TxSCO Update

July 11, 2024 ADVI & HillCo



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2024 Election: Debate Fallout



New Medicare Part B Drug Reimbursement Proposal from Former Trump Advisor

June 18, 2024: Theo Merkel (former Trump National Economic Council) released a proposal that would tie coverage and reimbursement of new Part B drugs to manufacturers contracting with a threshold of Medicare Advantage (MA) plans.

Coverage

MA plans would not initially be required to cover "novel" therapies under Part B

Instead, each year, MA plans would have the opportunity to negotiate a contract with the manufacturer to cover a given drug at a mutually agreed-upon price

If a threshold of plans (e.g., 50% by enrollment) achieve such a contract, the drug would be required to be covered by Medicare (MA and fee-for-service (FFS))*

If the coverage threshold is not met, the drug would not be covered by Medicare for the next year and the process would repeat for the next plan year

Provider Reimbursement

Buy-and-bill remains intact

 This proposal keeps buy-and-bill intact, as opposed to the IPI** which would have established a "CAP 2.0" vendor model

Medicare Advantage

- The highest-priced contract above the "volume threshold" would determine the "clearing price" for the drug, which would be used to set the price of the drug as well as reimbursements to MA plans
- Manufacturers would be required to sell the drug for, at most, the clearing price minus 1%
- MA plans that reached a contract would receive reimbursement equal to the clearing price minus 1%
- MA plans that did not reach a contract would receive reimbursement equal to the clearing price

Fee-For-Service

- The clearing price would be used to set the reimbursement rates paid to providers who see traditional FFS Medicare beneficiaries
- Instead of being reimbursed at ASP + 6%, providers would be reimbursed at the clearing price plus "an addon payment"

While former President Trump remains focused on international reference pricing (IRP), Merkel argued IRP is not appropriate for *new* Part B drugs, as these therapies are often not available ex-US until one or more years following the US launch.

Merkel also noted the IRA's price controls do not address *new* Part B drugs, as biologics are ineligible for price controls for 13 years post launch, and smallmolecule drugs are ineligible for 9 years.

Under a Trump 2.0 administration, CMMI could pursue an IRP approach for *older* Part B drugs and this proposal for *new* Part B drugs.

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*All MA plans would be required to cover the drug, but they would also be reimbursed separately, outside the capitated payment for this subset of drugs **IPI: International Pricing Index Model (<u>link</u>); MFN: Most Favored Nation Model (<u>link</u>) Source: Manhattan Institute, "How to Deliver Lower Prices for Seniors A Market-Based Reform for Expensive Drugs with Limited Competition" (6/18/24, link)

New Medicare Part B Drug Reimbursement Proposal from Former Trump Advisor

Under both examples listed below, the contract threshold for guaranteed coverage is 50% of plans (by enrollment)

Figure 1

Two examples of how the process might play out.

Example 1:



Outcome: The drug must be covered and the manufacturer must sell at clearing price of \$2,970. Reimbursement to Medicare Advantage plans 1 through 4 set at \$2,970. Reimbursement for plan 5 set at \$3,000. Fee-for-service reimbursement set at \$3,000 plus an administration fee.

Example 2:



Outcome: Medicare Advantage plans with only 35% of enrollment reached a deal to cover this drug. Therefore, the drug would not be covered by Medicare and the contracting process would start again the next year.

ADVI Advisor Insights

- Negative impact on innovation given the non-guarantee of Medicare coverage
- Expect higher Part B drug launch prices to account for the model
- MA plan incentives: The proposal claims that "MA plan sponsors want to cover as many drugs as possible in order to make the plan attractive to potential enrollees," but our advisors disagree because MA enrollees do not typically choose plans with Part B drug coverage in mind (e.g., an enrollee is not expecting to be diagnosed with cancer next year, therefore they will not pick a plan based on its coverage of the newest cancer drugs)

ingering Questions

- ASP implications: if Part B sales at the mandated price are included in the ASP calculation, the model could result in lower provider reimbursement with commercial and Medicaid patients (i.e., the "ASP spiral" concern with Part B drugs subject to a negotiated price under the IRA)
- Negotiation timeline and mid-year launch implications: an advisor noted negotiation might align with the Part D formulary calendar, meaning it may be a full year from time of approval until clear Medicare coverage
- Role of compendia in coverage decisions
- Treatment of combination therapies

