
  - If there is no applicable All-Payer Model Agreement, amount determined by state law; or
  - If neither of the foregoing apply, the lesser amount of either the billed charge or the *qualifying payment amount* ("QPA").
    - QPA is generally the plan's median contracted rate in 2019 for the same or similar items or services provided by a similar provider in the same geographic region adjusted by CPI.

(*CMS, Requirements Related to Surprise Billing; Part I Interim Final Rule with Comment Period*, https://www.cms.gov/newsroom/fact-sheets/requirements-related-surprise-billing-part-i-interim-final-rule-comment-period)

INSURED PATIENTS: TOTAL PAYMENT TO PROVIDER

- Total amount paid to OON provider or OON facility, including any patient cost-sharing amount, is based on:
  - Amount determined by applicable All-Payer Model Agreement under the SSA; or
  - If there is no applicable All-Payer Model Agreement, amount determined by state law; or
  - If neither of the foregoing apply, an amount agreed upon by the plan and provider or facility; or
  - If plan and provider/facility cannot agree on charge, amount determined by independent dispute resolution ("IDR") entity.

(*CMS, Requirements Related to Surprise Billing; Part I Interim Final Rule with Comment Period*, https://www.cms.gov/newsroom/fact-sheets/requirements-related-surprise-billing-part-i-interim-final-rule-comment-period)

INSURED PATIENTS: TOTAL PAYMENT TO PROVIDER

- 30 days to attempt agreement during open negotiation period.
- 4 days to request IDR.
- Parties select certified IDR entity.
- Payer and OON provider/facility each submit their proposal.
- IDR entity must consider:
  - Qualified payment amount ("QPA"), which is presumed amount.
  - Provider's training and experience.
  - Complexity of procedure or medical decision-making.
  - Patient's acuity.
  - Market share of the insurer and provider.
  - Teaching status of facility.
  - Scope of services.
  - Demonstrations of good faith efforts to agree on payment amount.
  - Contracted rates for prior year.
- IDR entity determines which proposal is reasonable.
- Loser pays administrative costs.

INSURED PATIENTS: IF RULE APPLIES--

Patient pays

- In-network rate for the covered service (copay, deductible, etc.) based on "recognized amount", i.e.,
  - All-Payer Model agreement;
  - Amount specified by state law; or
  - QPA, i.e., median contracted rate for similar service and provider.

Plan or insurer pays

- Amount determined by:
  - All-Payer Model agreement;
  - Amount specified by state law;
  - Agreed amount; or
  - IDR decision
- Less the patient's cost-sharing amount.

INSURED PATIENTS: EMERGENCY SERVICES

- If a covered patient receives emergency services at a hospital emergency dept or an independent freestanding emergency dept,
  - OON facility may not balance bill the patient above the cost-sharing amount for an in-network facility; and/or
  - OON provider may not balance bill the patient above the cost-sharing amount for an in-network provider
- Except for certain post-stabilization items or services if:
  - Patient is able to travel to an in-network facility within a reasonable distance in nonmedical transport;
  - Patient is given required written notice;
  - Patient gives valid consent; and
  - Facility satisfies any additional state law requirements.
- May never balance bill for unforeseen, urgent medical needs that arise at the time the services are rendered.

(45 CFR 149.410; 86 FR 36905)

INSURED PATIENTS: NON-EMERGENCY SERVICES

- An OON provider who provides non-emergency services at a facility may not balance bill above applicable cost-sharing amount
- Unless the following are satisfied:
  - Patient is given required written notice; and
  - Patient gives valid consent.
- May never balance bill for:
  - Unforeseen, urgent care that arises when services rendered.
  - Certain ancillary services, i.e.,
    - Items or services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology;
    - Assistant surgeons, hospitalists, and intensivists;
    - Diagnostic services, including radiology and labs; and
    - Items or services provided by an OON provider if there is an in-network provider who can furnish them at the facility.

(45 CFR 149.420)

INSURED PATIENTS: NOTICE OF PROTECTIONS

- Providers and facilities must notify insured patients of balance billing protections.
  - Prominent sign in provider's or facility's location (if have one).
    - E.g., where patients schedule, check in, or pay bills. (86 FR 36914)
  - Post on website (if have one):
    - Required info or link on searchable homepage of website.
    - Must be able to access without charge, setting up account, or giving personal information. (86 FR 36913)
  - Give notice to each patient who receives items or services.
    - One page, double-sided page using print ≥ 12-point font.
    - Provide in-person, mail or e-mail as selected by patient.
    - No later than the date and time:
      - When provider or facility requests payment from patient; or
      - If provider does not request payment from patient, when provider or facility submits claim to plan or insurer.

