HEALTHCARE COMPLIANCE: 2021 REVIEW → 2022 AHEAD

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(12-21)

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COMPLIANCE: YEAR IN REVIEW

What a year!

- COVID-19 Vaccine Mandates
- No Surprise Billing Rules
- Hospital Price Transparency
- PRF Payments and Reporting
- Stark and Anti-Kickback Statute Revisions
- Information Blocking Rule
- HIPAA and Patient Privacy
- 42 CFR part 2 Revisions
- Ongoing Cybersecurity Concerns
- Others?

VACCINE MANDATES FOR HEALTHCARE WORKERS, 42 CFR 482, 483, 485, +

Effective
December 6, 2021
January 4, 2022

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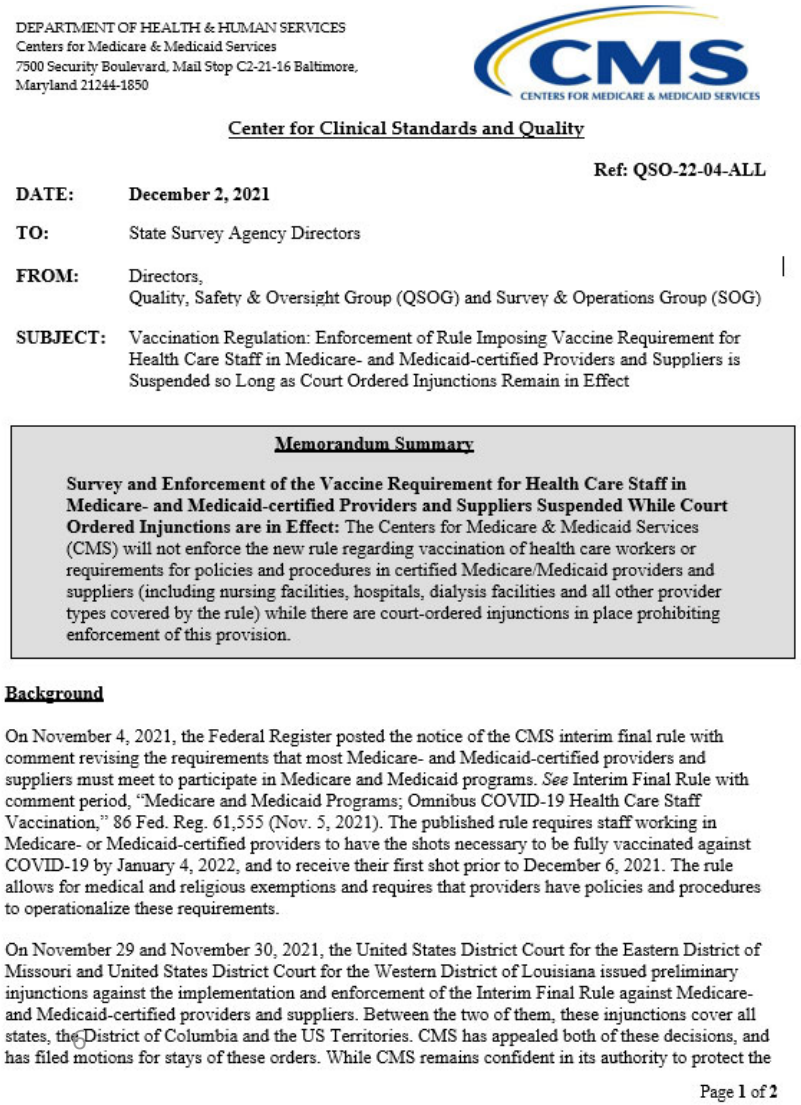
CMS VACCINE MANDATE

- Requires certain facilities regulated by CMS to implement policies to ensure personnel receive first dose by 12/6/21 and fully vaccinate by 1/4/22.
- Exceptions:
  - 100% remote.
  - Delay due to medical contraindication.
  - Required by federal anti-discrimination laws, e.g.,
    - Medical disability, or
    - Sincere religious belief.
- Failure to do so would violate conditions of participation.

(86 FR 61555)

- D.Mo: preliminary injunction in 10 states.
  - Appealed to 8th Circuit.
  - CMS moved to stay injunction.
  - Plaintiffs' brief due 12/8/21.
- D.La: preliminary injunction in remaining states.
  - Appealed to 5th Circuit.
  - CMS moved to stay injunction.
  - 5th Circuit has not acted.
- D.Fl: denied preliminary injunction
  - Appealed to 11th Circuit.
  - 11th Circuit denied state's request to stay district court's decision.
- Likely fast track to Supreme Court.

CMS VACCINE MANDATE



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

Ref: QSO-22-04-ALL

DATE: **December 2, 2021**

TO: State Survey Agency Directors

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

SUBJECT: Vaccination Regulation: Enforcement of Rule Imposing Vaccine Requirement for Health Care Staff in Medicare- and Medicaid-certified Providers and Suppliers is Suspended so Long as Court Ordered Injunctions Remain in Effect

Memorandum Summary

Survey and Enforcement of the Vaccine Requirement for Health Care Staff in Medicare- and Medicaid-certified Providers and Suppliers Suspended While Court Ordered Injunctions are in Effect: The Centers for Medicare & Medicaid Services (CMS) will not enforce the new rule regarding vaccination of health care workers or requirements for policies and procedures in certified Medicare/Medicaid providers and suppliers (including nursing facilities, hospitals, dialysis facilities and all other provider types covered by the rule) while there are court-ordered injunctions in place prohibiting enforcement of this provision.

Background

On November 4, 2021, the Federal Register posted the notice of the CMS interim final rule with comment revising the requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in Medicare and Medicaid programs. *See* Interim Final Rule with comment period, "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination," 86 Fed. Reg. 61,555 (Nov. 5, 2021). The published rule requires staff working in Medicare- or Medicaid-certified providers to have the shots necessary to be fully vaccinated against COVID-19 by January 4, 2022, and to receive their first shot prior to December 6, 2021. The rule allows for medical and religious exemptions and requires that providers have policies and procedures to operationalize these requirements.

On November 29 and November 30, 2021, the United States District Court for the Eastern District of Missouri and United States District Court for the Western District of Louisiana issued preliminary injunctions against the implementation and enforcement of the Interim Final Rule against Medicare- and Medicaid-certified providers and suppliers. Between the two of them, these injunctions cover all states, the District of Columbia and the US Territories. CMS has appealed both of these decisions, and has filed motions for stays of these orders. While CMS remains confident in its authority to protect the

Page 1 of 2

- CMS "will not enforce the new rule regarding vaccination of health care workers or requirements for policies and procedures in certified Medicare/ Medicaid providers and suppliers … while there are court-ordered injunctions in place prohibiting enforcement of this provision."
- "Health care facilities, of course, may voluntarily choose to comply with the Interim Final Rule."

(CMS QSO 22-04-ALL)

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OSHA LARGE EMPLOYER MANDATE

- Generally requires employers with 100+ employees to require full vaccination or weekly testing by 1/4/22.
- Exceptions
  - Required by federal discrimination laws, e.g.,
    - Medical disability
    - Sincere religious belief
  - Healthcare settings subject to the OSHA healthcare ETS.

(29 CFR 1910.502)

- 5th Circuit imposed nationwide injunction.
- Consolidated cases transferred to 6th Circuit.
  - 6th Circuit denied OSHA's motion to dissolve the stay.
- Yesterday, Senate voted to repeal the employer mandate.

OSHA ETS FOR HEALTHCARE WORKERS

- Applies in all settings where any employee provides healthcare services or healthcare support services, e.g.

(29 CFR 1910.502 et seq.)

- Onerous requirements to protect against COVID-19, e.g.,
  - Plan
  - Hazard assessment
  - Vaccinations or controls
  - Monitor plan effectiveness
  - Patient screening
  - PPE
  - Physical distancing
  - Physical barriers
  - Sanitation
  - Others

OSHA ETS FOR HEALTHCARE WORKERS

Does not apply to:

- Non-hospital ambulatory care settings where all non-employees are screened prior to entry and people with suspected or confirmed COVID-19 are not permitted to enter;
- Well-defined hospital ambulatory care settings where all employees are fully vaccinated and all non-employees are screened prior to entry and people with suspected or confirmed COVID-19 are not permitted to enter;
- First aid performed by a non-provider employee;
- Retail pharmacies;
- Home healthcare settings where all employees are fully vaccinated and all nonemployees are screened prior to entry and people with suspected or confirmed COVID-19 are not present;
- Healthcare support services not performed in a healthcare setting.
- Telehealth services.

(29 FR 1910.502)

➢ *These healthcare entities may be subject to OSHA large employer vaccine mandate.*

HTTPS://WWW.OSHA.GOV/CORONAVIRUS/ETS

Healthcare ETS | Occu

osha.gov/coronavirus/ets

UNITED STATES
DEPARTMENT OF LABOR

Occupational Safety and Health Administration

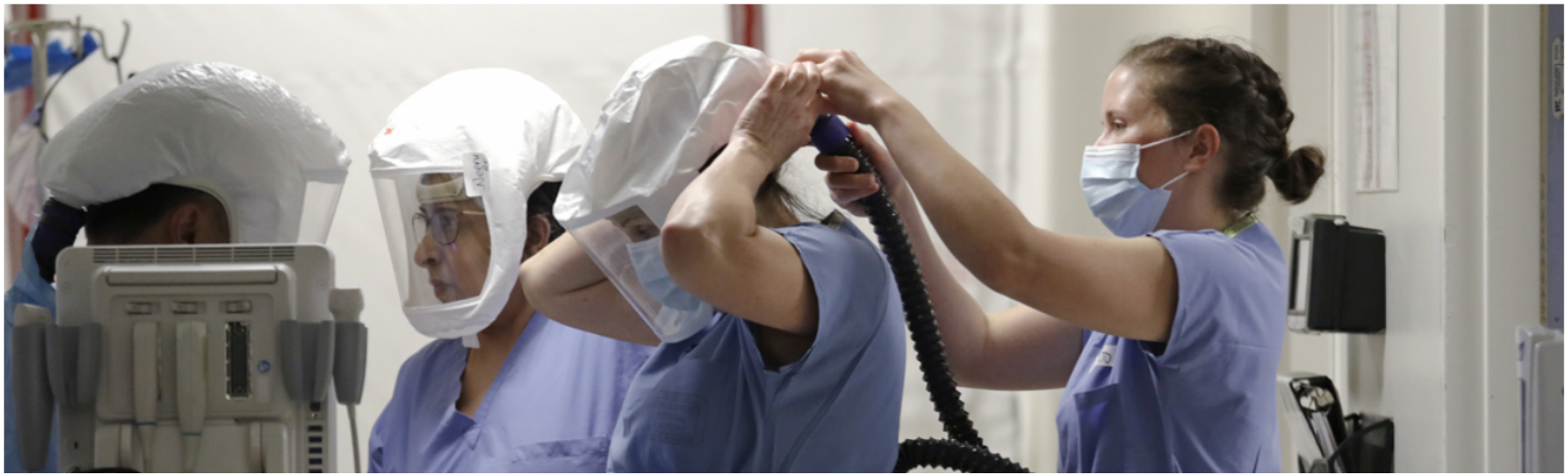
CONTACT US FAQ A TO Z INDEX ENGLISH ESPAÑOL

OSHA | STANDARDS | ENFORCEMENT | TOPICS | HELP AND RESOURCES | NEWS | SEARCH OSHA

Coronavirus Disease (COVID-19) / COVID-19 Healthcare ETS

EMERGENCY TEMPORARY STANDARD

COVID-19 Healthcare ETS



FEDERAL CONTRACTOR VACCINE MANDATE

- Executive Order requires contractors to ensure workers are vaccinated and follow masking and social distancing policies by 1/8/22.
- Not simply participation in Medicare/Medicaid.