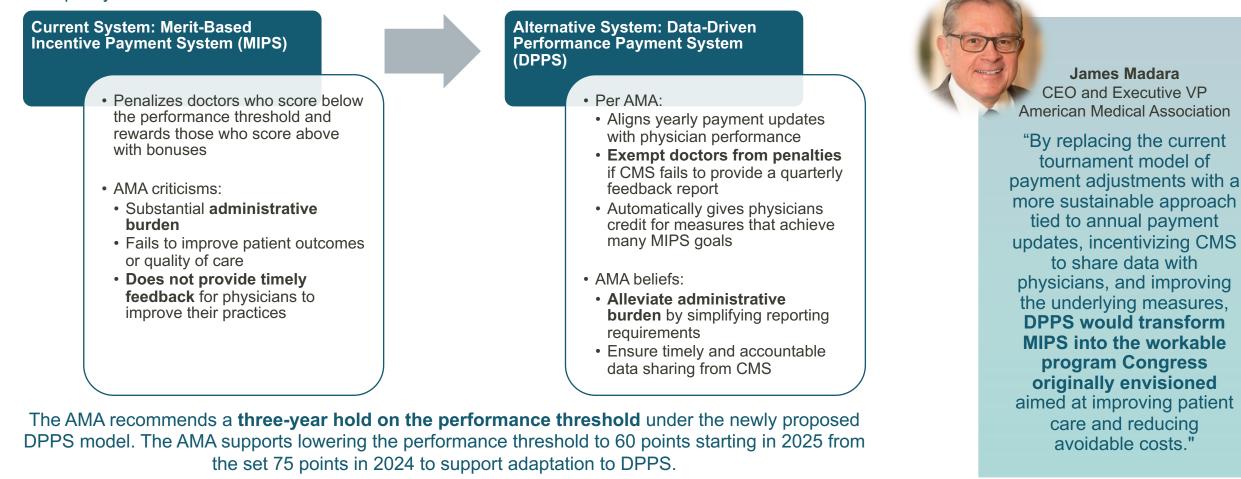
New Medicare Part B Drug Reimbursement Proposal from Former Trump Advisor

Under the proposal, provider reimbursement for Part B drugs will be based on the clearing price. Examples below outline provider reimbursement for Figure 1, Example 1 on the previous slide.

Curre	nt Policy	Proposed Policy				
ASP	\$4,000	Clearing Price	\$3,000			
Purchase Price (assumes no discounts)	\$4,000	Purchase Price (Clearing Price – 1%)	\$2,970			
Reimbursement (ASP + 6%)	\$4,240	Reimbursement (Clearing Price + "add- on payment")	\$3,000 + "add-on payment"			
Provider Earnings	\$240	Provider Earnings	\$30 + add-on payment			

AMA Supports Legislation to Replace MIPS with DPPS

The American Medical Association (AMA) supports draft legislation to **replace the Merit-Based Incentive Payment System (MIPS) with the proposed Data-Driven Performance Payment System (DPPS)** with the goal of reducing administrative burden and improving patient outcomes and quality of care.



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Note: Draft text has not yet been released as of June 25, 2024. Above content is based on press and AMA comments. Source: IHP (6/24/24, <u>link</u>); AMA (6/7/24, <u>link</u>; 6/12/24, <u>link</u>)

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Supreme Court Rulings: Healthcare Implications

On June 28, the Supreme Court ruled to overturn the principle of Chevron deference in *Relentless, Inc. v. Dep't of Commerce* (decided 6-3) and *Loper Bright Enterprises v. Sec. of Commerce* (decided 6-2). On June 27, the Supreme Court ruled in *SEC v. Jarkesy* (decided 6-3) that when the SEC seeks civil monetary penalties (CMPs) against a defendant, that defendant is entitled to a jury trial.