(45 CFR 149.430(c), (d))

INSURED PATIENTS: NOTICE OF PROTECTIONS

- Notice must state in clear and understandable language:
  - Explain the requirements and prohibitions relating to balance billing.
  - If applicable, explain state law requirements concerning balance billing.
  - Contact information for appropriate federal and state agencies to report violations.

(45 CFR 149.430(b))

➢ *HHS working on model notice.*

- *Use of model notice is deemed good faith compliance.*

➢ *Notice must satisfy language accessibility standards.*

(86 FR 36912-13)

SELF-PAY PATIENTS: GOOD FAITH ESTIMATE

- Providers/facilities must determine if patient is self-pay.
- Providers/facilities must inform self-pay patients that they may obtain a good faith estimate of expected charges.
  - Written notice on website, in the office, and on-site where scheduling or questions of costs occur.
  - Orally when scheduling an items or services or when questions occur about costs.
  - Made available in accessible formats.

(45 CFR 149.610)

SELF-PAY PATIENTS: GOOD FAITH ESTIMATE

- Good faith estimate must include:
  - Patient name and birthdate.
  - Description of primary item or service.
  - Itemized list of anticipated items or services grouped by each provider or facility.
  - Applicable diagnosis codes and associated charges.
  - Name, NPI, TIN of each provider and facility.
  - Location where each items or services provided.
  - List of items or services that will require separate scheduling + disclaimer of separate good faith estimate.
  - Disclaimer that:
    - That there may be additional items that are not listed.
    - This is only estimate; actual charges may vary.
    - Patient may initiate provider-patient dispute process if billed charges are substantially in excess of good faith estimate.
    - Estimate is not a contract and does not require patient to pay.

(45 CFR 149.610)

SELF-PAY PATIENTS: GOOD FAITH ESTIMATE

- Upon patient request or when scheduling the patient:
  - Within 1 business day, "convening" provider/facility must contact "co"-provider/facility to obtain good faith estimate.
  - Provide good faith estimate:
    - 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 estimate for recurring charges if certain conditions satisfied.

(45 CFR 149.610)

SELF-PAY PATIENTS: GOOD FAITH ESTIMATE

- Good faith estimate:
  - Must be provided in writing, either paper or electronically.
  - Must be maintained in same manners as the patient's medical record.
  - Patient may obtain copy for 6 years.

(45 CFR 149.610)

SELF-PAY PATIENTS: GOOD FAITH ESTIMATES

- If actual charges are "substantially in excess" of good faith estimate (i.e., at least $400 more than expected charges), patient may initiate Selected Dispute Resolution ("SDR") process.

(45 CFR 149.620).

SELF-PAY PATIENTS: GOOD FAITH ESTIMATES

- SDR process:
  - Within 120 days of receipt of bill, patient must submit request and 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 SDR process.
  - Within 10 days of appointment of SDR, provider must submit good faith estimate and other relevant information.
  - SDR considers whether services were medically necessary and unforeseen circumstances not reasonably anticipated when good faith estimate prepared.
  - SDR will look to median payment amount for same or similar provider in same geographic area.

(45 CFR 149.620)