- D.Ga: nationwide preliminary injunction.
  - Likely to be appealed to 11th Circuit

VACCINE MANDATES

Additional considerations

- Pending injunctions do not apply to:
  - State mandates.
  - Voluntary mandates.
  - ➢ *So far, state and private mandates have generally been upheld in the courts if they allow for medical or religious exemptions.*
- Some states have enacted laws that affect vaccine mandates, e.g.,
  - Prohibit vaccine mandates.
  - Require additional exemptions, e.g., personally held beliefs.
  - ➢ *Know and comply with local laws while waiting for federal decisions.*

NO SURPRISE BILLING RULES, 45 CFR 149 (AND OTHERS)

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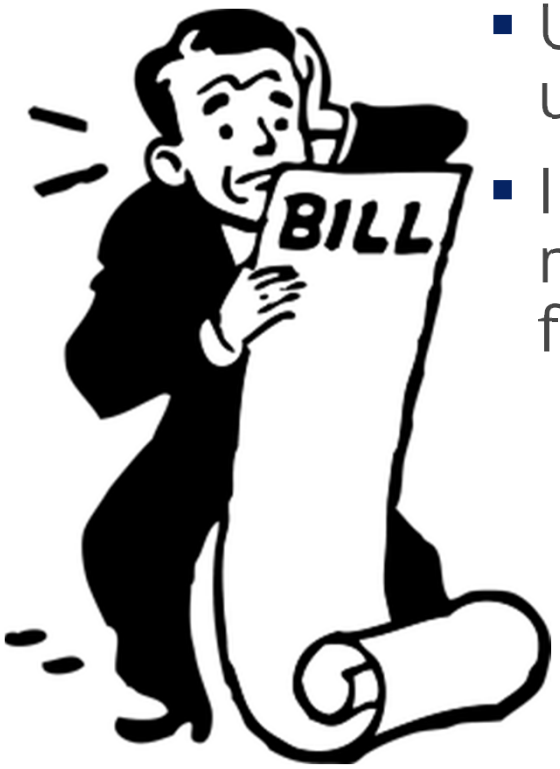
PROBLEM: SURPRISE MEDICAL BILLS



- Uninsured or self-pay patient receives unexpected medical bill.
- Insured patient receives unexpected medical bill from out-of-network ("OON") facility or provider:
  - Emergency services rendered by OON facility or provider.
    - E.g., payer limits coverage for emergency services, requires preauthorization, etc.
  - OON providers at in-network facility bill separately from facility.
    - E.g., surgeons, anesthesiology, radiology, pathology, surgical assists, labs, etc.

NO SURPRISE BILLING RULES

Insured Patients

- Limits amount OON provider/facility may bill patient and payer for
  - Emergency services at emergency facility, or
  - Non-emergency services by OON provider at in-network facility, or
  - Air ambulance services.
- Notice of rights to patient.

(Part 1, 86 FR 36872 (7/13/21)

- Independent dispute resolution process ("IDR") for OON providers/facilities and payers

(Part 2, 86 FR 55980 (9/30/21))

Self-Pay Patients

- Providers/facilities must give patient a good faith estimate of charges.
- Selected dispute resolution process ("SDR") if actual bill is substantially in excess of good faith estimate.
- Notice of rights to patient.

(Part 2, 86 FR 55980 (9/30/21))

➢ Penalties
- $10,000 civil penalty (see No Surprise Act § 2799D; 45 CFR 150.513; 86 FR 51730)
- Limited or denied payment (see regulations)

INSURED PATIENTS: OON PAYMENTS TO PROVIDERS

- 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 BALANCE BILLING

- Patient's cost-sharing for OON 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 OON 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: LIMITS ON BALANCE BILLING

- OON provider/facility may avoid limits on balance billing if prior to services:
  - Give required written notice of patient rights to patient; and
  - Obtain patient's written informed consent to bill above limits on cost-sharing.
- Notice and consent exception does not apply to certain services, including:
  - Unforeseen, urgent medical needs that arise at time services rendered.
  - Pre-stabilization emergency services.
  - Certain non-emergency services, e.g., anesthesiology, pathology, radiology, neonatology; assistant surgeons, hospitalists, and intensivists; diagnostic services, including radiology and labs; and items or services provided by OON provider if there is an in-network provider who can furnish them at the facility.
- OON provider/facility must notify insurer if obtain consent to balance bill.

(45 CFR 149.410-.420)

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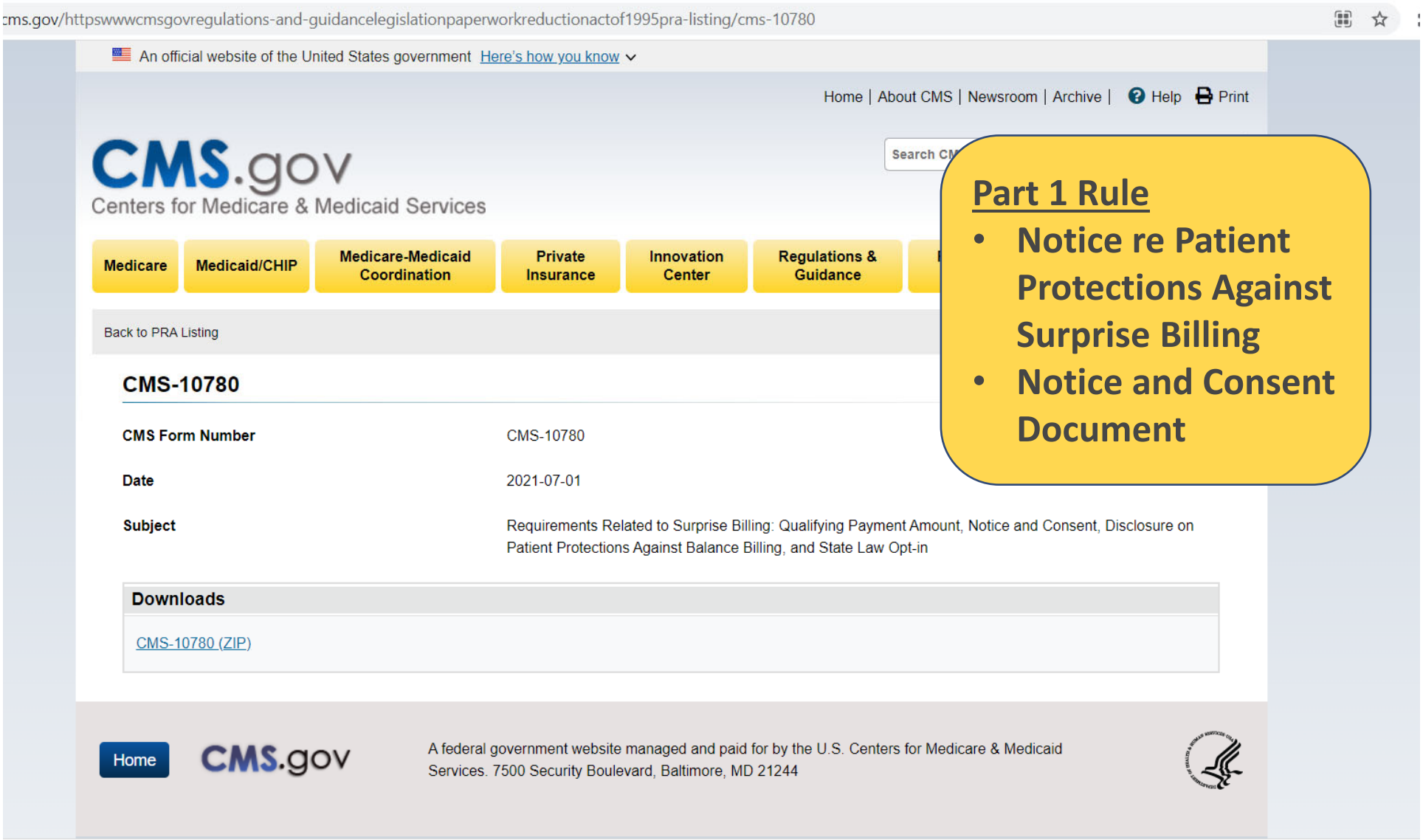

Part 1 Rule

- **Notice re Patient Protections Against Surprise Billing**
- **Notice and Consent Document**

INSURED PATIENTS: NOTICE OF PATIENT RIGHTS

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 billed for these post-stabilization services.

[*Insert plain language summary of any applicable state balance billing laws or requirements OR state-developed model language as appropriate*]

Certain services at an in-network hospital or ambulatory surgical center
When you get services from an in-network hospital or ambulatory surgical center, certain providers there may be out-of-network. In these cases, the most those providers may bill you is your plan's in-network cost-sharing amount. This applies to emergency medicine, anesthesia, pathology, radiology, laboratory, neonatology, assistant surgeon, hospitalist, or intensivist services. These providers **can't** balance bill you and may **not** ask you to give up your protections not to be balance billed.

If you get other services at these in-network facilities, out-of-network providers **can't** balance bill you, unless you give written consent and give up your protections.

You're never required to give up your protections from balance billing. You also aren't required to get care out-of-network. You can choose a provider or facility in your plan's network.

[*Insert plain language summary of any applicable state balance billing laws or requirements OR state-developed model language regarding applicable state law requirements as appropriate*]

When balance billing isn't allowed, you also have the following protections:

- You are only responsible for paying your share of the cost (like the copayments, coinsurance, and deductibles that you would pay if the provider or facility was in-network). Your health plan will pay out-of-network providers and facilities directly.
- Your health plan generally must:
  - Cover emergency services without requiring you to get approval for services in advance (prior authorization).
  - Cover emergency services by out-of-network providers.
  - Base what you owe the provider or facility (cost-sharing) on what it would pay an in-network provider or facility and show that amount in your explanation of benefits.
  - Count any amount you pay for emergency services or out-of-network services toward your deductible and out-of-pocket limit.

If you believe you've been wrongly billed, you may contact [*applicable contact information for entity responsible for enforcing the federal and/or state balance or surprise billing protection laws*].

Visit [*website*] for more information about your rights under federal law.
[*If applicable, insert:* Visit [*website*] for more information about your rights under [state laws].]

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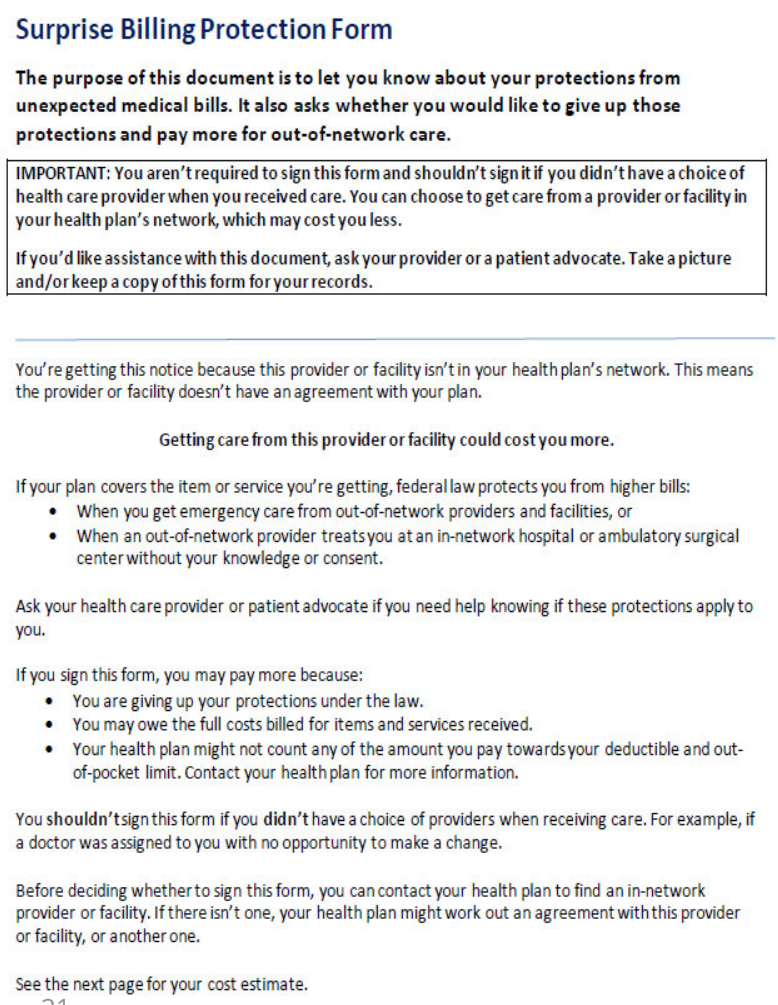
INSURED PATIENTS: NOTICE AND CONSENT FORM



Surprise Billing Protection Form

The purpose of this document is to let you know about your protections from unexpected medical bills. It also asks whether you would like to give up those protections and pay more for out-of-network care.