Overturn of *Chevron* Impact

- The Court's decision to overturn Chevron deference will require Congress to draft less ambiguous legislation to provide the framework for agencies
 - Policy counsel and trade associations could play an increasingly key role in drafting legislation due to subject matter expertise
- Impact on 340B Contract Pharmacies
 - HRSA has issued guidance on requiring 340B prices to be offered to covered entities' contract pharmacies – not regulation
 - Chevron deference applies to rulemaking/regulation, not sub-regulatory guidance
 - HRSA may be less likely to formalize this policy in regulation; if they choose to do so, they will likely face lawsuits alleging the agency is exceeding statutory authority

SEC v. Jarkesy Impact

- The Supreme Court ruled that the 7th amendment's right to a jury trial applies to "suits at common law," including statutory claims that are "legal in nature," like CMPs
 - The Court applied this to the SEC's issuance of CMPs, ruling that a trial by jury is necessary
- While the case applies only to the SEC, other agencies may face increased scrutiny on their use of CMPs
 - CMS can impose CMPs in response to information blocking and in the IRA's Drug Negotiation Program
 - HHS OIG can impose CMPs for HIPAA violations
 - FDA can assess CMPs against numerous companies for failure to comply with certain requirements

Source: Supreme Court Majority Opinion "*Relentless, Inc. v. Dep't of Commerce*" and *"Loper Bright Enterprises v. Sec. of Commerce*" (6/28/24, <u>link</u>); 340B Report (7/2/24, <u>link</u>); Supreme Court Opinion "*Securities and Exchange Commission v. Jarkesy et al.*" (6/27/24, <u>link</u>); Sidley (7/1/24, <u>link</u>)

Energy and Commerce Advances Stark Law Reform

June 12, 2024: House Energy and Commerce Committee unanimously advanced 13 health related bills, including the Seniors' Access to Critical Medications Act.

Bill	Summary	Revisions Made in Markup	Vote
Seniors' Access to Critical Medications Act (H.R.5526)	Clarifies that delivering medicines by mail, courier, or other methods and allowing a family member or caregiver to pick up medicines on behalf of a patient would not violate the Stark Law.	 Flexibilities would last until December 31, 2029, before needing to be reauthorized Requires doctor and patient to meet physician inperson at least once annually Requires CMS to conduct a study on the impact of the flexibilities on utilization and costs Additional inclusion criteria for Medicare coverage of external infusion pumps and non-self-administrable drugs 	41-0

Rep. Pallone (D-NJ-6) supported the amendments to the Seniors' Access to Critical Medications Act, saying the exception would help patients while "protecting Medicare beneficiaries by ensuring provider decisions are made on basis of clinical criteria."



Source: Full Committee Markup Recap: E&C Advances 13 Health Related Bills to the Full House (6/12/24, <u>link</u>); Accelerating Kids Access to Care Act (H.R.4758) (<u>link</u>); Seniors' Access to Critical Medications Act (H.R.5526) (<u>link</u>)

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CBO 340B Spending Data for 2010-2021

On June 17, 2024, CBO released data on the growth of the 340B program from 2010 to 2021 by drug class, facility type, and contract pharmacy status.

Overview

- CBO found that from 2010-2021:
- 340B spending grew 19% annually, to \$44 billion
- 73% of spending growth was attributable to cancer drugs, anti-infectives, and immunosuppressants

