No Surprises Act … Part 3?

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Agenda

- Brief recap of the No Surprises Act and Interim Final Rules
- Recent Developments – or Not for the NSA and IDR Process
  - Preparing for GFE for Insureds
    - Provider/Hospital alliances and compliance considerations

- Other Compliance Updates
  - CARES Act – OIG processes
  - Price Transparency
  - The Supreme Court Weighs In On Rulemaking
  - Reimbursement Issues

The "No Surprises Act"

- **Passed by Congress in late 2020 as part of the broader Consolidated Appropriations Act (CAA)**
  - Intends to largely eliminate surprise billing, particularly in the emergency department setting
  - Patient liable only for in-network cost-sharing amount
  - Establishes an independent dispute resolution (IDR) process for settling reimbursement disputes between payors and providers
  - Implements price transparency requirements for payors, including an advanced EOBs, and more accurate provider directories

Interim Final Rules

- **July 1, 2021 IFR**
  - Intends to largely eliminate surprise billing, particularly in ED setting
  - Patient liable only for in-network cost-sharing amount
  - Establishes IDR process for settling payment disputes between payors and providers
  - Implements price transparency requirements for payors, including more accurate provider directories
- **September 30, 2021 IFR**
  - Provides additional protections and more information about good faith estimates and IDR process
- **November 17, 2021 IFR**
  - Implements new requirements for group health plans and issuers to submit certain information about prescription drug and health care spending

Enforcement Agreements

- CMS has issued letters to nearly every state outlining the collaborative enforcement agreement between CMS and the state

- However, as of yesterday, *there is still no enforcement letter for Tennessee*
  - Tennessee is one just two states without an enforcement letter
    - (NY also has not received an enforcement letter)

- Enforcement letters can be viewed here: https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/CAA

Why hasn't Tennessee executed one?

Litigation Regarding IDR Process

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT

Memorandum Regarding Continuing Surprise Billing Protections for Consumers

Date: February 28, 2022

On February 23, 2022, the United States District Court for the Eastern District of Texas, in the case of *Texas Medical Ass'n, et al. v. United States Department of Health and Human Services, et al.*, Case No. 6:21-cv-425 (E.D. Tex.), invalidated portions of an interim final rule, Requirements Related to Surprise Billing; Part II, 86 Fed. Reg. 55,980 (Oct. 7, 2021) (the "Rule"), issued by the Departments of Health and Human Services, Labor, and the Treasury (the "Departments") governing aspects of the federal independent dispute resolution (IDR) process under the No Surprises Act.

This court's order *did not* affect any of the Departments' other rulemaking under the No Surprises Act. **Thus, consumers continue to be protected from surprise bills for out-of-network emergency services, out-of-network air ambulance services, and certain out-of-network services received at in-network facilities.** The patient-provider dispute resolution process for uninsured and self-pay consumers to dispute bills that exceed a provider's or facility's good faith estimate by $400 or more also remains available and unchanged by the court's order. To learn more about these protections, visit www.cms.gov/nosurprises.

Litigation Regarding IDR Process

- **April 22, 2022** – HHS files appeal of Texas court's ruling
  - ***But then requests a hold of appeal until the final rule is released***

- **May 3, 2022** – Court grants Government's request to pause proceedings while the Government issues a final rule….

    - Coming this summer?

United States Court of Appeals
for the Fifth Circuit

No. 22-40264

TEXAS MEDICAL ASSOCIATION; ADAM CORLEY,

Plaintiffs—Appellees,

versus

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF LABOR; UNITED STATES DEPARTMENT OF TREASURY; UNITED STATES OFFICE OF PERSONNEL MANAGEMENT; XAVIER BECERRA, *Secretary, U.S. Department of Health and Human Services*; JANET YELLEN, *Secretary, U.S. Department of Treasury*; MARTIN WALSH, *Secretary, U.S. Department of Labor*; KIRAN AHUJA, *Director of the Office of Personnel Management*,

Defendants—Appellants.