SELF-PAY PATIENTS: GOOD FAITH ESTIMATES

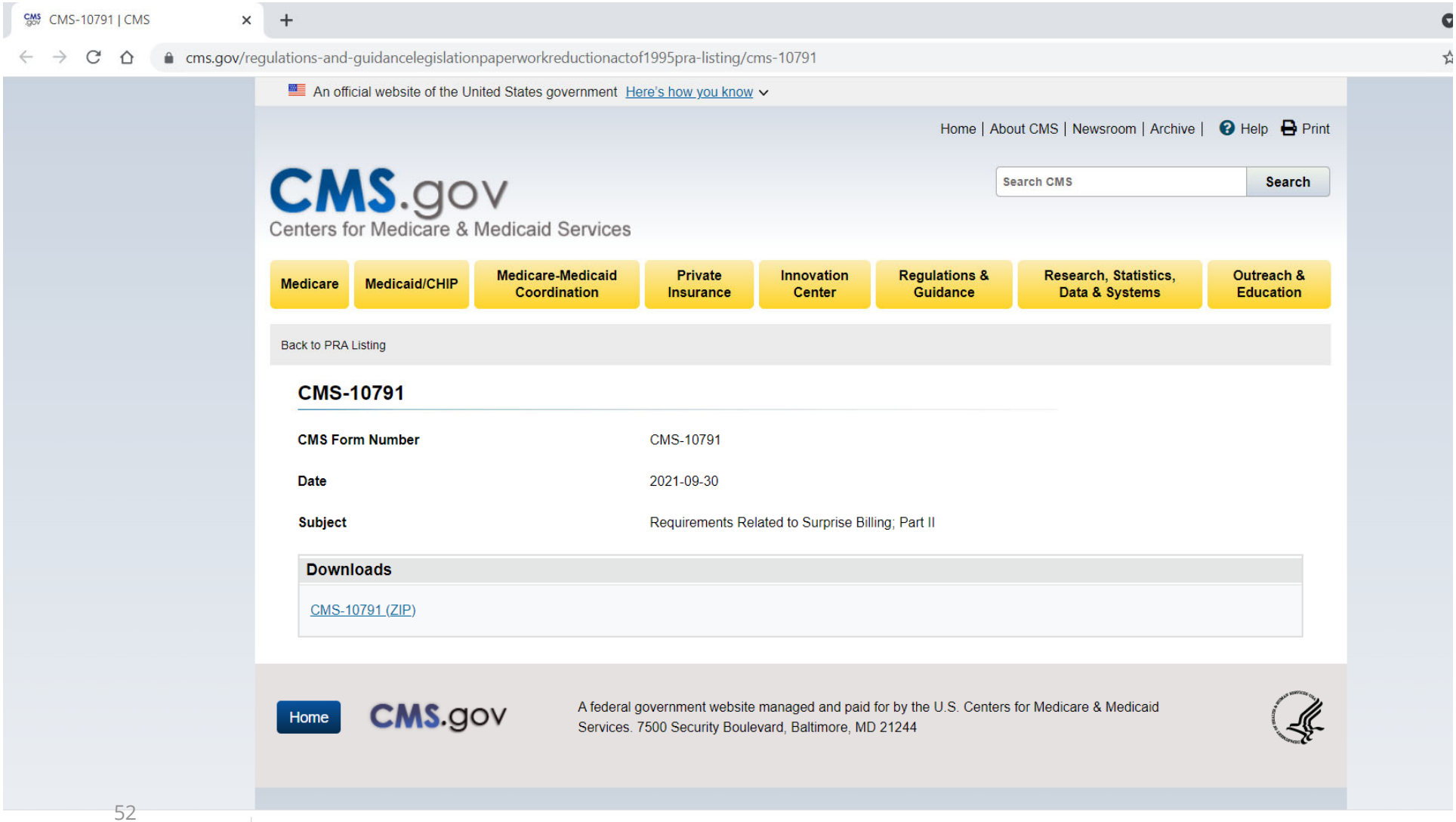
- Rules apply to good faith estimates:
  - Requested on or after 1/1/22, or
  - Required to be provided in connection with items or services scheduled on or after 1/1/22.

(45 CFR 149.610)

- HHS postponed requirements for good faith estimates to insured patients and payers.

HTTPS://WWW.CMS.GOV/NOSURPRISES

HTTPS://WWW.CMS.GOV/REGULATIONS-AND-GUIDANCELEGISLATIONPAPERWORKREDUCTIONACTOF1995PRA-LISTING/CMS-10791



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 information network/exchange.

(45 CFR 171.101)

- Prohibits information blocking, i.e., practice that is likely to interfere with access, exchange, or use of electronic health information,

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.
- Not required to:
  - Establish patient portal.
  - Push info out absent request.
  - Create or convert info to electronic format.