IMPORTANT: You aren't required to sign this form and shouldn't sign it if you didn't have a choice of health care provider when you received care. You can choose to get care from a provider or facility in your health plan's network, which may cost you less.

If you'd like assistance with this document, ask your provider or a patient advocate. Take a picture and/or keep a copy of this form for your records.

You're getting this notice because this provider or facility isn't in your health plan's network. This means the provider or facility doesn't have an agreement with your plan.

Getting care from this provider or facility could cost you more.

If your plan covers the item or service you're getting, federal law protects you from higher bills:

- When you get emergency care from out-of-network providers and facilities, or
- When an out-of-network provider treats you at an in-network hospital or ambulatory surgical center without your knowledge or consent.

Ask your health care provider or patient advocate if you need help knowing if these protections apply to you.

If you sign this form, you may pay more because:

- You are giving up your protections under the law.
- You may owe the full costs billed for items and services received.
- Your health plan might not count any of the amount you pay towards your deductible and out-of-pocket limit. Contact your health plan for more information.

You **shouldn't** sign this form if you **didn't** have a choice of providers when receiving care. For example, if a doctor was assigned to you with no opportunity to make a change.

Before deciding whether to sign this form, you can contact your health plan to find an in-network provider or facility. If there isn't one, your health plan might work out an agreement with this provider or facility, or another one.

See the next page for your cost estimate.

- Notice and consent must contain certain info.
  - Provider is OON.
  - Good faith estimate of charges.
  - Notice is not a contract.
  - Consent is optional.
  - Patient may receive care from in-network provider.
  - Info about services.

(42 CFR 164.520(c))

➢See HHS Form.

INSURED PATIENTS: OON PAYMENT TO PROVIDERS

- Total amount paid to OON provider/facility, including any patient cost-sharing amount =
  - 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 payer and provider/facility during 30-day "open negotiation" period; or
  - If plan and provider/facility cannot agree, amount determined through independent dispute resolution ("IDR") process.

(*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: IDR PROCESS

OMB Control No. 1210-0169
Expiration Date: 4/30/2022

Open Negotiation Notice

[Enter date of this notice]

You are receiving this notice because [*Enter name of party initiating negotiations*], a(n) [group health plan, health insurance issuer, Federal employee health benefits (FEHB) carrier, health care provider, health care facility, or provider of air ambulance services] is disputing the out-of-network rate for [*insert appropriate descriptor of the item(s) or service(s)*] provided. More information regarding these items or services is provided below. The No Surprises Act provides a Federal independent dispute resolution (Federal IDR) process that group health plans, health insurance issuers of group and individual health insurance coverage, and FEHB carriers and out-of-network or nonparticipating health care providers, facilities, and providers of air ambulance services may utilize to determine the out-of-network rate for certain services following the end of an open negotiation period. The Federal IDR process is available only for certain services, such as out-of-network emergency services, certain services provided by out-of-network providers at an in-network facility, or air ambulance services. The Federal IDR process is also only available if a state All-Payer Model Agreement or specified state law does not apply.

What is an open negotiation period?

The open negotiation period is a period of up to 30 business days to determine an agreed-upon amount for the total out-of-network rate (including any cost sharing) for an item or service furnished by a nonparticipating provider, nonparticipating facility, or a nonparticipating provider of air ambulance services to a participant, beneficiary, or enrollee in a group health plan, group or individual health insurance policy, or FEHB carrier and for which a payment is required to be made by the plan or coverage.

What happens at the end of the open negotiation period?

If we have not agreed upon a payment amount by the end of the open negotiation period [*insert date 30 business days after the date on the open negotiation notice*], either of us may initiate the Federal IDR process by [*insert date 4 business days after the open negotiation period*], under which a certified IDR entity will select the payment amount for the item(s) and/or service(s) at issue.

Initiating the Federal IDR process does not prohibit us from agreeing on a payment amount after the open negotiation period has ended and before the certified IDR entity determines the payment amount.

For more information on the Federal IDR process and to obtain the notice to initiate the Federal IDR process, visit https://www.nsa-idr.cms.gov.

- Within 30 days after receipt of partial payment or denial, send notice starting open negotiating period.
  - Notice must contain required info.
  - ➢ See HHS form.
- Attempt to negotiate resolution during 30-day negotiation period.

(45 CFR 149.510(b))

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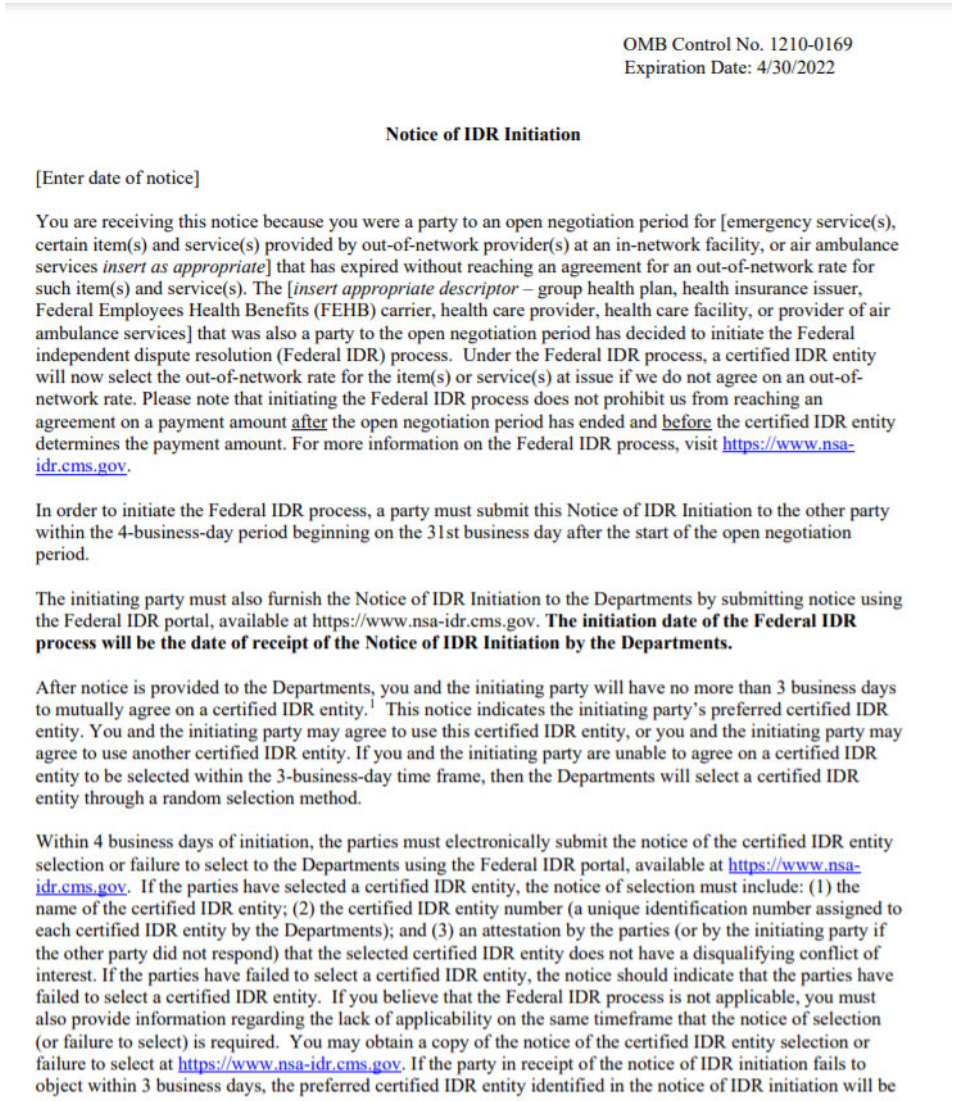
INSURED PATIENT: IDR PROCESS



OMB Control No. 1210-0169
Expiration Date: 4/30/2022

Notice of IDR Initiation

[Enter date of notice]

You are receiving this notice because you were a party to an open negotiation period for [emergency service(s), certain item(s) and service(s) provided by out-of-network provider(s) at an in-network facility, or air ambulance services *insert as appropriate*] that has expired without reaching an agreement for an out-of-network rate for such item(s) and service(s). The [*insert appropriate descriptor* – group health plan, health insurance issuer, Federal Employees Health Benefits (FEHB) carrier, health care provider, health care facility, or provider of air ambulance services] that was also a party to the open negotiation period has decided to initiate the Federal independent dispute resolution (Federal IDR) process. Under the Federal IDR process, a certified IDR entity will now select the out-of-network rate for the item(s) or service(s) at issue if we do not agree on an out-of-network rate. Please note that initiating the Federal IDR process does not prohibit us from reaching an agreement on a payment amount after the open negotiation period has ended and before the certified IDR entity determines the payment amount. For more information on the Federal IDR process, visit https://www.nsa-idr.cms.gov.

In order to initiate the Federal IDR process, a party must submit this Notice of IDR Initiation to the other party within the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

The initiating party must also furnish the Notice of IDR Initiation to the Departments by submitting notice using the Federal IDR portal, available at https://www.nsa-idr.cms.gov. **The initiation date of the Federal IDR process will be the date of receipt of the Notice of IDR Initiation by the Departments.**

After notice is provided to the Departments, you and the initiating party will have no more than 3 business days to mutually agree on a certified IDR entity.[1] This notice indicates the initiating party's preferred certified IDR entity. You and the initiating party may agree to use this certified IDR entity, or you and the initiating party may agree to use another certified IDR entity. If you and the initiating party are unable to agree on a certified IDR entity to be selected within the 3-business-day time frame, then the Departments will select a certified IDR entity through a random selection method.

Within 4 business days of initiation, the parties must electronically submit the notice of the certified IDR entity selection or failure to select to the Departments using the Federal IDR portal, available at https://www.nsa-idr.cms.gov. If the parties have selected a certified IDR entity, the notice of selection must include: (1) the name of the certified IDR entity; (2) the certified IDR entity number (a unique identification number assigned to each certified IDR entity by the Departments); and (3) an attestation by the parties (or by the initiating party if the other party did not respond) that the selected certified IDR entity does not have a disqualifying conflict of interest. If the parties have failed to select a certified IDR entity, the notice should indicate that the parties have failed to select a certified IDR entity. If you believe that the Federal IDR process is not applicable, you must also provide information regarding the lack of applicability on the same timeframe that the notice of selection (or failure to select) is required. You may obtain a copy of the notice of the certified IDR entity selection or failure to select at https://www.nsa-idr.cms.gov. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be

- If cannot agree during 30-day open negotiate period, request IDR by filing notice within 4 business days after 30-day open negotiation period ends.
  - Notice must contain required info.
  - ➢ See HHS form.

(45 CFR 149.510(b))

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INSURED PATIENT: IDR PROCESS

- Within 3 business days after IDR initiated, the parties may agree or object to the IDR entity.
  - E.g., conflict of interest.
- Within 4 days after IDR initiated, initiating party must notify HHS of IDR entity if parties agreed.
- Within 4 days after IDR initiated, receiving party must submit any objections to IDR process.
- Within 6 days after IDR initiated, if parties fail to agree to IDR entity, HHS will appoint the IDR entity.
  - IDR entity's fees may be greater than if selected by parties.
- Parties must pay IDR administrative fee set by HHS.
- If parties agree on OON rate while IDR is pending, they most notify HHS within 3 days after agreement.
- IDR amounts may be submitted in batches or bundled payment arrangements.

