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Polsinelli's 6th Annual Health Care Reimbursement Virtual Summit – Part 2

March 9, 2022

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Session 1 - Hot Topics in Commercial Contracting and Payor Disputes

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Topics

- Update on the No Surprises Act
- Latest Trends in Unilateral Payor Policies
- Covid-19 Testing & Vaccine Reimbursement
- Trends and Areas of Interest in Value-based Contracting

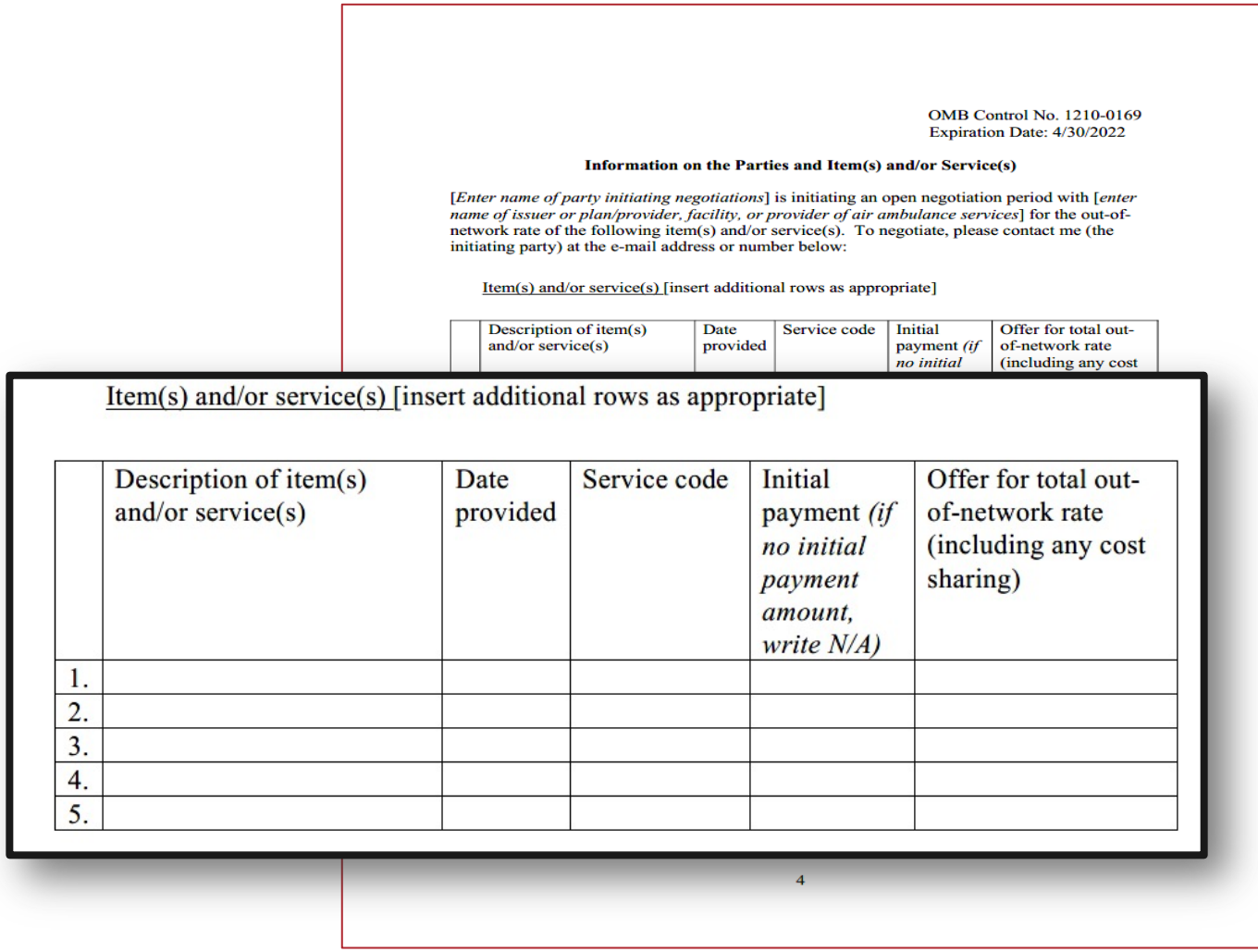
No Surprises Act

- Requires coverage for:
  - OON emergency services (including post-stabilization services in some situations)
  - Most non-emergency services furnished by OON providers at INN facilities (unless notice and consent criteria are met)
  - OON air ambulance services
- Prohibits facilities / providers from balance billing patients
- Limits patients' financial responsibility to applicable in-network cost-sharing
- Requires plans to pay providers directly
  - Plans must first make an "initial payment" within 30 calendar days of claim submission
  - If the provider / facility disputes the amount of the "initial payment," proceed to the IDR process