Key findings

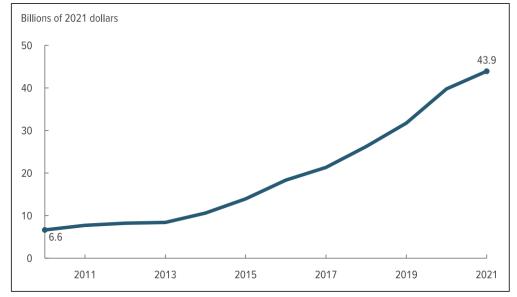
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- CBO concluded that only a portion of the growth in 340B spending could be explained by market trends or disproportionate spending growth for certain drug classes
- CBO calculated that 88% of the growth in 340B spending from 2010 to 2021 can be attributed to spending on drugs prescribed by hospitals and their affiliated off-site clinics
- CBO further attributed 20% of the growth in 340B spending to drugs dispensed at contract pharmacies
- 47% of 340B spending at hospital-based facilities in 2021 was on cancer treatments
- In contrast, 77% of 340B spending by federal grantees was on anti-infective agents

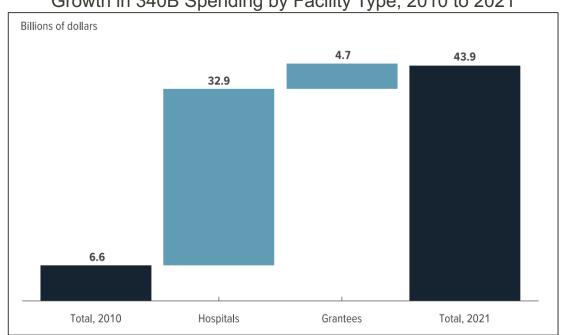
Other factors which likely contributed to 340B spending growth

- Integration of hospitals and clinics
- Expanded facility participation under the Affordable Care Act
- Expanded use of contract pharmacies.

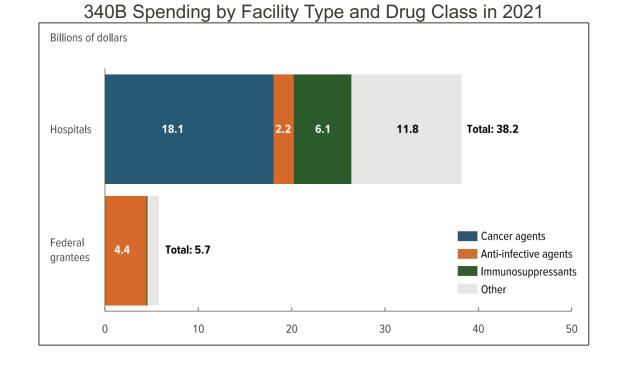
Spending in the 340B Program, 2010 to 2021













NIH Announces New AI Immunotherapy Tool for Cancer Treatment

On June 3, 2024, the NIH unveiled the Logistic Regression-Based Immunotherapy Response Score (LORIS) tool, which assesses the likelihood of response to immune checkpoint blockade therapy.

LORIS

- Uses AI and machine learning to determine the potential impact of immune checkpoint inhibitors (tumor mutational burden and PD-L1) on cancer patients
- Uses six criteria to assess whether a patient's cancer will respond to immune checkpoint inhibitors
- Age
- Cancer type
- History of systemic therapy
- Blood albumin level
- Blood neutrophil-to-lymphocyte ratio
- Tumor mutational burden

Accuracy

- Researchers from NCI and Memorial Sloan Kettering found that the model accurately predicted:
- A patient's likelihood of responding to an immune checkpoint inhibitor
- Patient lifespan; specifically, higher LORIS scores predicted better overall survival response for all except one individual cancer type (pancreatic)
- Patients with low tumor mutational burden who could be effectively treated with immunotherapy
- Researchers also noted that larger studies are needed to further evaluate the model in clinical settings

Researchers compiled a dataset of 2,881 participants with 18 solid tumor types, including data from Memorial Sloan Kettering



To assess patient outcomes, researchers measured objective response, progressionfree survival, and overall survival response

NATIONAL CANCER INSTITUTE LOgistic Regression-based Immunotherapy-response Score

Your Inform	ation	
Patient age (years):	65	
Cancer type:	Small cell lung cancer 🗸	
Previous systemic therapy:	no 🗸	
Blood albumin (g/dL):	3.5	Cal
Blood neutrophil-to-lymphocyte ratio:	8	<u>C</u>
Tumor mutational burden (mut/Mb):	56	