(45 CFR 149.510(c))

INSURED PATIENTS: IDR PROCESS

- Within 10 days after IDR entity selected, each party submits OON rate offer.
  - Both in dollar amount and % of QPA.
  - Info requested by IDR entity.
  - Additional info as appropriate:
    - Size of practice or facility (i.e., number of employees)
    - Practice specialty
    - QPA for the applicable year for the same or similar item or service.
  - Additional info the party believes is appropriate.
- Both parties submit IDR entity's fee.
  - Winner receives a refund.

(45 CFR 149.510(c)(4))

INSURED PATIENTS: IDR PROCESS

- Within 30 days after IDR entity selected, IDR issues written decision selecting one of the offers based on:
  - QPA for applicable year for same or similar item/service.
  - Info requested by IDR entity.
  - Additional info submitted by parties relating to:
    - Provider's training, experience, quality, outcomes.
    - Market share.
    - Acuity of patient or complexity of item/service.
    - Facility's teaching status, case mix scope of services.
    - Prior network agreements between the parties.
  - Additional info submitted by parties.
  - Info must be credible.

(45 CFR 149.510(c))

INSURED PATIENTS: IDR PROCESS

- *IDR is skewed heavily in favor of QPA.*
  - "IDR entity must select the offer closest to the QPA, unless the credible info submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate OON rate…"

  (86 FR 55995)
  - Additional info must clearly demonstrate that the QPA is materially different from the appropriate OON rate.
  - If IDR entity does not choose the offer closest to the QPA, the IDR entity's written decision must explain how the credible info demonstrates that the appropriate OON is materially different from the QPA.

  (45 CFR 149.510(c)(4)(vi)(B))

INSURED PATIENTS: IDR PROCESS

- Effect of decision:
  - Binding on parties absent fraud or intentional misrepresentation of a material fact.
  - Not subject to judicial review.
  - Party who initiated IDR may not initiate another IDR involving same party and same or similar claims for 90 days.
- Within 30 days of decision:
  - Loser pays balance due other party.
  - Loser remains responsible for IDR entity fee.
  - Winner's prepaid fee is refunded.

(45 CFR 149.510(c)(4)(vii)-(ix))

SELF-PAY PATIENTS: INQUIRE IF PATIENT IS SELF-PAY

- Convening provider/facility must:
  - Determine if an individual is a self-pay individual:
    - Ask if the patient is covered by a plan, insurance or a federal healthcare program.
    - If patient has coverage, ask if patient wants to have the claim submitted to the payer for the primary item or service.
  - If patient is self-pay, inform the patient that they may obtain a good faith estimate expected charges upon:
    - Scheduling the item or service, or
    - Upon request.

(45 CFR 149.610(b)(1))

SELF-PAY PATIENTS: NOTICE OF GOOD FAITH ESTIMATE

- Convening provider/facility must inform self-pay patients about right to good faith estimate by:
  - Written notice prominently displayed
    - On provider/facility's website;
    - In its office; and
    - Onsite where scheduling or questions about cost of items or services occur.
  - Orally inform patient when scheduling item or service or when patient asks about cost of items or services.
- Notice must be made available in accessible formats and the language spoken by the patient.

(45 CFR 149.610(b)(1))

SELF-PAY PATIENTS: NOTICE OF GOOD FAITH ESTIMATE

OMB Control Number [XXXX-XXXX]
Expiration Date [MM/DD/YYYY]

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

Under the law, health care providers need to give **patients who don't have insurance or who are not using insurance** an estimate of the bill for medical items and services.

- You have the right to receive a Good Faith Estimate for the total expected cost of any non-emergency items or services. This includes related costs like medical tests, prescription drugs, equipment, and hospital fees.
- Make sure your health care provider gives you a Good Faith Estimate in writing at least 1 business day before your medical service or item. You can also ask your health care provider, and any other provider you choose, for a Good Faith Estimate before you schedule an item or service.
- If you receive a bill that is at least $400 more than your Good Faith Estimate, you can dispute the bill.
- Make sure to save a copy or picture of your Good Faith Estimate.

For questions or more information about your right to a Good Faith Estimate, visit www.cms.gov/nosurprises or call [INSERT PHONE NUMBER].

- Notice must contain required info.
- ➢ See HHS form.

SELF-PAY PATIENTS: PROVIDE GOOD FAITH ESTIMATE

- If self-pay person
  - Requests a good faith estimate (including inquiry or discussion about costs), or
  - Upon scheduling a primary item or service,

convening facility must:

  - Within 1 business day, ask co-providers/facilities to submit good faith estimate to the convening provider/facility by due date.*
  - Timely provide written good faith estimate to the patient.

(45 CFR 149.610(b)(1))

** Rules re co-providers not enforced until 1/1/23.*

SELF-PAY PATIENTS: PROVIDE GOOD FAITH ESTIMATE

- If item/service scheduled at least 3 days in advance, provide good faith estimate not later than 1 business day after the date of scheduling.
- If item/service scheduled at least 10 days in advance, provide good faith estimate not later than 3 business days after the date of scheduling.
- If patient requests good faith estimate, provide good faith estimate not later than 3 business days after the date of the request.
- If patient requested good faith estimate and then schedules services, must provide new good faith estimate within time frames described above.
- If any change to anticipated charges, must provide updated good faith estimate no later than 1 business day before the items/services are scheduled to be rendered.

(45 CFR 149.610(b)(1))

SELF-PAY PATIENTS: PROVIDE GOOD FAITH ESTIMATE

- If convening providers/facilities or co-providers/facilities listed in good faith estimate change less than 1 business day before the item/service is scheduled to be provided:
  - Replacement provider/facility must accept the existing good faith estimate as its good faith estimate.
  - Replacement providers/facilities are bound by the existing good faith estimate.

(45 CFR 149.610(b)(1)(viii)-(2)(iii))

➢ *Replacement providers should review good faith estimate and provide new good faith estimate if there is time.*

SELF-PAY PATIENTS: GOOD FAITH ESTIMATE

OMB Control Number [XXXX-XXXX]
ExpirationDate [MM/DD/YYYY]

[NAME OF CONVENING PROVIDER OR CONVENING FACILITY]

Good Faith Estimate for Health Care Items and Services

Patient		
Patient First Name	Middle Name	Last Name
Patient Date of Birth: _____/_____/_____		
Patient Identification Number:		
Patient Mailing Address, Phone Number, and Email Address		
Street or PO Box		Apartment
City	State	ZIP Code
Phone		
Email Address		
Patient's Contact Preference:	[ ] By mail	[ ] By email
Patient Diagnosis		
Primary Service or Item Requested/Scheduled		
Patient Primary Diagnosis		Primary Diagnosis Code
Patient Secondary Diagnosis		Secondary Diagnosis Code

- Good faith estimate must include required info:
  - Patient name and birthdate;
  - Items and services by codes and charges.
  - Discounts or adjustments.
  - Name, NPI, TIN of co-provider/facility,
  - Location where each item/service is provided;
  - List of items/services that will require separate scheduling; and
  - Disclaimers

(45 CFR 149.610(c))

- See HHS form
- ***Make sure good faith estimate is accurate and complete because you are likely going to be bound by it…***

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: SDR PROCESS

- Within 120 days of receiving bill containing disputed charges, patient must notify HHS of intent to pursue SDR and pay $25 fee.
- If SDR entity determines SDR is appropriate, it will notify provider/facility.
- While SDR pending, provider/facility may not:
  - Move the disputed bill to collections or threaten to do so;
  - If bill moved to collections, cease collection efforts;
  - Suspend accrual of late fees on unpaid bill amounts;
  - Take or threaten any retribution against patient to obtain resolution of dispute.

(45 CFR 149.620(c)(1)-(2))

SELF-PAY PATIENTS: SDR PROCESS

- Within 10 days of notice to provider, provider must submit to SDR entity:
  - Copy of the good faith estimate relevant to dispute.
  - Copy of the billed charges that are subject to dispute.
  - If available, documentation showing that the difference between billed charge and good faith estimate reflects:
    - Cost of medically necessary item/services; and
    - There were unforeseen circumstances that could not have reasonably been anticipated by provider/facility when the good faith estimate was provided.

- Within 30 days, SDR entity issues decision.

(45 CFR 149.620(c), (f))

SELF-PAY PATIENTS: BILLED CHARGE IS ON ESTIMATE

If billed charge is listed on the good faith estimate:

- If billed charge ≤ expected charge:
  - Patient pays the billed charge
- If billed charge > expected charge and provider failed to prove medical necessity and unforeseeability:
  - Patient pays the expected charge from estimate.
- If billed charge > expected charge and provider proves medical necessity and unforeseeability:
  - Patient pays the lesser of the:
    - Billed charge, or
    - Expected charge if expected charge > median rate paid by a payer for same/similar service by same/similar provider in the geographic area as listed in independent database, or
    - Median rate if expected charge < median rate.

(45 CFR 149.620(f)(3)(iii)(A))

SELF-PAY PATIENTS: BILLED CHARGE NOT ON ESTIMATE

If billed charge is not listed on good faith estimate:

- If provider failed to prove medical necessity and unforeseeability:
  - Patient pays $0 for the item/service.
- If provider proves medical necessity and unforeseeability:
  - Patient pays the lesser of the:
    - Billed charge, or
    - Median rate paid by a payer for same/similar service by same/similar provider in the geographic area as listed in independent database.

(45 CFR 149.620(f)(3)(iii)(B))

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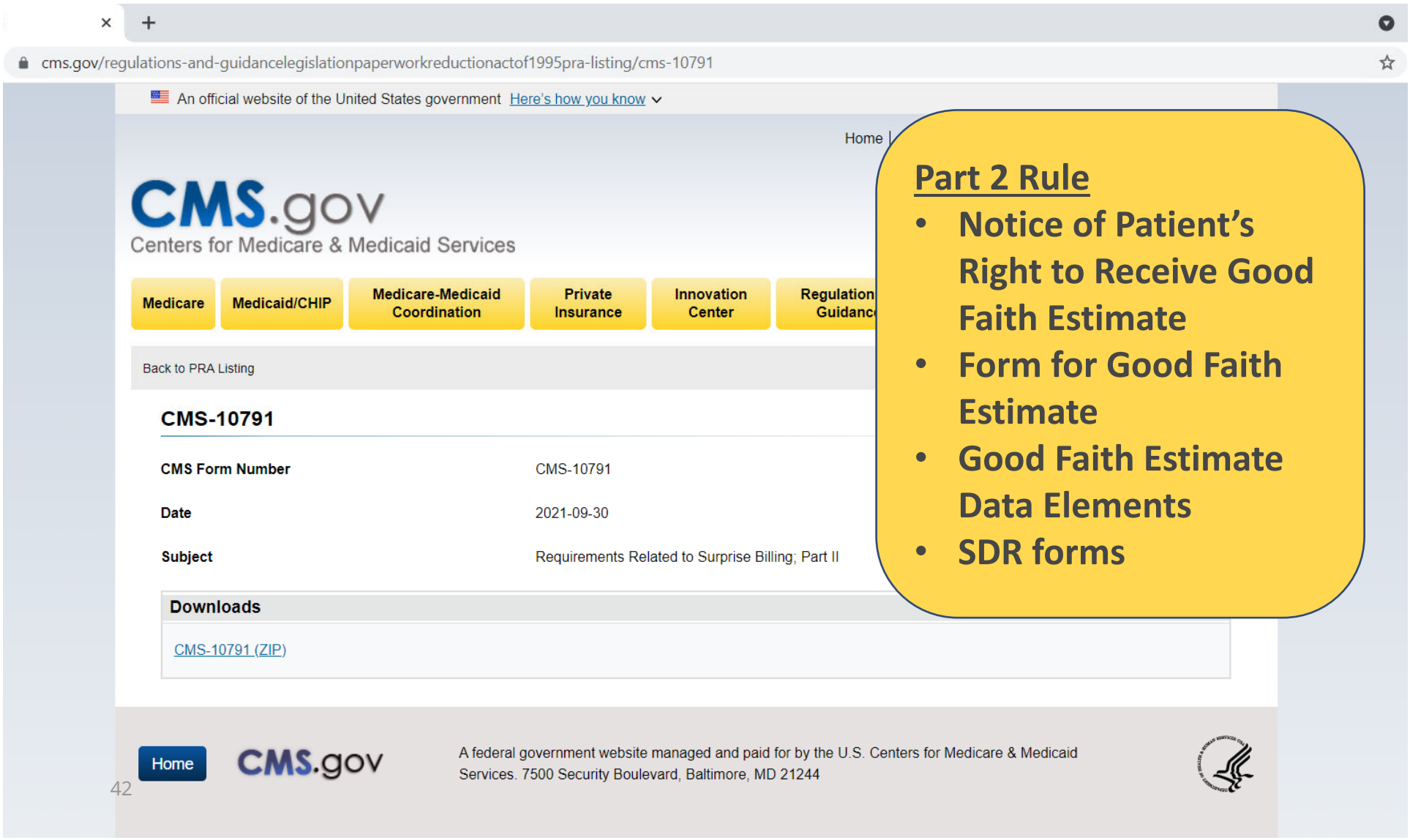