No Surprises Act

IDR Begins with Negotiation Period

- Provider files notice of open negotiation period within 30 business days of initial payment
- Must use the CMS form: "Open Negotiation Notice"
- Form notice includes line-by-line detail



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

Information on the Parties and Item(s) and/or Service(s)

[*Enter name of party initiating negotiations*] is initiating an open negotiation period with [*enter name of issuer or plan/provider, facility, or provider of air ambulance services*] for the out-of-network rate of the following item(s) and/or service(s). To negotiate, please contact me (the initiating party) at the e-mail address or number below:

Item(s) and/or service(s) [insert additional rows as appropriate]

	Description of item(s) and/or service(s)	Date provided	Service code	Initial payment *(if no initial payment amount, write N/A)*	Offer for total out-of-network rate (including any cost sharing)
1.					
2.					
3.					
4.					
5.					

4

No Surprises Act

IDR Process After Negotiations Fail

- Independent "IDR entity" determines the reimbursement rate (no hearing)
- Baseball-style arbitration (IDR Entity picks one of two offers made)
- Congress requires the IDR entity to consider these factors:
  - QPA (plan's median contracted rate)
  - Level of training, experience, and qualify outcome measurements of the provider / facility
  - Market share of the parties
  - Patient acuity and complexity of the service
  - In the case of a hospital, its teaching status, case mix, and scope of services
  - Good faith efforts (or lack thereof) to enter INN agreements and contracted rates in the previous 4 years (if any)
  - Any additional non-prohibited information
- ***Congress did not place any greater weight on any of the above considerations***

No Surprises Act

IDR Process Regulations

- Three federal agencies (HHS, DOL, IRS) had Congressional authority to issue regulations implementing the IDR process

- An "Interim Final Rule" ("IFR") was published on October 7, 2021

- The IFR said:
  - The **QPA is presumed to be appropriate rate**
  - The IDR entity cannot deviate from the QPA unless "credible" and "relevant" information "clearly demonstrates" that the median in-network rate is "materially different from the appropriate out-of-network rate"

No Surprises Act

Texas Court Vacated the Regulations

- Struck down and vacated the IFR's QPA presumption
- Refused to remand to the Departments
- Decision applies nationwide, not just to named plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION and ADAM CORLEY,

Plaintiffs,

v. Case No. 6:21-cv-425-JDK

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Plaintiff healthcare providers challenge an interim final rule issued
to the No Surprises Act ("Act"). The Rule governs the arbitration process for
payment disputes between certain out-of-network providers and group hea
and health insurance issuers. As explained below, the Court concludes that the Rule
conflicts with the Act and must be set aside under the Administrative Proc
("APA"). Defendants also improperly bypassed notice and comment requir
APA, and thus the Rule must be set aside for this additional reason. Accord
Court **GRANTS** Plaintiffs' motion for summary judgment (Docket No
DENIES Defendants' cross-motion for summary judgment (Docket No. 62)

> and health insurance issuers. As explained below, the Court concludes that the Rule conflicts with the Act and must be set aside under the Administrative Procedure Act ("APA"). Defendants also improperly bypassed notice and comment required by the APA, and thus the Rule must be set aside for this additional reason. Accordingly, the