Appeal from the United States District Court
for the Eastern District of Texas
USDC No. 6:21-CV-425

ORDER:

IT IS ORDERED that Appellants' unopposed motion to stay further proceedings in this court pending ongoing rulemaking proceedings involving provisions of the No Surprises Act, with a status report due every sixty (60) days, is GRANTED.

IDR Process

- In April, the Government issued guidance for Certified IDR Entities, but note disclaimer language →
- The Government issued similar guidance for Disputing Parties containing same language

Disclaimer Language

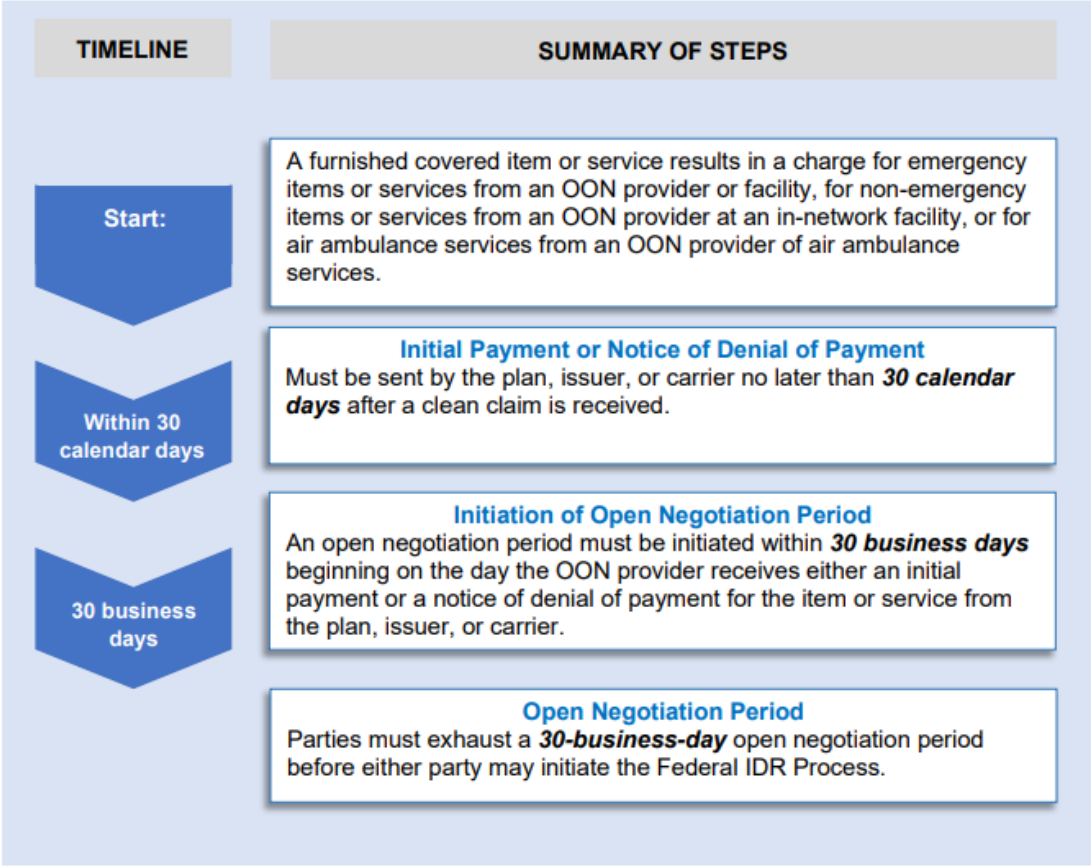
The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

This document is up-to-date as of April 12, 2022; please visit www.cms.hhs.gov/nosurprises for the most current guidance documents related to the Federal IDR Process.