Part 2 Rule

- **Notice of Patient's Right to Receive Good Faith Estimate**
- **Form for Good Faith Estimate**
- **Good Faith Estimate Data Elements**
- **SDR forms**

HTTPS://WWW.CMS.GOV/NOSURPRISES

HOSPITAL PRICE TRANSPARENCY, 45 CFR 180

Effective January 1, 2021; New Penalties Effective January 1, 2022

HOLLAND&HART LLP

HOSPITAL PRICE TRANSPARENCY

Effective 1/1/21 (in effect now)

Hospital Price Transparency Rule, 45 CFR part 180, 84 FR 54424 (11/27/19)

- 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)

HOSPITAL PRICE TRANSPARENCY: ENFORCEMENT

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

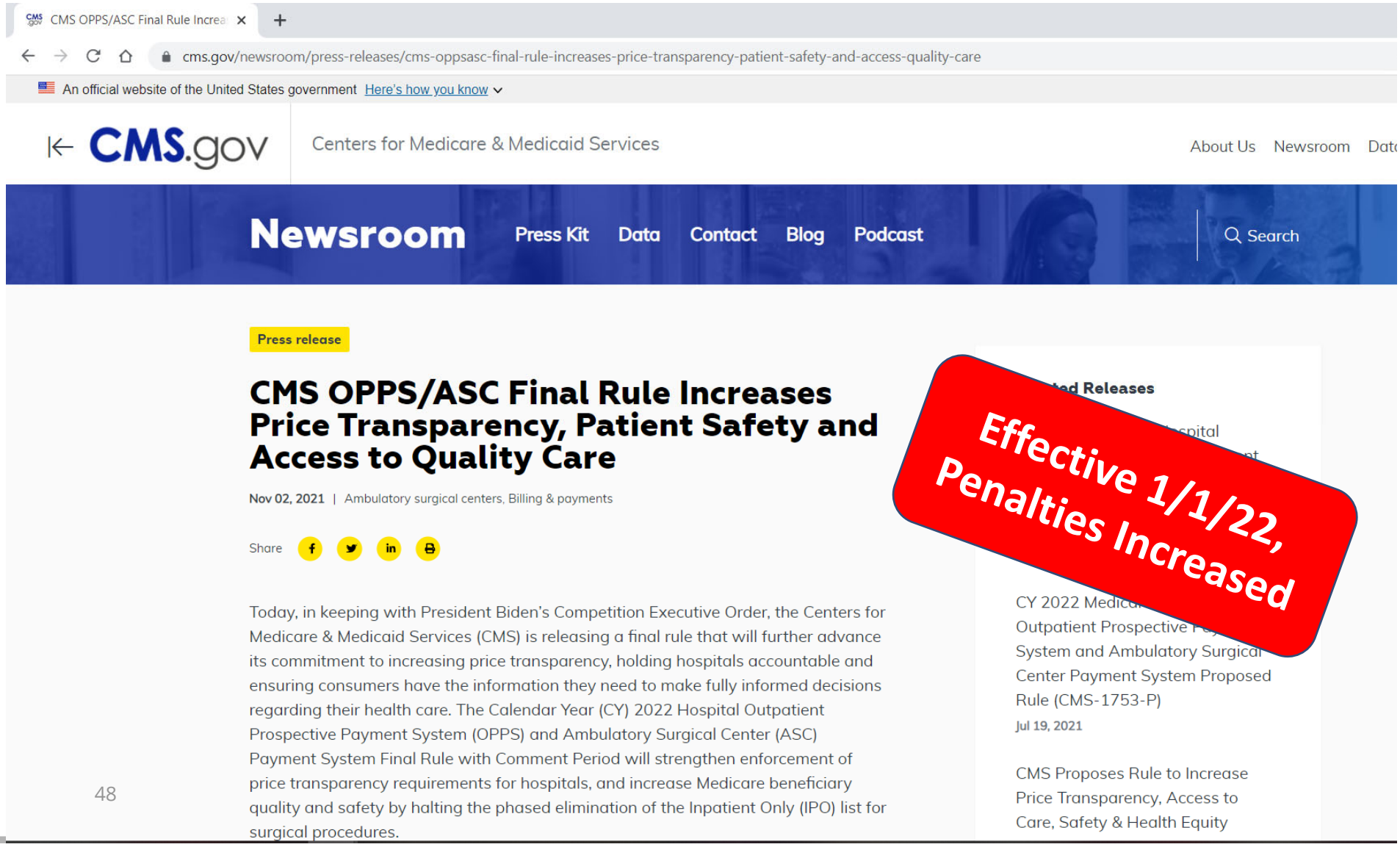
(45 CFR 180.70)

- CMS may enforce by:
  - Written warning notice
  - Corrective action plan
  - Penalty of $300 per day
  - Post penalty on CMS website

(45 CFR 180.70-.90)

- But…

2022 OPPS RULE



HOSPITAL PRICE TRANSPARENCY: PENALTIES

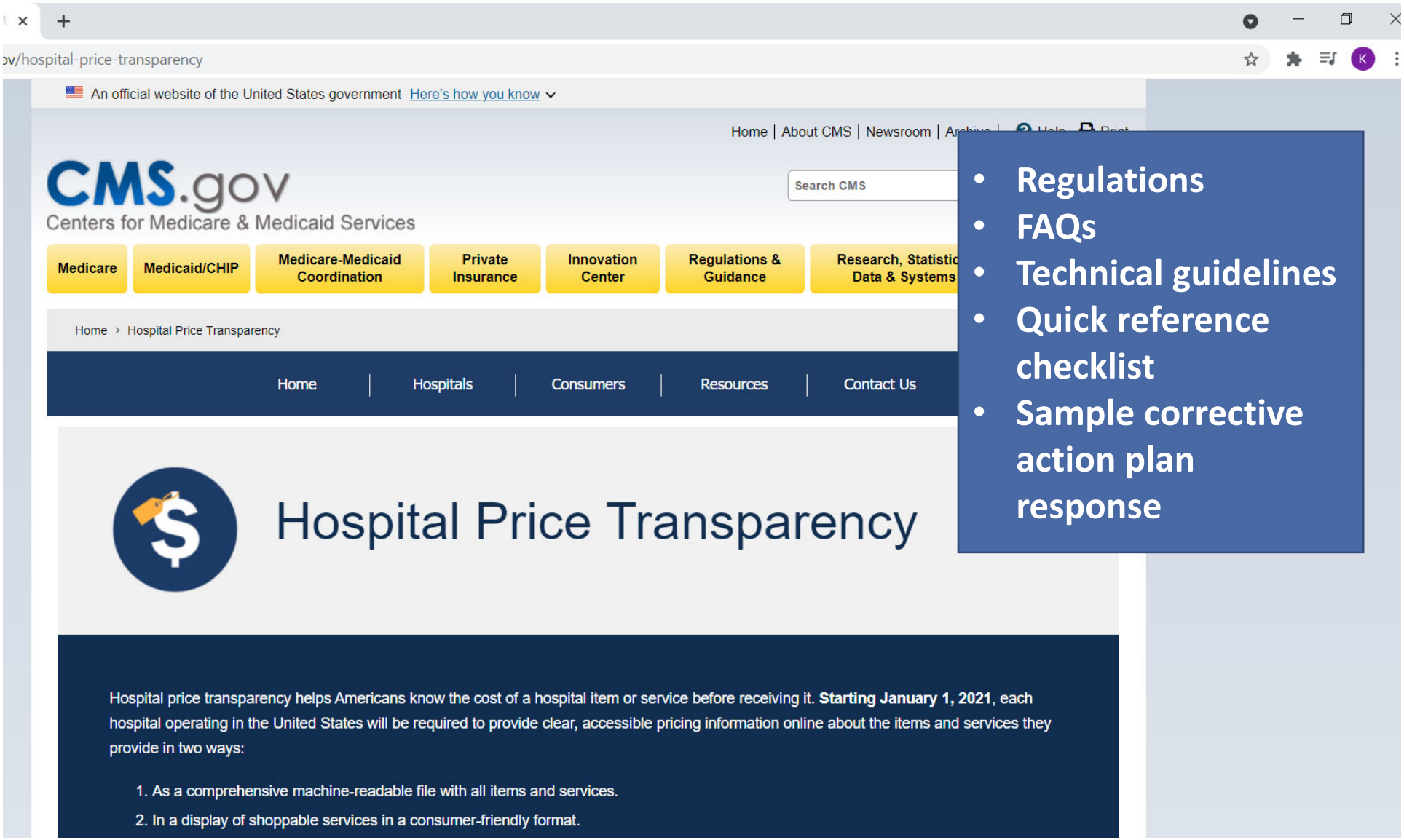
Effective 1/1/22

- Small hospitals (≤30 beds)
  - Maximum of $300 per day
- Large hospitals (>30 beds)
  - Minimum of $10 per bed per day,
  - Maximum of $5,500 per day.

➢ Range of $109,500 to $2,007,500 per hospital per year.