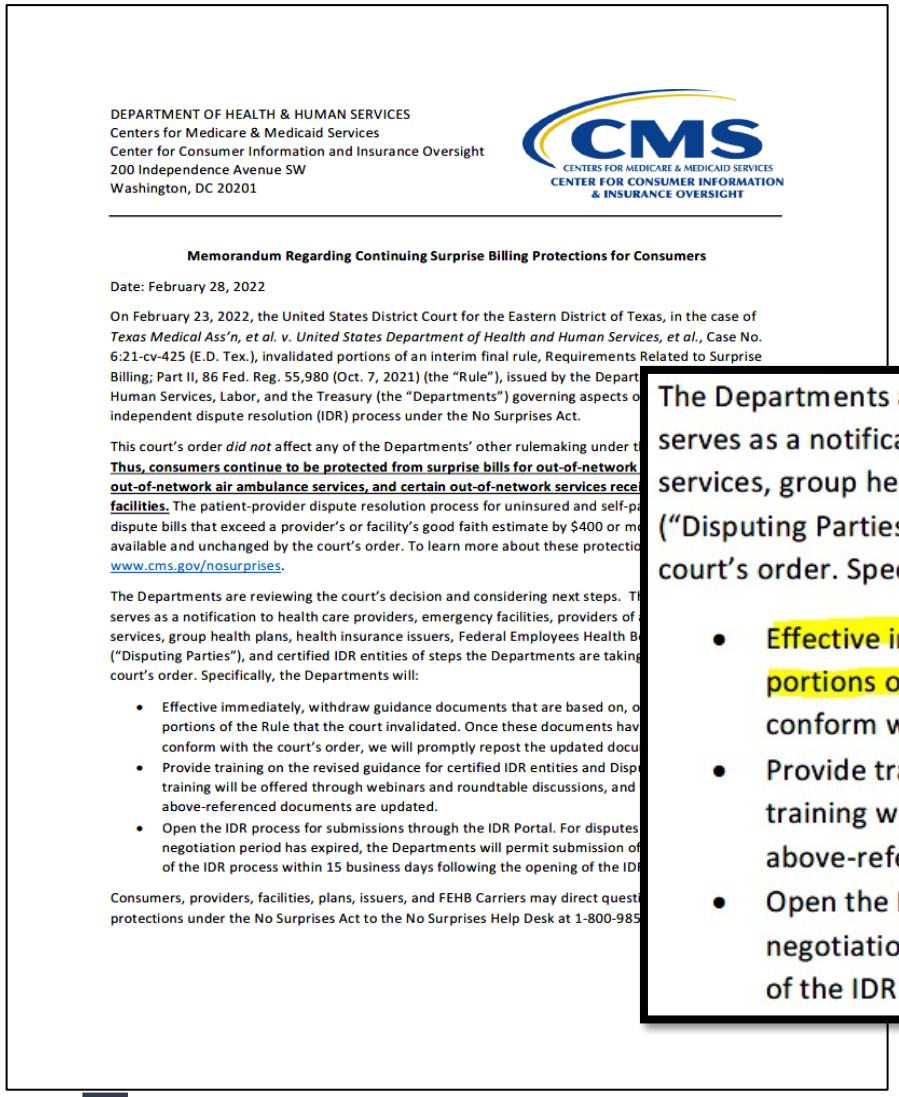
> Here, the seriousness of the deficiency weighs heavily in favor of vacatur. As explained above, the Rule conflicts with the unambiguous terms of the Act in several key respects. This means that there is nothing the Departments can do on remand to rehabilitate or justify the challenged portions of the Rule as written. *Sw. Elec. Power Co.*, 920 F.3d at 1022 (vacating and remanding part of final rule that was contrary to statute).

> The Departments also request that any vacatur apply only to the named Plaintiffs in this case. But "[w]hen a court holds unlawful and sets aside agency rules that are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,' 'the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.'" *Franciscan All., Inc. v. Azar*, 414 F. Supp.

***Texas Medical Ass'n v. HHS* (E.D. Tex. Feb. 23, 2022)**

No Surprises Act

CMS Then Withdrew IDR Entity Guidance



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 Depart Human Services, Labor, and the Treasury (the "Departments") governing aspects o independent dispute resolution (IDR) process under the No Surprises Act.

This court's order *did not* affect any of the Departments' other rulemaking under t **Thus, consumers continue to be protected from surprise bills for out-of-network out-of-network air ambulance services, and certain out-of-network services rece facilities.** The patient-provider dispute resolution process for uninsured and self-p dispute bills that exceed a provider's or facility's good faith estimate by $400 or m available and unchanged by the court's order. To learn more about these protectio www.cms.gov/nosurprises.