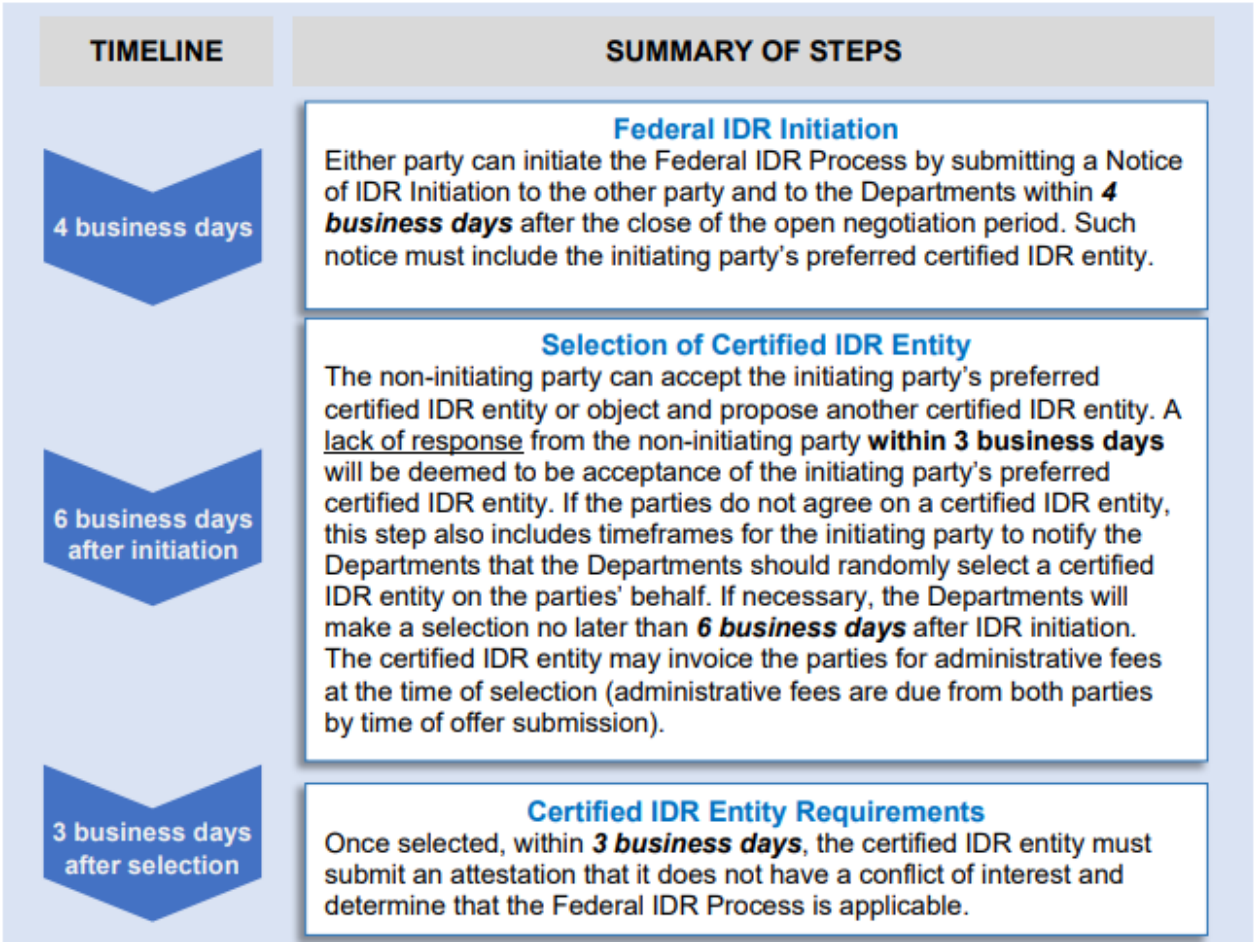
This communication was printed, published, or produced and disseminated at U.S. taxpayer expense.