INFO BLOCKING EXCEPTIONS

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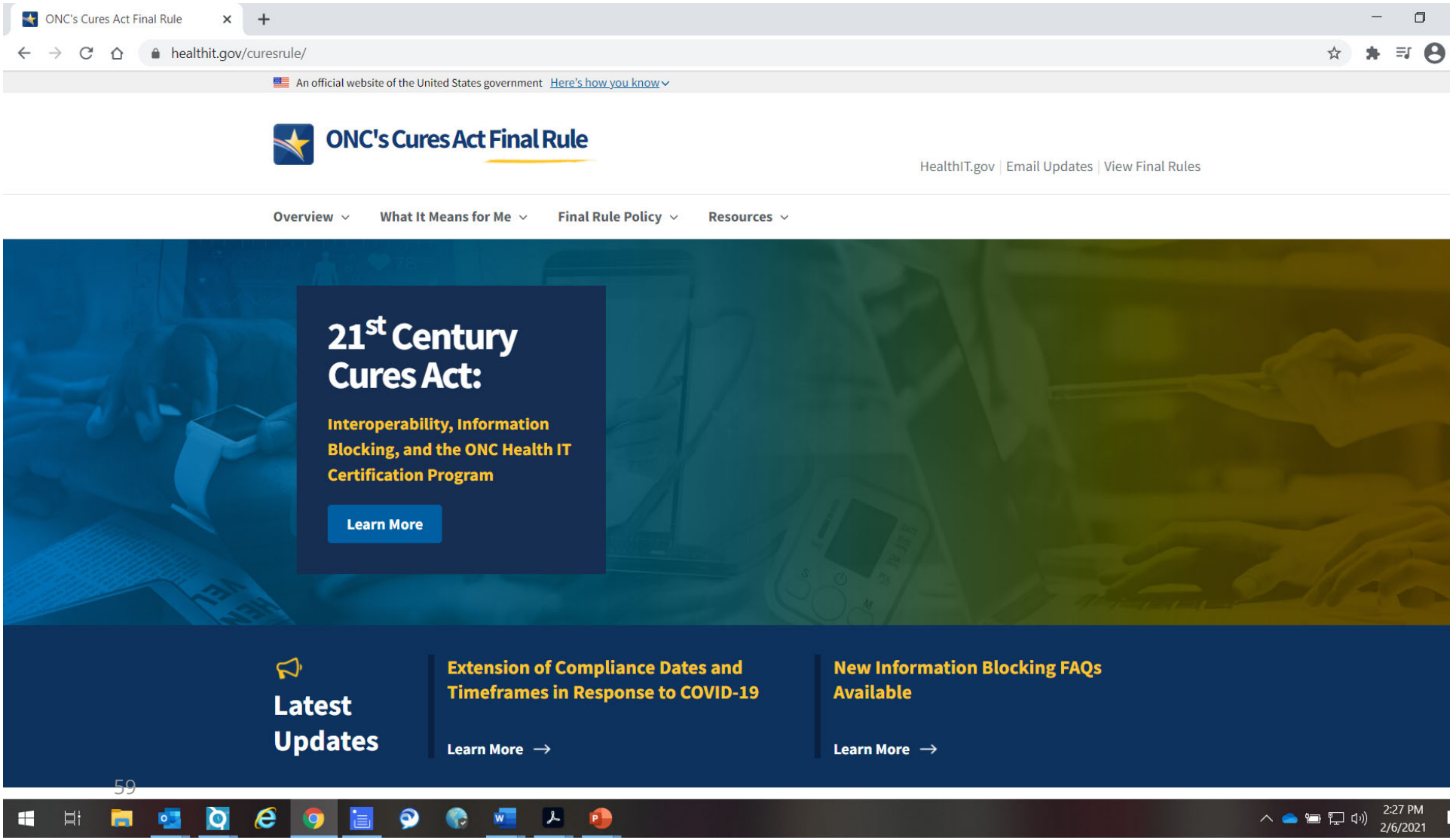
HTTPS://WWW.HEALTHIT.GOV/CURESRULE/



SUMMARY: "IS IT INFO BLOCKING?"

Whether info blocking occurred depends on whether:

- The individual or entity engaging in the practice is an "actor" as defined in 45 CFR 171.102;
- The claim involves "EHI" as defined in 45 CFR 171.102;
- The action was required by law;
- The action met the conditions of an exception under 45 CFR 171;
- The action rose to the level of an interference under 45 CFR 171; and,
- The actor met the requisite knowledge standard.
  - Providers: "knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of electronic health information."
  - Health IT developers, HINs, and HIEs: "knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information."

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

INFORMATION BLOCKING: BEWARE!