The Departments are reviewing the court's decision and considering next steps. T serves as a notification to health care providers, emergency facilities, providers of services, group health plans, health insurance issuers, Federal Employees Health B ("Disputing Parties"), and certified IDR entities of steps the Departments are takin court's order. Specifically, the Departments will:

- Effective immediately, withdraw guidance documents that are based on, o portions of the Rule that the court invalidated. Once these documents hav conform with the court's order, we will promptly repost the updated docu
- Provide training on the revised guidance for certified IDR entities and Disp training will be offered through webinars and roundtable discussions, and above-referenced documents are updated.
- Open the IDR process for submissions through the IDR Portal. For disputes negotiation period has expired, the Departments will permit submission o of the IDR process within 15 business days following the opening of the ID

Consumers, providers, facilities, plans, issuers, and FEHB Carriers may direct quest protections under the No Surprises Act to the No Surprises Help Desk at 1-800-985

The Departments are reviewing the court's decision and considering next steps. This announcement serves as a notification to health care providers, emergency facilities, providers of air ambulance services, group health plans, health insurance issuers, Federal Employees Health Benefits (FEHB) Carriers ("Disputing Parties"), and certified IDR entities of steps the Departments are taking to conform to the court's order. Specifically, the Departments will:

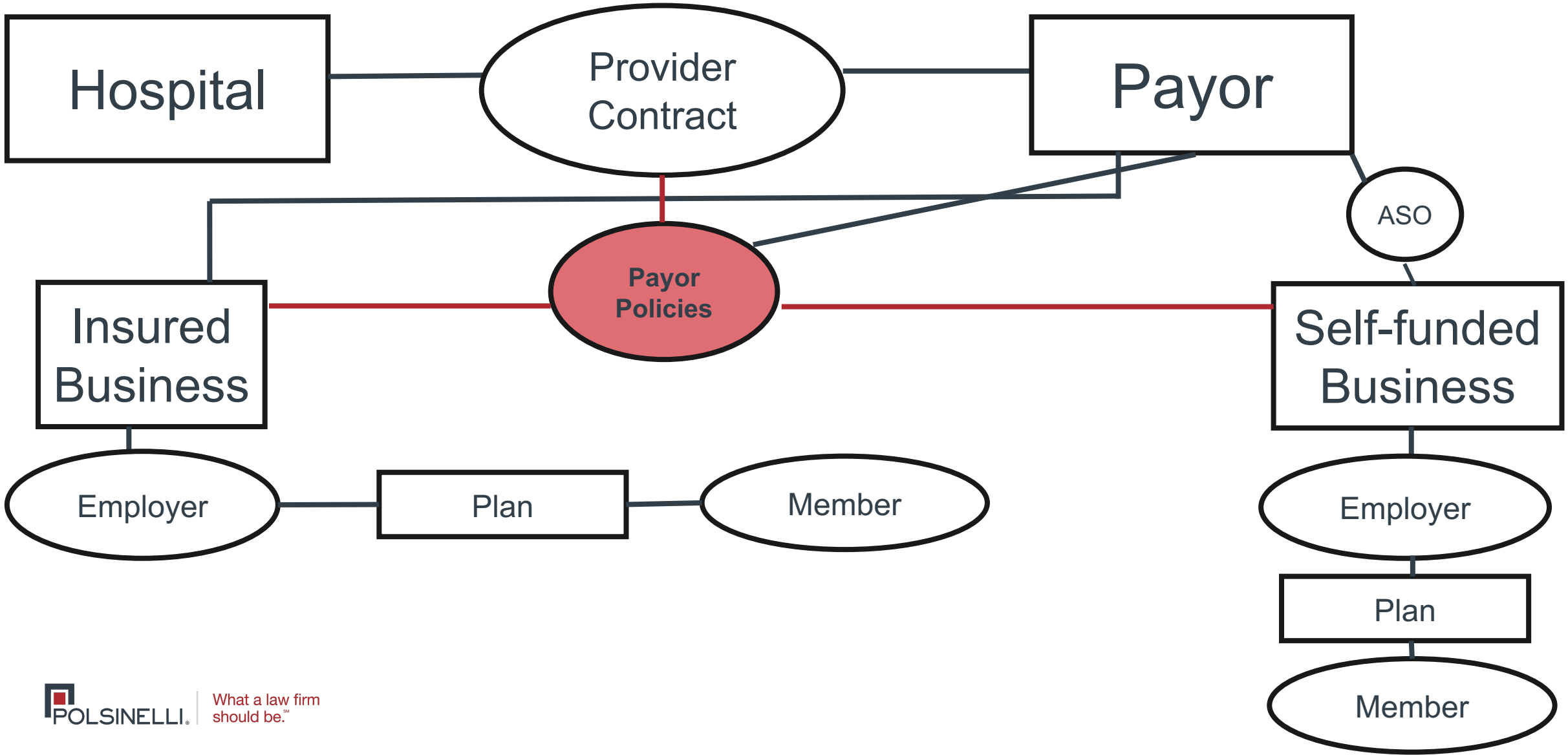
- Effective immediately, withdraw guidance documents that are based on, or that refer to, the portions of the Rule that the court invalidated. Once these documents have been updated to conform with the court's order, we will promptly repost the updated documents.
- Provide training on the revised guidance for certified IDR entities and Disputing Parties. This training will be offered through webinars and roundtable discussions, and will occur after the above-referenced documents are updated.
- Open the IDR process for submissions through the IDR Portal. For disputes for which the open negotiation period has expired, the Departments will permit submission of a notice of initiation of the IDR process within 15 business days following the opening of the IDR Portal.