Your result

The likelihood of response to immune checkpoint blockade therapy (95% confidence interval)

72%	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	
(60 - 83%)																					

This result predicts how likely you are to respond to immune checkpoint blockade therapy. The likelihood means that out of 100 patients with similar characteristics, approximately 72 may benefit from this therapy. More specifically, we're 95% confident that 60 - 83 out of 100 patients may benefit from this therapy, based on our training data. However, it's important to recognize that this is just a rough ballpark estimate. Individual patient outcomes can vary significantly, and a healthcare provider can provide a more precise assessment, taking into account a broader range of factors and personal medical history.

Disclaimer: This tool is provided for informational purposes only and should **NOT** be considered as medical advice or a

State Updates



- On June 21, 2024, the Texas Medical Board adopted <u>final rules</u> regarding exceptions to the ban on abortions.
- The board issued these final rules after receiving feedback from private citizens, physicians, and associations.
- The adopted version of the rules specifically addresses concerns that references to ectopic pregnancy better track with existing statutory references on the matter.
- The rules stresses that the lack of imminent risk of death or substantial impairment to a patient should not preclude a physician from doing what is medically necessary.
- The rules also reaffirm that documentation in the medical records of a physician's actions and reasoning should be done in a manner that helps explain actions taken, but not slow down or preempt what may need to be done quickly to save the life of a woman.



Speaker Politics

- The race for House Speaker continues to dominate discussions regarding next session.
- For the time being, it seems Speaker Phelan has the necessary support to maintain his position, however, opposing factions continue to attempt to draw his supporters away and erode his credibility.
- Regardless of who becomes Speaker, the next session will present challenges between the House and the Senate.







Fifth Circuit Court of Appeals Partially Reverses Braidwood v. Becerra Ruling

On June 21, 2024, the Fifth Circuit Court of Appeals reversed a District Court ruling that previously blocked the enforcement of the ACA's requirement for employer plans to cover preventive care. However, the court also said that the plaintiffs could not be forced to provide its workers with insurance that covers the services.

-Sept. 7, 2022: In the U.S. District Court for the Northern District of Texas, Judge Reed O'Connor ruled the ACA's delegation to USPSTF violates the Appointments Clause because the HHS Secretary cannot direct USPSTF to give a specific preventive service an "A" or "B" Rating

-HHS Secretary does not have any authority to direct which services are covered under §300gg-13(a)(1) and concludes that USPSTF members are officers of the United States and that their selection does not comply with the Appointments Clause procedures.

-The Court also found that the ACA's delegation to ACIP and HRSA are not in violation of the Appointments Clause since the HHS Secretary effectively has the authority to ratify or not the ACIP and HRSA recommendations.

-March 30, 2023: Judge O'Connor issued a ruling to block HHS from enforcing the ACA's requirement that private health insurers cover without cost sharing all services rated "A" or "B" by the USPSTF

-This ruling applies the decision nationally

-The ruling also eliminates the PrEP-specific coverage requirement on grounds that it violates the Religious Freedom Restoration Act (RFRA)

The Fifth Circuit Court agreed with the plaintiffs that the USPTF members were not "validly appointed," but countered that the district court's decision to "universally enjoin" its ruling nationally was "an error."

Next Steps:

- The case will return to the Texas District Court which will hear arguments on whether the USPTF has the proper authority to decide what services insurers must cover
- The plaintiffs can appeal the Fifth Circuit Court decision to the Supreme Court before the District Court issues a decision

Overall, stakeholders from both sides have expressed mixed reactions to the decision. Advocates of the preventive service coverage requirements are "thankful" that coverage has been preserved but are concerned about the long-term potential USPSTF-related requirements to be weakened. Experts have suggested that the decision opens the possibility of other employers using the ruling to evade providing insurance that would cover these services. While it is not certain whether the case will be taken up by the Supreme Court, an appeal could be filed this summer and heard by the high court as early as next term.