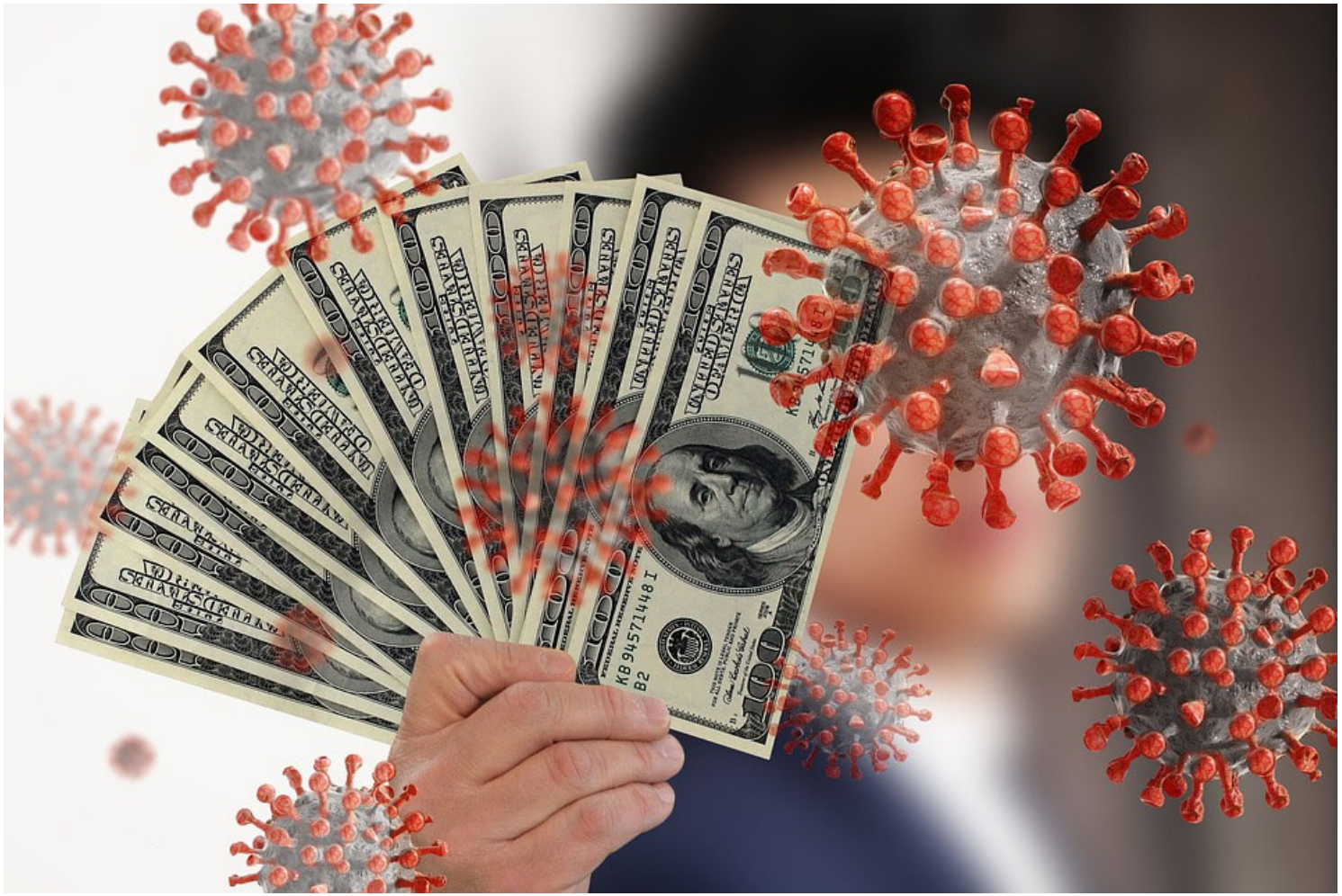
- 2022 OPPS Rule, https://public-inspection.federalregister.gov/2021-24011.pdf
- CMS Fact Sheet, https://www.cms.gov/newsroom/press-releases/cms-oppsasc-final-rule-increases-price-transparency-patient-safety-and-access-quality-care

HTTPS://WWW.CMS.GOV/HOSPITAL-PRICE-TRANSPARENCY



- Regulations
- FAQs
- Technical guidelines
- Quick reference checklist
- Sample corrective action plan response

PROVIDER RELIEF FUND AND REPAYMENTS



PRF REPORTING PERIOD 1 CLOSED

Provider Relief Fund Reporting Requirements and Auditing

Reporting Period 1 Is Closed

Providers with unused funds:

- Return unused funds as soon as possible after submitting your report. All unused funds must be returned no later than 30 days after the end of the grace period (December 30, 2021). More information:
  - Return Unused PRF Funds Portal
  - Returning Funds Fact Sheet (178 KB)

Providers who have not reported, but were required to report in Reporting Period 1:

- You are out of compliance with the PRF Terms and Conditions and must return your PRF payment(s) to HRSA
- Non-compliant providers will be excluded from receiving and/or retaining future PRF payments – including any applicable Phase 4 payments
- HRSA will seek repayment on all PRF payments received between April 10, 2020 - June 30, 2020 and not reported on during Reporting Period 1
- For more details on non-compliance, review the new Reporting Non-Compliance Fact Sheet (PDF - 158 KB)

- **PRF Reporting Period 1 ended 11/30/21.**
- **Unused funds for Period 1 must be returned by 12/30/21.**
- **Failure to report = violation of Terms and Conditions; must return all PRF payments received between 4/10/20 and 6/30/20.**

PRF REPORTING DEADLINES

Home > Provider Relief Fund > Provider Relief Fund Reporting Requirements and Auditing > Important Dates for Reporting

Important Dates for Reporting

Recipients who received one or more payments exceeding $10,000, in the aggregate, during a Payment Received Period are required to report in each applicable Reporting Time Period as outlined in the table below.

	Payment Received Period (Payments Exceeding $10,000 in Aggregate Received)	Deadline to Use Funds	Reporting Time Period
Period 1	From April 10, 2020 to June 30, 2020	June 30, 2021	July 1, 2021 to September 30, 2021*
Period 2	From July 1, 2020 to December 31, 2020	December 31, 2021	January 1, 2022 to March 31, 2022
Period 3	From January 1, 2021 to June 30, 2021	June 30, 2022	July 1, 2022 to September 30, 2022
Period 4	From July 1, 2021 to December 31, 2021	December 31, 2022	January 1, 2023 to March 31, 2023

Download Important Dates (PDF - 81 KB)

*Grace period ended on November 30, 2021.

Reporting Requirements and Auditing

Overview

Important Dates

Allowable Expenses

Resources

Audit Requirements

Frequently Asked Questions

https://www.hrsa.gov/provider-relief/reporting-auditing/important-dates

HTTPS://WWW.HRSA.GOV/PROVIDER-RELIEF/FAQ/REPORTING

STARK AND ANTI-KICKBACK AMENDMENTS

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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 paym… provide… referral.
- Repayment w/in …
- Civil penalties.
  - $26,125+ per claim
  - $174,172+ per scheme

(42 CFR 411.353, 1003.310; 45 CFR 102.3)

More changes effective 1/1/22

➢ *Likely False Claims Act violation*

➢ *Likely Anti-Kickback Statute violation*

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NEW STARK SAFE HARBORS

Effective 1/19/21 (now in effect)

- Value based compensation arrangements. (42 CFR 411.357(aa))
  - Full financial risk.
  - Meaningful downside risk.
  - Value-based arrangements.
- Remuneration to physician < $5000 per calendar year for service rendered if:
  - Not based on volume or value of referrals.
  - Does not exceed fair market value.
  - Arrangement is commercially reasonable even if no referrals.
  - Compensation for leases satisfy certain conditions.

  (42 CFR 411.357(z))
- Payments by physicians for items or services if FMV and arrangement not otherwise covered by 42 CFR 411.357(a)-(h). (42 CFR 411.357(i); 85 FR 77603).
- Cybersecurity technology and services. (42 CFR 411.357(bb))
- Isolated transactions include settlements. (42 CFR 411.357(f))

ADDITIONAL STARK CHANGES

Effective 1/19/21 (now in effect)

- Modified definitions of "fair market value" and "commercially reasonable". (42 CFR 411.351)
- Clarified meaning of "set in advance." (42 CFR 411.354(d))
- Clarified meaning of varying with the "volume or value of referrals." (42 CFR 411.354(c), (d))
- Eliminates "period of noncompliance". (42 CFR 411.353)
- May correct inadvertent overpayment/underpayment within 90 days of termination of arrangement. (42 CFR 411.353(g))
- Gives 90-day grace period to obtain necessary signatures. (42 CFR 411.354(e)).
- Mandates compliance with 42 CFR 411.354(d)(4) if arrangement directs referrals.

STARK GROUP PRACTICE CHANGES

Effective 1/1/22

- Modified compensation portion of "group practice definition" so—
  - Share of profits must be based on profits from all DHS profits for the group or component of the group consisting of at least 5 physicians; you cannot share some profits from DHS but not others.
  - If allocate compensation based on services that are not DHS, may only use services that would not be DHS if payable by Medicare.
  - Added value-based income option.

(42 CFR 411.352(i))

➢ *May require review and update of group compensation structures.*

OPPS RULE (11/2/21): INDIRECT COMP ARRANGEMENT

Effective 1/1/22

- No indirect compensation arrangement if:
  1. Unbroken chain of financial relationships, and
  2. Both the following are satisfied:
     - A. Referring physician's aggregate compensation from direct financial relationship varies with volume or value of referrals or other business generated by the physician; and
     - B. Amount of compensation that referring physician receives per individual unit*:
       - i. Is not FMV; or
       - ii. Increases/decreases with referrals; or
       - iii. Increases/decreases with other business generated; or
       - iv. Is payment for the lease of office space or equipment or for use of premises or equipment; and
  3. Entity knows or should know of the financial relationship.

* Unit = item/service/time if physician is compensated per item/service provided.

(42 CFR 411.354(c)(2))

STARK OPPS RULE (11/2/21): COVID-19 VACCINATIONS

Effective 1/1/22

- Safe harbor for "preventative screening tests and vaccines" applies to COVID-19 vaccines even if there is no CMS frequency limits.

(42 CFR 411.355(h))

STARK OPPS RULE (11/2/21): UPDATED DHS CODE LIST

Effective 1/1/22

- Updated list of CPT/HCPCS Codes that are "designated health services" as listed on the CMS website, *Code List for Certain Designated Health Services (DHS).*
  - Published solely at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.
  - Updated annually.

(42 CFR 411.351)

ANTI-KICKBACK STATUTE

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

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

- "One purpose" test

(*US v. Greber* (1985))

Penalties

- Felony
- 10 years in prison
- $100,000 criminal fine
- $105,563+ 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))

NEW AKS SAFE HARBORS

Effective 1/19/21 (now in effect)

- Outcomes-based payments. (42 CFR 1001.952(d)(2))
- Care coordination arrangements to improve quality, health and efficiency. (42 CFR 1001.952(ee)
- Value-based arrangements with substantial downside risk. (42 CFR 1001.952(ff))
- Value-based arrangements with full financial risk. (42 CFR 1001.952(gg))
- Arrangements for patient engagement and support to improve quality, health outcomes and efficiency. (42 CFR 1001.952(hh))
- CMS-sponsored model arrangements and CMS-sponsored model patient incentives (42 CFR 1001.952(ii))
- ACO beneficiary incentive program. (42 CFR 1001.952(kk)
- Cybersecurity technology and related services. (42 CFR 1001.952(jj))

ANTI-KICKBACK STATUTE: ADDITIONAL CHANGES

Effective 1/19/21 (now in effect)

- Personal services safe harbor modified.
  - No need to specify schedule for services.
  - Aggregate compensation need not be set in advance.