No Surprises Act

Further Guidance from CMS

- IDR portal launch date of February 28, 2022 was missed; new date was not established
- Once portal is live, submitters will have 15 business days to submit prior disputes
- CMS says it is considering feedback on concerns of claim volume and problems with their forms and systems

Unilateral Payor Policies



Unilateral Payor Policies

Historical Foundation for Managed Care Contracts

- Prices are set based on assumption that full range of services will be offered and available to network members
- Proposed contract terms are modeled to be sure an adequate margin will be achieved
- Terms of the contract control
- Amendments to non-financial contract terms are nominal and “administrative”

Unilateral Payor Policies

Current Trend

Many payors are aggressively seeking to amend contract terms through documents outside the contract through the alleged incorporation of the following into existing contracts:

- Administrative guidelines/ provider manual
- Protocols
- Payment/Reimbursement Policies; and
- Clinical Policies

Unilateral Payor Policies

EXAMPLES

PAYOR	SERVICE	EFFECTIVE DATE
Anthem	ER Downcoding	04/20/2020
	Hospital-based Ambulatory Procedures, including Endoscopy, Site of Care Policy	08/20/2020
	Sepsis-3	June 2019
	Not separately reimbursable (NSR)	Various
	Covid-19 vaccine reimbursement	June 2021
Cigna	Sepsis-3	January 2020
	ER Downcoding	August 2021
Excellus BCBS	Avoidable Readmissions: Medicare Advantage	10/01/2018
	▪ Commercial	06/01/2019
United Healthcare	Arthroscopic Site of Service	11/01/2019
	ER Downcoding	January 2020
	Interoperability Protocol	01/01/2021
	Reference Lab Protocol	10/01/2020
	Screening Colonoscopy Site of Service	01/01/2021
	Sepsis-3	01/01/2019
	Site of Care Medicaid	11/01/2019
	▪ Commercial	12/01/2019
	▪ Medicare Advantage	09/01/2020
	Specialty Medication Purchase Requirement (White-bagging)	04/01/2020

Unilateral Payor Policies

Potential Consequences of Policies

- Access to care diminished
- Quality of care threatened
- Contract is unilaterally amended
- Contract modeling is undermined
- Administrative burden is increased
- Lost benefit of the bargain in the contract
- Introduces more unpredictability of expected reimbursement from commercial payors

Unilateral Payor Policies

Example: White-bagging Policies

- **Aetna**: "Aetna Specialty CareRx refers to a pharmacy benefit plan design for certain specialty drugs. You may get your first fill of these drugs at a retail pharmacy. To achieve best coverage, all refills must come from an in-network specialty pharmacy, like Aetna Specialty Pharmacy. Your plan may require you to get your refills through Aetna Specialty Pharmacy."
- **Anthem/BCBS**: ". . . [P]roviders will be required to obtain specialty pharmacy medications administered in the office or outpatient hospital setting through CVS Specialty effective July 1, 2020. . . For dates of services on or after July 1, 2020, providers will be required to contact CVS Specialty's dedicated Anthem line listed below to order specialty medications for Medicaid HMO members."