IDR Process

Steps Preceding the Federal IDR Process



IDR Process



TIMELINE	SUMMARY OF STEPS
4 business days	**Federal IDR Initiation** Either party can initiate the Federal IDR Process by submitting a Notice of IDR Initiation to the other party and to the Departments within ***4 business days*** after the close of the open negotiation period. Such notice must include the initiating party's preferred certified IDR entity.
6 business days after initiation	**Selection of Certified IDR Entity** The non-initiating party can accept the initiating party's preferred certified IDR entity or object and propose another certified IDR entity. A lack of response from the non-initiating party **within 3 business days** will be deemed to be acceptance of the initiating party's preferred certified IDR entity. If the parties do not agree on a certified IDR entity, this step also includes timeframes for the initiating party to notify the Departments that the Departments should randomly select a certified IDR entity on the parties' behalf. If necessary, the Departments will make a selection no later than ***6 business days*** after IDR initiation. The certified IDR entity may invoice the parties for administrative fees at the time of selection (administrative fees are due from both parties by time of offer submission).
3 business days after selection	**Certified IDR Entity Requirements** Once selected, within ***3 business days***, the certified IDR entity must submit an attestation that it does not have a conflict of interest and determine that the Federal IDR Process is applicable.

IDR Process

Notice of IDR Initiation

Use this form if you participated in an open negotiation period that has expired without an agreement for an out-of-network total payment amount for the qualified IDR item or service.

You can start the Federal Independent Dispute Resolution (IDR) process within 4 business days after the end of the 30-business-day open negotiation period if a determination of the total payment for the qualified IDR item(s) or service(s), including cost-sharing, wasn't reached.

You will need to **provide information for both parties involved** in the dispute.

The parties can still reach an agreement on a payment amount during the IDR process, but you must reach an agreement before the certified independent dispute resolution entity determines the payment amount.

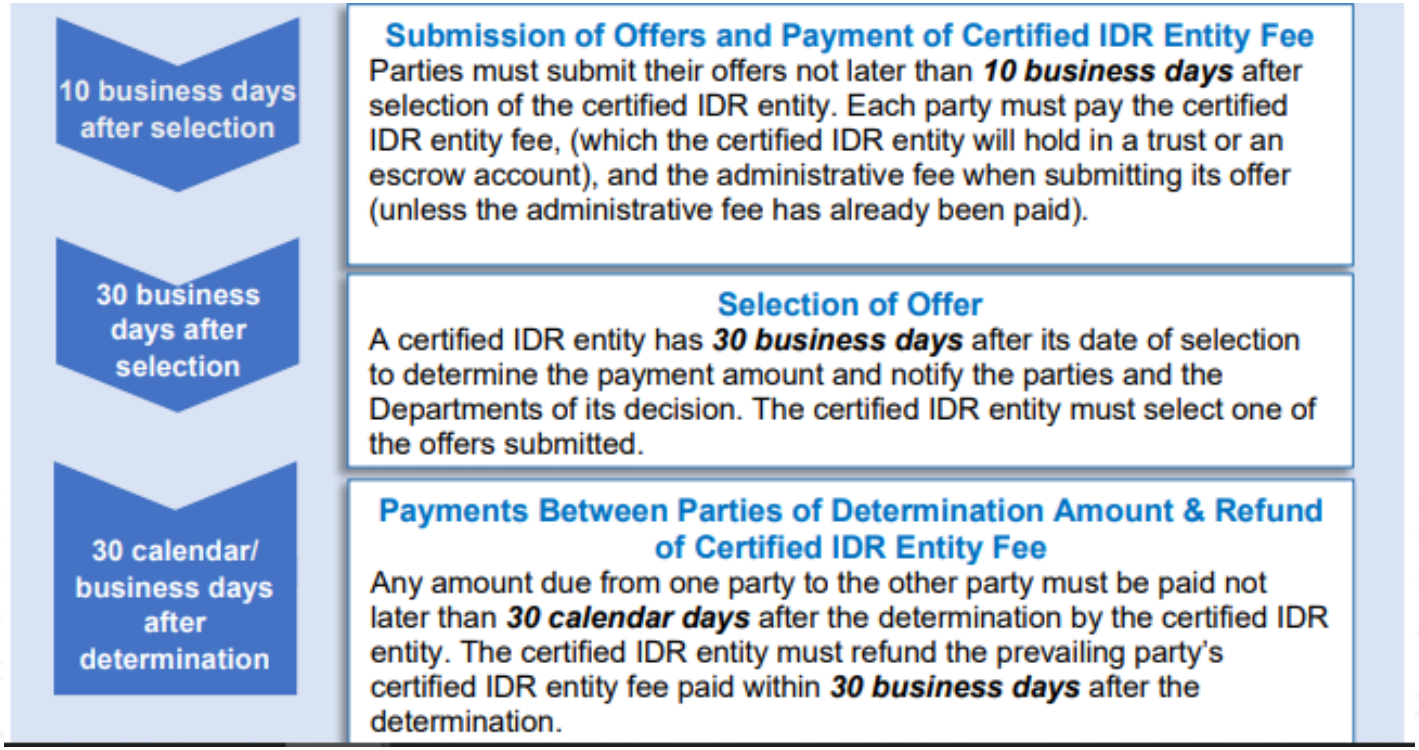
Review the IDR State list to determine which states will have processes that apply to payment determinations for the items, services, and parties involved. FEHB plans are subject to the Federal IDR process unless OPM contracts with FEHB carriers to include terms that adopt state law as governing for this purpose.