  (42 CFR 1001.952(d))
- Warranty safe harbor modified. (42 CFR 1001.952(g))
- Electronic health records safe harbor modified. (42 CFR 1001.952(y))
- Local transportation safe harbor modified. (42 CFR 1001.952(bb))

ELIMINATING KICKBACK IN RECOVERY ACT ("EKRA")

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

(18 USC 220(a))

<u>Penalties</u>

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

(18 USC 220(a))

➢ *Labs: beware, including COVID testing*

➢ *Applies to private or public payors.*

➢ *Still no safe harbors…*

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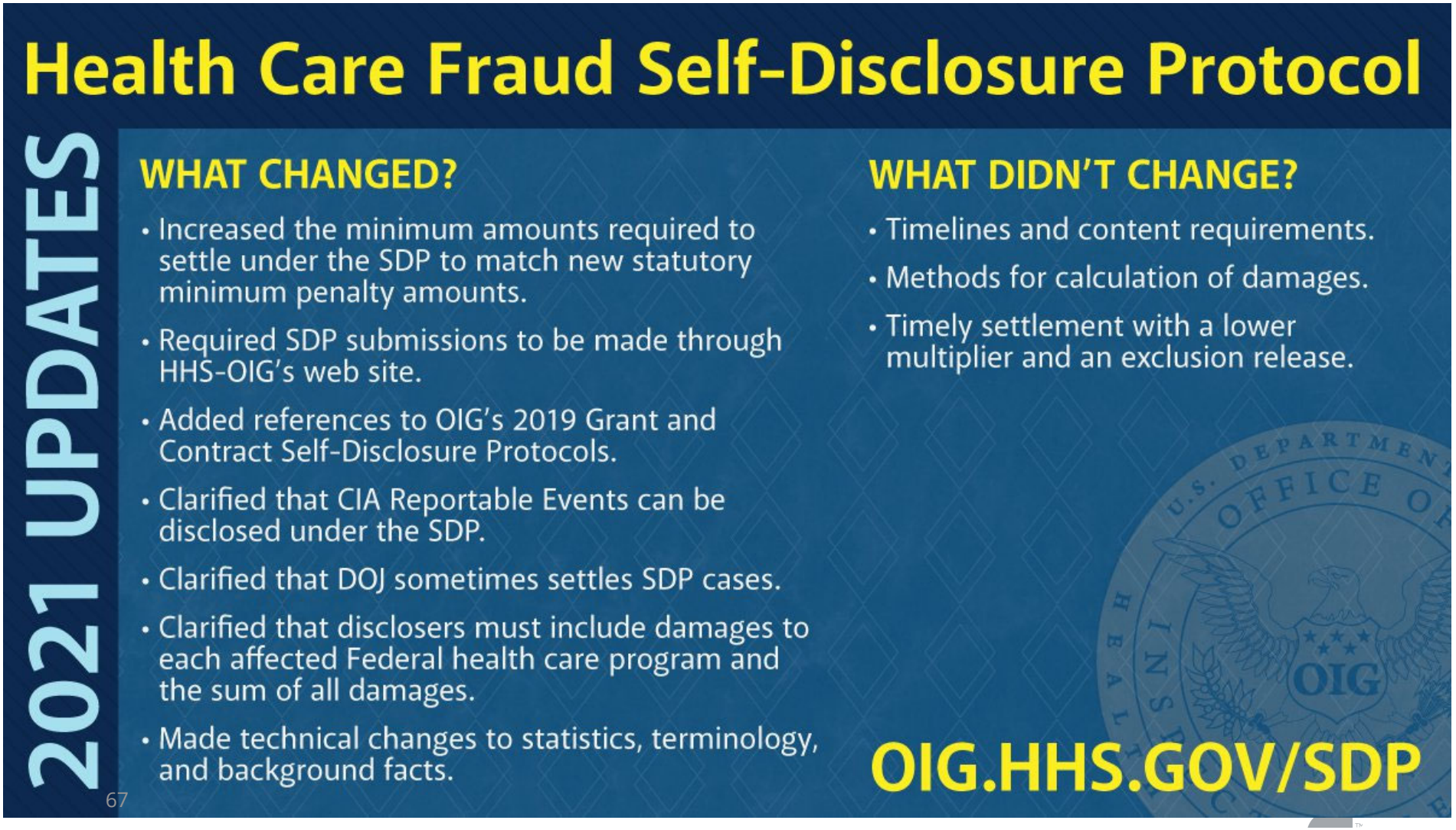
UPDATED OIG SELF-DISCLOSURE PROTOCOL



FALSE CLAIMS ACT AND CYBERSECURITY

THE UNITED STATES DEPARTMENT of JUSTICE

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Home » Office of Public Affairs » News

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Wednesday, October 6, 2021

Deputy Attorney General Lisa O. Monaco Announces New Civil Cyber-Fraud Initiative

Deputy Attorney General Lisa O. Monaco announced today the launch of the department's Civil Cyber-Fraud Initiative, which will combine the department's expertise in civil fraud enforcement, government procurement and cybersecurity to combat new and emerging cyber threats to the security of sensitive information and critical systems.

"For too long, companies have chosen silence under the mistaken belief that it is less risky to hide a breach than to bring it forward and to report it," said Deputy Attorney General Monaco. "Well that changes today. We are announcing today that we will use our civil enforcement tools to pursue companies, those who are government contractors who receive federal funds, when they fail to follow required cybersecurity standards — because we know that puts all of us at risk. This is a tool that we have to ensure that taxpayer dollars are used appropriately and guard the public fisc and public trust."

The creation of the Initiative, which will be led by the Civil Division's Commercial Litigation Branch, Fraud Section, is a direct result of the department's ongoing comprehensive cyber review, ordered by Deputy Attorney General Monaco this past May. The review is aimed at developing actionable recommendations to enhance and expand the Justice Department's efforts against cyber threats.

Civil Cyber-Fraud Initiative Details

The Civil Cyber-Fraud Initiative will utilize the False Claims Act to pursue cybersecurity related fraud by government contractors and grant recipients. The False Claims Act is the government's primary civil tool to redress false claims for federal funds and property involving government programs and operations. The act includes a unique whistleblower

DOJ to use False Claims Act against gov contractors and grant recipients who:

- Knowingly provide deficient cybersecurity products;
- Knowingly misrepresent cybersecurity practices; or
- Knowingly violate obligations to monitor and report incidents.

➢ Scope is unclear.

CYBERSECURITY IN HEALTHCARE

- Ransomware encrypts your IT system so that you may not access it, including:
  - Patient records
  - Financial records
  - Employment records
- Hacker accesses data on your system
- Hacker manipulates or corrupts data on medical devices
- Employee error leads to access to thousands of patient records

- Harm to patients
- Inability to access data
- Corruption of data
- Forced to transfer patients
- Disruption of operations
- Lost revenue
- Cost of response
- Loss or damage to equipment
- Bad public relations
- Fines and penalties
- Lawsuits
- Others?

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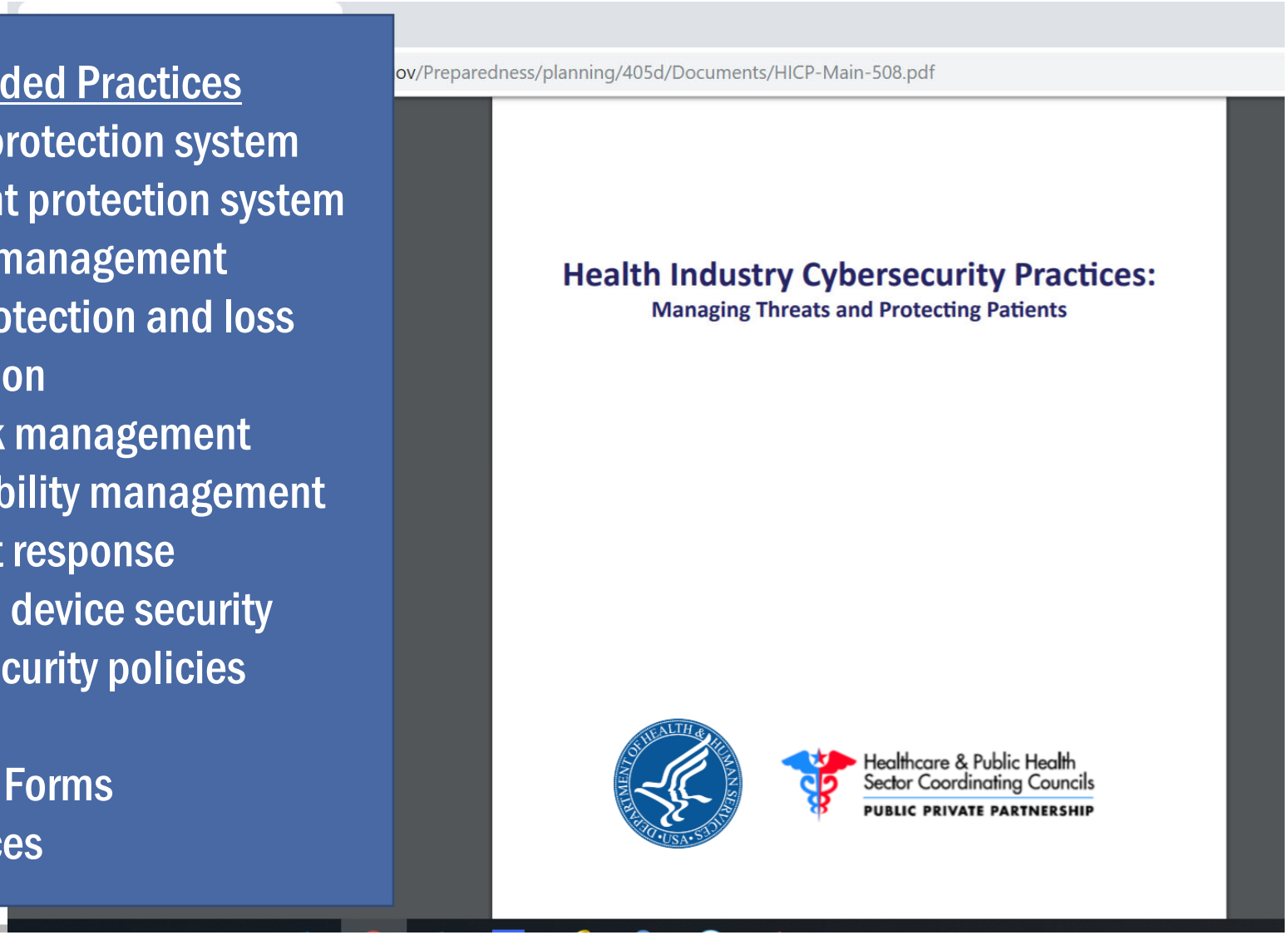
HTTPS://WWW.PHE.GOV/PREPAREDNESS/PLANNING/405D/DOCUMENTS/HICP-MAIN-508.PDF

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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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)

Effective 4/5/21 (in effect)

- 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

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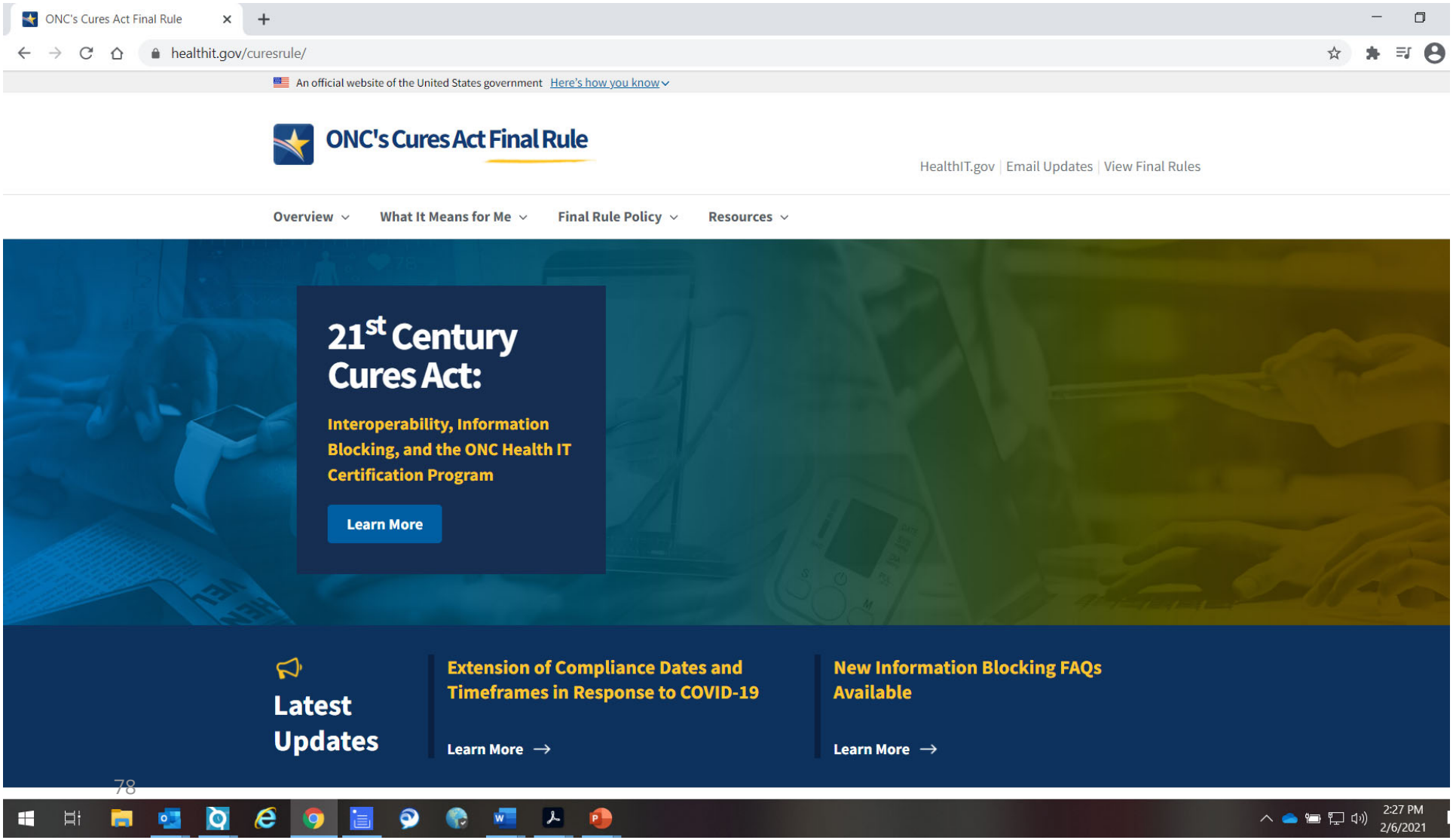
HTTPS://WWW.HEALTHIT.GOV/CURESRULE/



TIME FOR RESPONDING TO PATIENT REQUESTS

"Q: [Does the IBR] require actors to proactively make electronic health information (EHI) available through "patient portals," application programming interfaces (API), or other health information technology?