Unilateral Payor Policies

Economic Effects of White-bagging Policies

- Payors stop paying the hospitals' contractual rates for high-cost drugs and infusion services and move the service to themselves through acquisition of Pharmacy Benefits Managers
  - Ex. Cigna, Express Scripts, Acrredo and Cigna Collective Care
- Patients do not save on out-of-pocket costs
- The Health Plan and the Pharmacy Benefits Manager increase administration fees
- The Health Plan receives the benefit of rebates and volume discounts

Unilateral Payor Policies

Challenging Payor Policies

- Legislation
- Breach of contract
- Violation of laws, regulations and public policy

Unilateral Payor Policies

WHITE-BAGGING LEGISLATION, *IN EFFECT*

- **Louisiana: LA SB191:** Bans white bagging (July 2021)

- **Texas: H.B. 1763 and HB A1919**
  - Bans steering patients or financially penalizing patients from seeking drugs from the pharmacy of choice and
  - Requires fair and uniform charges for drugs from plans and pharmacies

- **Georgia: Ga. Code § 26-4-119** "Pharmacy Anti-Steering and Transparency Act"

- **New Jersey: N.J. Admin. Code § 13:39-3.10** "Pharmacy Steering Prohibited"

Unilateral Payor Policies

LEGISLATION, *PROPOSED*

- **California**: **SB No. 958:** introduced 2/9/2022 proposal to ban white-bagging as to IVG; CA Board of Pharmacy considering white-bagging
- **Massachusetts**: **247 CMR 9.01 (4):** "...a pharmacist shall not redispense any medication which has been previously dispensed"
- **Ohio**: **OAC 4729 9 04:** "No drug that has been dispensed ... and has left the physical premises of the terminal distributor ... shall be dispensed or personally furnished"
- **Florida**: **Fla. Reg. of Professions and Occupation, Section 465.003(6):** "'Dispense' means the transfer of possession...medicinal drug by a pharmacist to the ultimate consumer or her or his agent"

Unilateral Payor Policies

Breach of Contract

- Unilateral amendment to the contract
- Payor policy conflicts with the terms of the contract
- Payor failed to give notice conforming to the contract's notice provision
  - Untimely notice
  - Notice was not in the correct form
  - Notice was not sent to the correct party/entity
- Payor applied policy over the provider's objection
- Key to success is favorable contract language
- Likely going to be resolved in arbitration

Unilateral Payor Policies

Violation of Laws, Regulations and Public Policy

- Corporate practice of medicine
- Interfering with the physician/patient relationship
- Prudent layperson standard
- Standards of care
- Other specific laws, such as the white-bagging laws

Unilateral Payor Policies

Other Examples of Potential Legal Violations

- **Sepsis-3**: payors are applying the new definition of sepsis which has been expressly rejected by CMS

- **E/M downcoding**: CMS forbids payors from adjusting emergency claims based on the discharge diagnosis, a practice which implicates the prudent layperson standard

COVID-19 Testing Reimbursement

CARES Act

*(1) If the health plan or issuer **has a negotiated rate** with such provider in effect before the public health emergency declared under section 319 of the Public Services Act (42 USC 247d), such negotiated rate shall apply through the period of such declaration.*

*(2) If the health plan or issuer does not have a negotiated rate with provider, such plan or issuer **shall reimburse the provider** in an amount that equals the **cash price for such service** as listed by the provider on a public internet website, or such plan or issuer may **negotiate a rate** with such provider for less than such cash price.*

Section 3202, Pub. L. 116-136, as amended through Pub L. 117-71, Enacted December 10,2021

COVID-19 Testing Reimbursement

Some Health Plans Seek to Avoid the Law

- Ignoring the negotiated rate for new codes
- Ignoring the published rate
- Paying the patients instead of the provider
- Engaging in stall tactics by pending claims for documentation