Need Help? Contact FederalIDRQuestions@cms.hhs.gov if you have any questions about this form.

Certified IDR Entities

- C2C Innovative Solutions, Inc.
- Federal Hearings and Appeals Services, Inc.
- Island Peer Review Organization, DBA: IPRO
- Keystone Peer Review Organization, Inc.
- Maximus Federal Services, Inc.
- MCMC Services, LLC
- Medical Evaluators of Texas, DBA: MET Healthcare Solutions
- National Medical Reviews, DBA: National Medical Reviews, Inc.
- Network Medical Review Company, DBA: Network Medical Review Company, Ltd.
- ProPeer Resources, LLC

IDR Process



IDR Process – What we are Hearing…

- Payors not giving enough detail in Notice of Denial of Payment
  - Many payors not including contact information for provider to initiate open negotiation, if necessary
- The IDR portal does not allow for sufficient detail to identify claims
- Entire IDR process likely to take many months
  - As of yesterday, we have not heard of anyone completing the process

IDR Process – CMS Hears the Cries?

- Earlier this month, CMS issued a checklist of requirements for plans and insurers in response to complaints that some plans are requiring providers to initiate the open negotiation period through a private issuer hosted web-portal which may not allow for the submission of the standard open negotiation notice as described under the rules
  - The checklist makes clear that within 30 calendar days after a claim is submitted, plans must make an initial payment or send a notice of denial of payment
  - The notice MUST provide contact information to initiate open negotiations

Full checklist available here: https://www.cms.gov/files/document/caa-NSA-Issuer-Requirements-Checklist.pdf

One Stop Shop for IDR Documents

- US Department of Labor website contains all the documents you'll need for the IDR process, including
  - Open Negotiation Period Notice
  - Notice of IDR Initiation
  - Notice of IDR Entity Selection
  - Notice of Offer

- https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/no-surprises-act

IDR Process

- If you run into issues with plans, you can contact the No Surprises Help Desk:
  - https://www.cms.gov/nosurprises/consumers/complaints-about-medical-billing

Some Perspective - NY IDR Process

- NY has had a surprise billing law in place since 2014
- That law includes an IDR proces
  - Process is similar:
    - Includes IDR entities which review disputes
    - Similar timeline
  - In making decision, IDR entities consider:
    - Whether there is a gross disparity between the fee charged by the provider and (1) fees paid to the provider for the same services rendered by that provider to other patients; and (2) fees paid by the plan to reimburse other similarly qualified providers who don't participate with the plan for the same services
- In 2019, NY released a report on the IDR process, noting that more than 2,500 decisions were rendered between 2015-2018
  - Trend: Payors "right" in ED rates – at first, but providers reported as high as 50% greater rate in final negotiation

Good Faith Estimate Requirement

- CMS has so far stated that they will not enforce this requirement of the IFRs until 2023 for insureds
- Burden is on “Convening Providers” per FAQs
- Collaboration with providers to share data?
  - Software platforms?
  - Compliance considerations
    - No “freebies” to referral sources
    - Joint employment for staff?