Source: Braidwood Management Inc. v. Becerra (<u>link</u>); IHP "Texas Judge Vacates ACA's Preventive Services Mandate, PrEP Coverage" (<u>link</u>); KFF "Q&A: Implications of the Ruling on the ACA's Preventive Services Requirement" (3/31/23, <u>link</u>), Advocates Highlight Braidwood's Importance Ahead Of Oral Arguments (3/3/24, <u>link</u>)



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December 27, 2020	July 2021	October 2021	February 23, 2022	August 19, 2022	September 21, 2022	September 23, 2022	November 30, 2022
• No Surprises Act (NSA) signed into law as part of the Consolidated Appropriations Act of 2021	• The Departments released the <u>"Requirements</u> <u>Related to Surprise</u> <u>Billing; Part 1,"</u> to restrict surprise billing for patients in job- based and individual health plans who get emergency care, non- emergency care from out-of-network providers at in- network facilities, and air ambulance services from out-of- network providers	• The Departments released the <u>"Requirements</u> <u>Related to Surprise</u> <u>Billing; Part II,"</u> which included establishing an independent dispute resolution (IDR) process to determine out-of- network payment amounts between providers or facilities and health plans	 The Eastern District of Texas in Texas Medical Association, et al. v. U.S. Dept of HHS vacated portions of the October 2021 interim final rules related to payment determinations under the Federal IDR process. Specifically vacated a portion of the interim final rule that required arbiters to put an emphasis on choosing the amount closest to the Qualifying Payment Amount (QPA) 	 The Departments issued final rules titled <u>"Requirements</u> <u>Related to Surprise</u> <u>Billing: Final Rules</u>" Rules finalize requirements under the July 2021 interim final rule relating to information that group health plans and health insurance issuers offering group or individual health insurance coverage must share about the QPA 	 AMA and AHA dropped a lawsuit that had been filed against the federal government in December, arguing the surprise billing arbitration process would harm providers leading to underpayment for out- of-network services After the release of the most recent final rule on the surprise billing arbitration process the lawsuit became moot according to an AHA spokesperson 	• TMA filed its second <u>lawsuit</u> asking the Eastern District Court of Texas to invalidate the challenged provisions for failing to heed Congress' direction in the No Surprises Act for the IDR process as well as for the court to instruct the agencies that any additional rules or guidance to IDR entities on the weighing of factors not privilege the Qualifying Payment Amount (QPA)	• TMA filed its third lawsuit challenging the methodology for calculating QPAs, arguing it will "deflate" payments



December 30, 2022 31, 2	uary 2023 February 6, 2023		bruary , 2023 March 2023	March 17, 2023	March 22, 2023	June 16, 2023	July 12, 2023	August 3, 2023
 CMS Initial Report on the IDR Process shows 90,000 disputes were initiated from April 15 – Sept. 30, 2022 In April 2022, the agency estimated there would be only 17,333 claims a year submitted TMA filed a fourth la challengir 600% incu in adminis fees asso with dispur- resolution 	wsuit, ruled in favor of g the TMA in its e ease second lawsuit, a trative invalidating d ciated provisions of the u te IDR process n	CMS instructed certified IDR entities to hold all payment determinations until further notice CMS allo certified I entities to resume payment determinations for services/i furnished October 2 2022	IDR <u>Federal IDR</u> o <u>guidance</u> for payment determinations ations made on or after February 6, /items 2023, for items d before and services	certified IDR entities to resume payment determinations for items and services furnished on or after October 25, 2022	hearing, HHS Sec. Becerra	CMS released No Surprises Act <u>website for</u> <u>consumers</u>	appellate brief with the U.S. Court of Appeals for the Fifth Circuit in Texas, appealing the decision made on TMA's second lawsuit	 Federal judge ruled in favor of TMA in its fourth lawsuit, invalidating administrative fee increases and certain rules narrowing batching claims for arbitration In response, CMS temporarily paused the Federal IDR