COVID-19 Testing Reimbursement

Pending Cases

- *Genesis Lab Management, LLC v. United Health Group, Inc*. (NJ, filed June 2021)
  - Alleging violations of FFCRA and CARES Acts due to failure to pay 51,000 claims for Covid tests
- *Diagnostic Affiliates of Northwest Hou, LLC v. United Health Services, Inc*. (TX, filed June 2021)
  - Court found a private right of action exist to enforce the CARES Act as related to Covid-19 testing
- *Murphy Medical Associates, et al v. Cigna Health and Life insurance Company (*Conn, filed Nov. 2021*)*
  - Plaintiff is a private physician with drive-through and walk-in testing sites
  - Cigna responded with allegations of price gouging and challenged the private right of action under the CARES Act.
- *Blue Cross and Blue Shield of Kansas City v. GS Labs LLC (*Missouri, filed June 2021*)*
  - BCBS alleges inflated rates
  - GS Labs countered with antitrust allegations

COVID-19 Vaccine Reimbursement

CARES Act

- Health insurance issuers and non-grandfathered group health plans must cover qualifying coronavirus preventative services without cost-sharing requirements.

- Qualifying coronavirus preventative services include immunizations/vaccines (cost of vaccine, plus cost the administration)

Section 3203, Pub. L. 116-136, as amended through Pub L. 117-71, Enacted December 10,2021

COVID-19 Vaccine Reimbursement

CARES Act

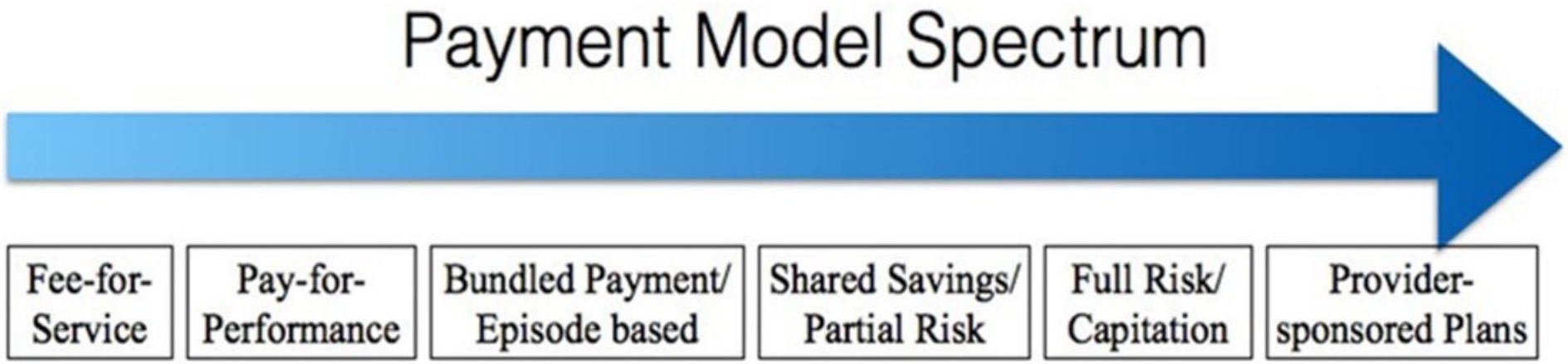
- Covers in-network and out-of-network providers
- For in-network providers, the CMS Toolkit on Covid-19 Vaccines states “issuers will typically pay negotiated rates.”
- For out-of-network providers, issuers will typically pay up to the allowed amount. Further, this amount must be reasonable, “as determined in comparison to prevailing market rates for such service; one example of reasonable rate would be the Medicare reimbursement rate.”
- Note: CMS tied the Medicare rate to out-of-network providers, not in-network providers.

COVID-19 Vaccine Reimbursement

NEVERTHELESS…

- UHC issued a payor policy stating it would reimburse all providers, in and out-of-network, at the CMS Rate of $40.

Value-based Contracting



Chee, Tingyin, Current State of Value-Based Purchasing Programs, AHA Journals, Vol. 133, No. 22 (2016).

- There is a growing trend to offer contract terms based on value and quality
- Appears reasonable, but caution

Value-based Contracting

Performance Metrics

- Metrics need to be objective and defined
- If payor has control of member attribution, include risk adjustment, if applicable
- Payment time should match time when metrics are measured (monthly, quarterly, etc.)
- Reconciliation to occur annually

Value-based Contracting

Other Considerations

- Limit application of separate provider manual
- Consider carefully the risk of taking on responsibility for third parties
- Determine the effect of termination on quality performance metrics and payment
- Consider unique appeal process that allow for transparency on payor calculations, specific timeframes for appeal and response, deference to calculations by independent accountants, and executive-level meet-and-confer

Questions

Thank You

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