CARES Act - PRF

- Through the CARES Act, HHS issued hundreds of millions of dollars to hospitals and other providers

- Many providers have completed or begun completing on the reporting elements required by HHS and HRSA

- Several providers (all nursing homes) in various states such as California, Idaho, and South Carolina have all reported receiving letters from the OIG requesting interviews relating to the PRF monies
  - OIG is sending letters to 30 nursing homes who will be part of a "forensic audit" of how they used PRF in 2020

- Also, several components of the PRF on OIG Work Plan →

CARES Act – PRF

Audit of CARES Act Provider Relief Funds: General and Targeted Distributions to Providers

The Coronavirus Aid, Relief, and Economic Security (CARES) Act and the Paycheck Protection Program and Health Care Enhancement Act appropriated $175 billion for the Provider Relief Fund (PRF) to support health care providers affected by the COVID-19 pandemic. In April 2020, the Health Resources and Services Administration began distributing the funds through general distributions to Medicare providers based on 2018 net patient revenue and targeted distributions for certain provider types (e.g., providers in areas particularly impacted by COVID-19, skilled nursing providers, and providers in rural areas). Providers such as hospitals may be eligible for PRF payments from the general and targeted distributions. We will select for audit a statistical sample of providers that received general and/or targeted distributions. Our objective is to determine whether providers that received PRF payments complied with certain Federal requirements, and the terms and conditions for reporting and expending PRF funds.

CARES Act – PRF

Hospital's Compliance With the Provider Relief Fund Balance Billing Requirement for Out – of – Network Patients

The Coronavirus Aid, Relief, and Economic Security (CARES) Act, Paycheck Protection and Health Care Enhancement Act, and Consolidated Appropriations Act, 2021, appropriated a combined $178 billion in relief funds to hospitals and other health care providers. This funding, known as the Provider Relief Fund (PRF), is administered by the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) and is intended to reimburse eligible health care providers for health care-related expenses or lost revenue attributable to COVID-19 and to ensure that Americans could get testing and treatment for COVID-19. Under the PRF terms and conditions, hospitals are eligible for PRF distribution payments if they attest to specific requirements, including a requirement that providers, such as hospitals, must not pursue the collection of out-of-pocket payments from presumptive or actual COVID - 19 patients in excess of what the patients otherwise would have been required to pay if the care had been provided by in-network providers. We refer to this limitation on balance billing, commonly referred to as "surprise billing," as the "balance billing requirement." We will perform a nationwide audit to determine whether hospitals that received PRF payments and attested to the associated terms and conditions complied with the balance billing requirement for COVID - 19 inpatients. We will assess how bills were calculated for out-of-network patients admitted for COVID-19 treatment, review supporting documentation for compliance, and assess procedural controls and monitoring to ensure compliance with the balance billing requirement.

Price Transparency

- Reminder – As of January 1, 2021, hospitals are required to provide clear, accessible pricing information online about the items and services they provide
  - As a comprehensive machine-readable file with all items and services and
  - In a display of shoppable services in a consumer-friendly format

- According to some reports, fewer than 6% hospitals posted prices per the rule during the early months of implementation

- After months of warnings, CMS issues first fines to two Georgia hospitals for price transparency violations:

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-15-12
Baltimore, Maryland 21244-1850

Center for Medicare

June 7, 2022

Reference Number: 162303422021

Unique Case Number (UCN): 2022HPT001

Via Certified Mail

Robert Quattrocchi
President and Chief Executive Officer
Northside Hospital Atlanta
1000 Johnson Ferry Road, NE
Atlanta, GA 30342