Federal IDR process



No Surprises Act: Timeline

August 11,	August 24,	September 19,	September 21,	October 6,	October 27,	November 9,	November 28,	December 12,
2023	2023	2023	2023	2023	2023	2023	2023	2023
 CMS released FAQs on administrative fees Administrative fee for disputes initiated on or after August 3, 2023 is \$50 per party per dispute Administrative fee for disputes initiated from January 1 – August 2, 2023 is \$350 	 U.S. District judge ruled in favor of TMA in its third lawsuit, stating "all but one regulation pertaining to the calculation of the QPA violate the plain text of the Act" Federal IDR process remains temporary paused in response 	 House Ways and Means Committee held a hearing on the "Flawed Implementation of the No Surprises Act" Committee members stated that the No Surprises Act "incentivizes health insurers to limit the number of physicians with whom they have contract agreements to cover their services" and faces operational challenges due to the "stop and go' implementation of this law" 	 Departments of HHS, Labor, and Treasury released a proposed rule increasing the administrative fee for the IDR process from \$50 to \$150 The Agencies also proposed to increase the range of fees that IDR entities can charge for using their service CMS instructed IDR entities to resume processing all disputes submitted on or before August 3, considering the QPA already submitted 	do not plan on releasing additional guidance •HHS <u>re-opened the</u> IDR portal for new	 Departments of HHS, Labor, and Treasury released a proposed rule including changes to the IDR process in the following areas: Communication between payers and providers Open negotiation requirements Updated batching provisions IDR eligibility timeline Collection of administrative fees Extenuating circumstances request Creation of an IDR registry 	 House Ways and Means Republicans sent a letter to the secretaries of HHS, Treasury, and Labor, expressing concerns around the law's implementation. Key points included: Some patients are still vulnerable to surprise bills The QPA interpretation has led to reduced rates and network cancellations IDR entities have been strained by the IDR portal's freezes The administration has not started rulemaking for the "advanced explanation of benefits," which had a January 2022 statutory deadline 	 New <u>quidance</u> released by the Department of Labor states the standards of determining whether a claim is eligible for batching will be based on requirements that haven't been vacated by courts, including that the claims are for the same provider groups, paid by the same issuer and within a set timeframe CMS <u>shared</u> with Inside Health Policy that the IDR portal will open for batched claims by the end of the year 	 A <u>GAO report</u> found that, as of June 2023, over 490,000 disputes had been submitted, with 61% of disputes remaining unresolved. In comparison, the departments expected to receive around 22,000 disputes The primary cause for the large number of unresolved disputes is the complexity of determining whether disputes are eligible for the IDR process

No Surprises Act: Timeline

•					Update
December 15, 2023	December 18, 2023	January 4, 2024	March 7, 2024	March 27, 2024	June 14, 2024
 IDR portal began accepting batched disputes Federal government is allowing for extensions of IDR deadlines for new batched disputes and new single disputes involving air ambulance services Parties can also resubmit disputes previously determined to be improperly batched 	 CMS finalized a rule establishing administrative fees An administrative fee of \$115 will be applied to disputes A certified IDR entity fee was finalized to be between \$200 and \$840 for a single determination and between \$268 and \$1,173 for batch rulings Fees are set annually 	•CMS <u>delays</u> until further notice the deadline for comments on the Oct. 27, 2023 proposed rule	 CBO releases presentation reviewing original budgetary analysis. CBO notes that there have been more implementation challenges regarding arbitration than anticipated. Initial IDR entity data suggest that party offers have been much higher than the QPA, meaning: IDR cases account for a small fraction of out-of- network care and spending Budgetary effects in original estimate were driven by changes in in- network prices, but it is unclear how these were affected by prohibitions on surprise billing, 	• A Brookings Institution report finds that the No Surprises Act's IDR process may actually increase in-network costs and premiums, contrasting the estimates from the CBO.	 New exception period announced: Any party unable to timely initiate the first step of the arbitration process due to the Change Healthcare cyberattack can begin open negotiation through October 12





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