- Info Blocking Rule may require you to do things you are not required to do under HIPAA.
  - HIPAA generally does not require you to disclose PHI except to patient.
  - Info Blocking Rule generally requires you provide access for permissible uses under HIPAA, e.g., for treatment, payment or operations.
  - Not required to violate HIPAA.
- Info Blocking Rule may require you to act more quickly than HIPAA.
  - HIPAA may give 30 days to respond
  - Info Blocking Rule may require faster response

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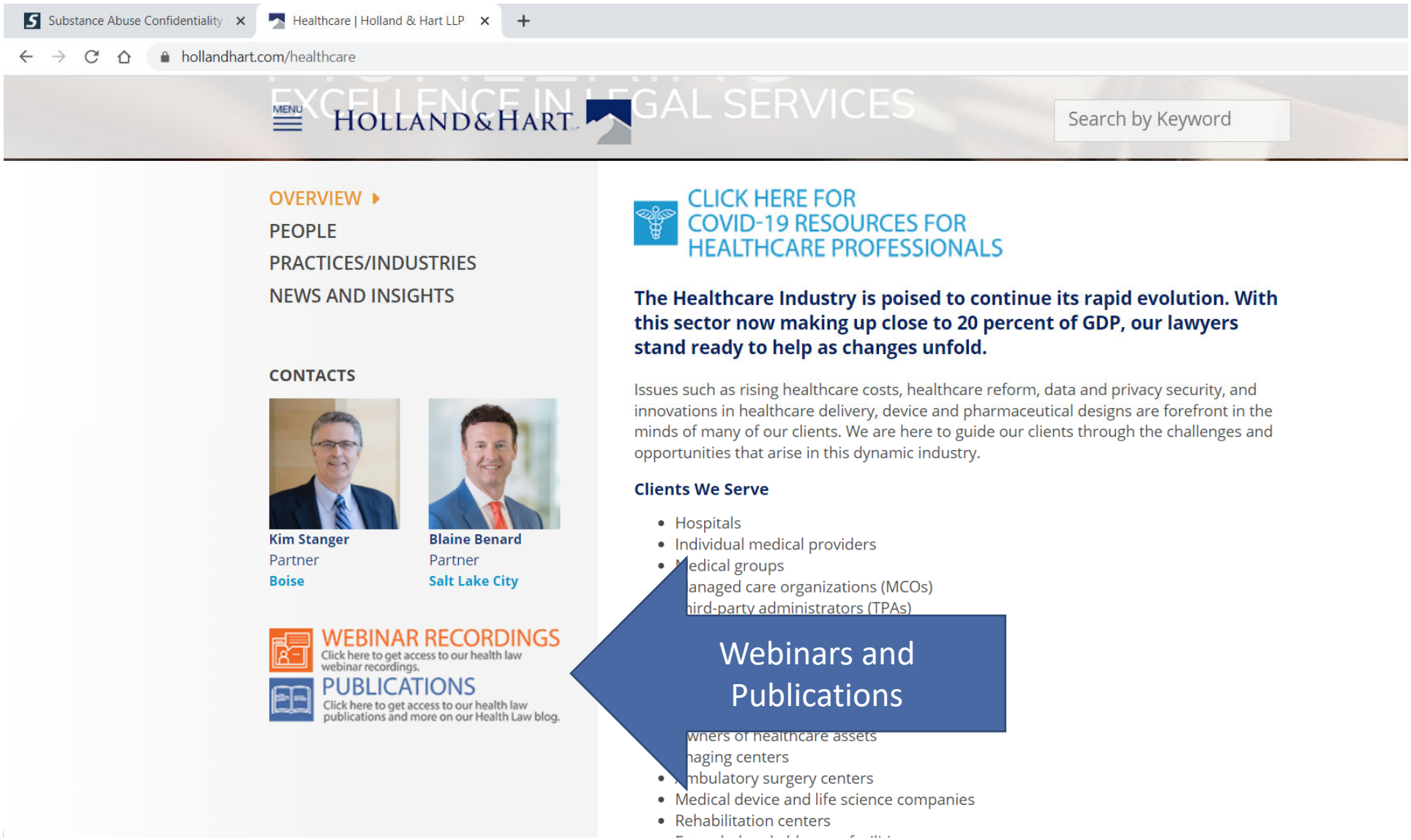

QUESTIONS?

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