RE: Hospital Price Transparency Notice of Imposition of a Civil Monetary Penalty (CMP)

Dear Robert Quattrocchi:

The Centers for Medicare & Medicaid Services (CMS) is imposing a civil monetary penalty (CMP) as described in 45 C.F.R.§180.90. CMS has determined that Northside Hospital Atlanta meets the definition of a hospital specified in 45 C.F.R.§180.20 and that as of the date of this notice, Northside Hospital Atlanta is noncompliant with the price transparency requirements for hospitals to make standard charges public under 45 C.F.R. Part 180 (https://www.govinfo.gov/content/pkg/FR-2019-11-27/pdf/2019-24931.pdf). CMS has documented that your hospital has been noncompliant since March 24, 2021.

Pursuant to 45 C.F.R. §180.70(b), CMS previously issued your hospital a Warning Notice dated April 19, 2021. Your hospital was provided the opportunity to respond and provide supporting documentation to CMS; it did not.

AHA v. Becerra – 340B

- Case involved Medicare cut to reimbursement for 340B hospitals
- In a unanimous opinion, the Court ruled against HHS and sided with the hospitals
- The Court wrote:

  "The question is this: If HHS has not conducted a survey of hospitals' acquisition costs, may HHS still vary the reimbursement rates for outpatient prescription drugs by hospital group? The answer is no.

  ….

  Under the text and structure of the statute, this case is therefore straightforward: Because HHS did not conduct a survey of hospitals' acquisition costs, HHS acted unlawfully by reducing the reimbursement rates for 340B hospitals."

- Full opinion: https://www.supremecourt.gov/opinions/21pdf/20-1114_09m1.pdf

AHA v. Becerra – 340B

- In addition to being a victory for 340B hospitals, the Court's unanimous opinion has significant implications for the *Chevron* doctrine
- While some organizations urged the Court to use the case to overhaul or even overturn the long-standing deference doctrine, the Court's 14-page opinion fails to even acknowledge the doctrine

- What could this mean going forward?

OCR Enforcement

- Trend: Fining fine providers **large and small** for failure to provide timely access to medical records

- Data Breaches

  - OCR Document requests

  - Risk assessment every 2-3 years?

  - Identity of individual who “took the bait” in phishing

FCA and Medicare Advantage

- In a press release issued early this year, the DOJ stated that an "important priority" is "investigating and litigating a growing number of matters related to the Medicare Advantage program"
- Upcoding to government –
  - Plans have "manipulated the risk adjustment process by submitting unsupported diagnosis codes to make patients appear sicker than they were"
- Cases
  - *Sutter Health* – submitted unsupported diagnosis codes
    - Paid $90 million
  - *Kaiser Foundation Health Plan of Washington* – submitted invalid diagnoses
    - Paid $6.3 million

Trends in Enforcement

- Telemedicine
  - April 2022 – Physician indicted in $10 million telemedicine fraud scheme
    - Did not examine patients or had phone conversations that lasted mere minutes
  - Potential fraud issues:
    - Up-coding time and complexity
    - Mispresenting virtual service provided
    - Billing for services not rendered'
    - Kickbacks
- Genetic testing that is not medically necessary
  - May 2021: $46 million fraud, kickback and money laundering scheme involving medically unnecessary cancer genetic tests
  - July 2021: *Virginia Diagnostic Testing Lab* - $1.4 million
  - April 2022: *Physician Partners of America* - $24.5 million
    - Genetic testing, among other things

Reimbursement Issues

- ALJs have clearly been put under pressure for quicker turnarounds
  - Anecdotally:
    - Reimbursement appeals involving statistical extrapolations are being set for hearing without much scheduling flexibility for appellants after years of sitting idle
    - Limitations on evidence that appellants may present at the hearing
      - In a case involving 30 individual beneficiary claims, ALJ would only hear 10
    - Hearings involving individual claims are being set more rapidly than before
      - Several instances of hearings being set within a month of ALJ hearing request being filed

Contacts

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