"No. There is no requirement under the [IBR] to proactively make available any EHI to patients or others who have not requested the EHI. We note, however, that a delay in the release or availability of EHI in response to a request for legally permissible access, exchange, or use of EHI may be an interference under the [IBR]."

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

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….

"Unlikely to be an Interference: If the delay is necessary to enable the access, exchange, or use of EHI, it is unlikely to be considered an interference …. For example, if the release of EHI is delayed … to ensure that the release complies with state law, it is unlikely to be considered an interference so long as the delay is no longer than necessary. Longer delays might also be possible … if no longer than necessary, in scenarios where EHI must be manually retrieved and moved from one system to another system …

"Likely to be an Interference: 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…. [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."

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

HIPAA
45 CFR 164

HOLLAND&HART LLP

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 V. INFO BLOCKING: RIGHT TO ACCESS

HIPAA

- Patients have right to access PHI in their "designated record set."
  - Info used to make decisions about patient.
  - Subject to certain exceptions.
  - May charge reasonable cost-based fee.
  - Must send e-PHI to third party if patient requests.

(45 CFR 164.524)

➢ OCR is actively enforcing individual's right of access.

IBR

- May not unreasonably block access to EHI
  - EHI = PHI in designated record set.
  - Subject to certain exceptions.

(45 CFR 171)

HIPAA V. INFO BLOCKING: RESPONDING TO REQUESTS

HIPAA

- Must provide records in response to patient's request within 30 days*.
- May obtain 30-day extension if needed, e.g., if records maintained offsite.

(45 CFR 164.524)

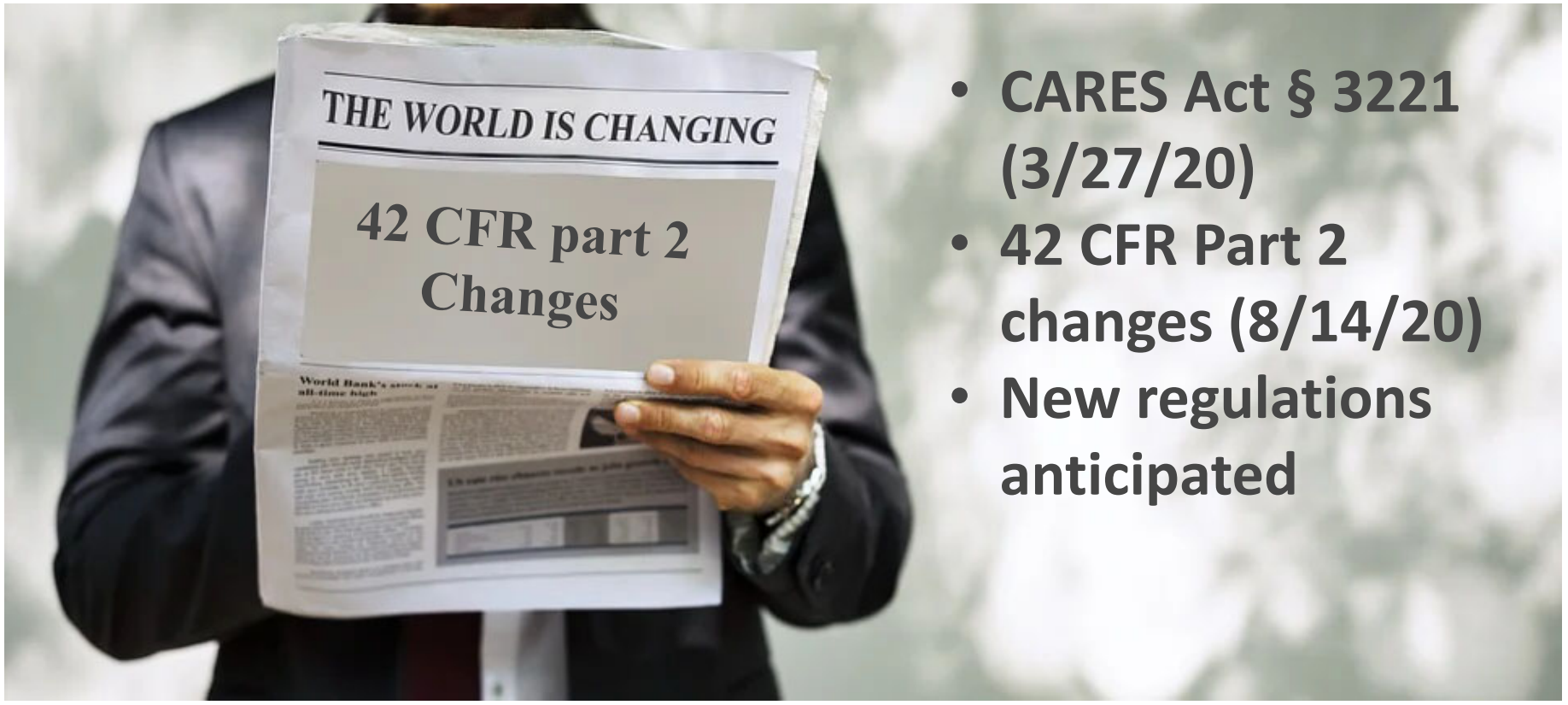
* Proposed rule would shorten to 15 days.

IBR

- May not "unreasonably delay" access.
- If disclosure is "infeasible", must respond within 10 days.

(45 CFR 164.171)

SUBSTANCE USE DISORDER RECORDS, 42 CFR PART 2



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

CARES ACT § 3221

- 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.
- 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)

➢ *In limbo until final rules issue…*

CARES ACT § 3221

42 CFR part 2

- Enforced by Dept. of Justice ("DOJ")
- Criminal penalty
  - $500 for first offense
  - $5000 for subsequent offenses

(42 CFR 2.3)

- Might be subject to private lawsuit, e.g.,
  - Common law privacy tort.
  - Negligence *per se*
  - Other?

CARES Act § 3221

- Eliminates criminal penalties.
- Incorporates HIPAA penalties for part 2 violation.
  - Penalties of $199* to $59,522* per violation.
  - Mandatory penalties of $11,904* to $59,522* per violation for "willful neglect."
- Must report breaches of unsecured PHI per HIPAA.

42 CFR PART 2 REGULATIONS (EFFECTIVE 8/14/20)

- Finalizes rules proposed in 2019, primarily 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 list of lawful holders.
  - Modifies rules for research disclosures.
  - Modifies rules for audit disclosures.
- Does not address CARES Act § 3221.

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

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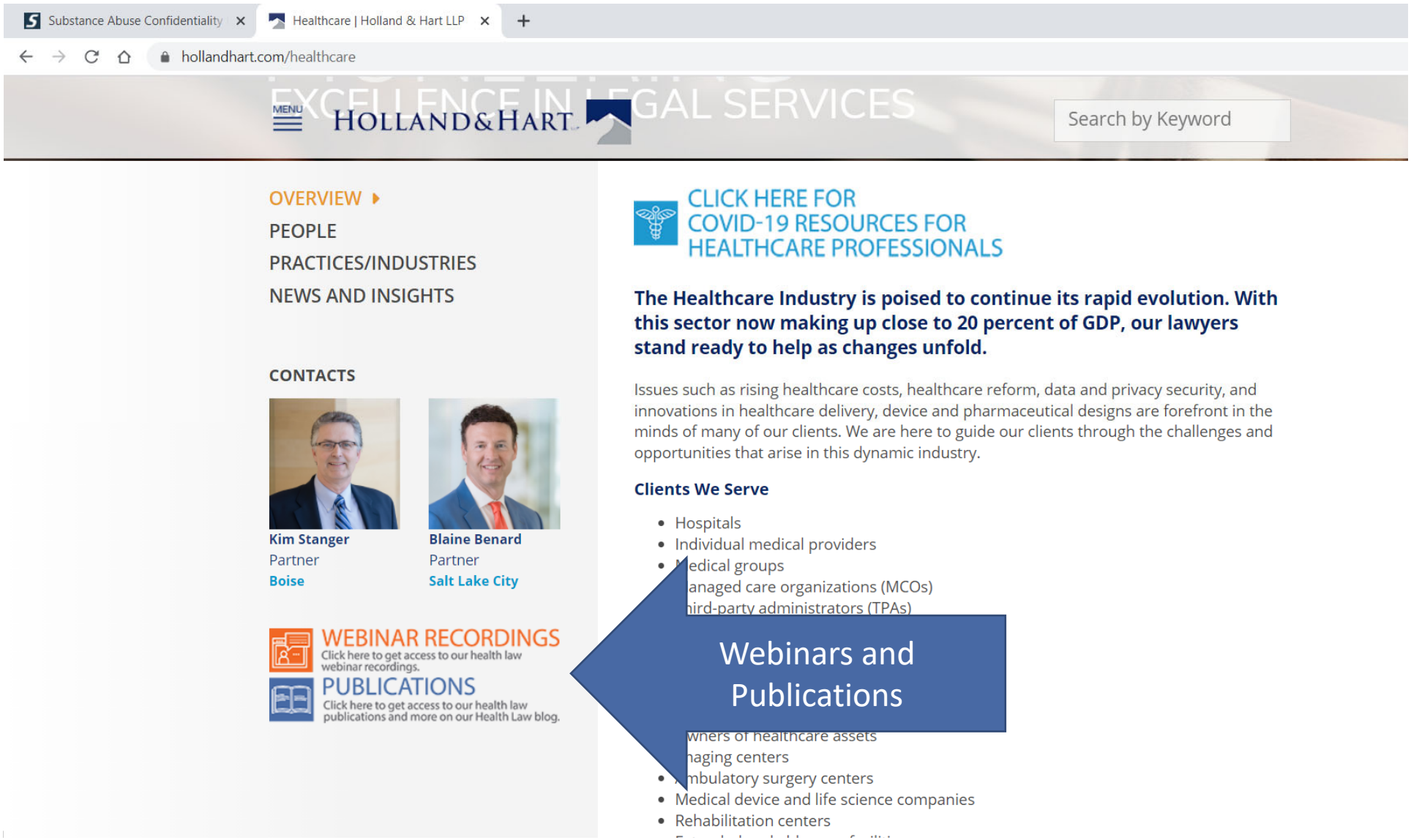

QUESTIONS?

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