36TH ANNUAL AHA RURAL HEALTH CARE | LEADERSHIP CONFERENCE

FEBRUARY 19-22, 2023 | SAN ANTONIO, TX

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American Hospital Association™

Advancing Health in America

AHA Events

The Changing 340B Landscape for Rural Hospitals

Aimee Kuhlman, AHA Vice President, Grassroots & Advocacy

Bharath Krishnamurthy, AHA Director, Health Policy & Analytics

Agenda

- Legislative Updates
- Good Stewardship Principles
- Legal Updates
- Regulatory Updates
- New 340B Data & Research
- Hear from the Field

Legislative Updates

Calls for 340B Transparency

The Gazette

HOME / OPINION / LETTERS TO THE EDITOR

Drug pricing program needs reform

Dwight Baldwin

Oct. 8, 2022 7:00 am

The New York Times

PROFITS OVER PATIENTS

How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits

Bon Secours Mercy Health, a major nonprofit health system, used the poverty of Richmond Community Hospital's patients to tap into a lucrative federal drug program.

THE HILL

OPINION > CONGRESS BLOG

THE VIEWS EXPRESSED BY CONTRIBUTORS ARE THEIR OWN AND NOT THE VIEW OF THE HILL

340B drug pricing program helps advance health for patients, communities

BY RICK POLLACK, OPINION CONTRIBUTOR - 10/10/22 6:00 PM ET

SHARE TWEET

Fulfilling a Social Responsibility: Comparing 340B and Non-340B Hospitals' Contributions to Their Communities

FIRST OPINION

After 30 years of 340B, it's time for data and an honest conversation

By John Michael O'Brien Oct. 26, 2022

Restoring the 340B OPPS Payment Policy: Good for Patients, Good for Providers

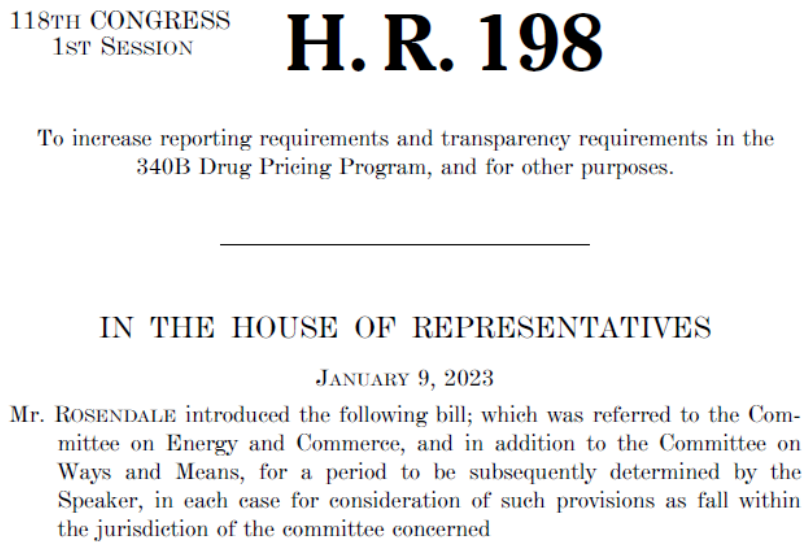
Sep 21, 2022 - 12:37 PM by Bharath Krishnamurthy, Senior Associate Director Health Analytics, Public Policy, Aimee Kuhlman, VP Advocacy Grassroots, Government Relations

AHA STAT

An American Hospital Association Blog

H.R. 198 – Rep. Rosendale (R-MT)

- Goal: To increase reporting requirements and transparency requirements in the 340B Drug pricing Program



118TH CONGRESS
1ST SESSION

H. R. 198

To increase reporting requirements and transparency requirements in the 340B Drug Pricing Program, and for other purposes.

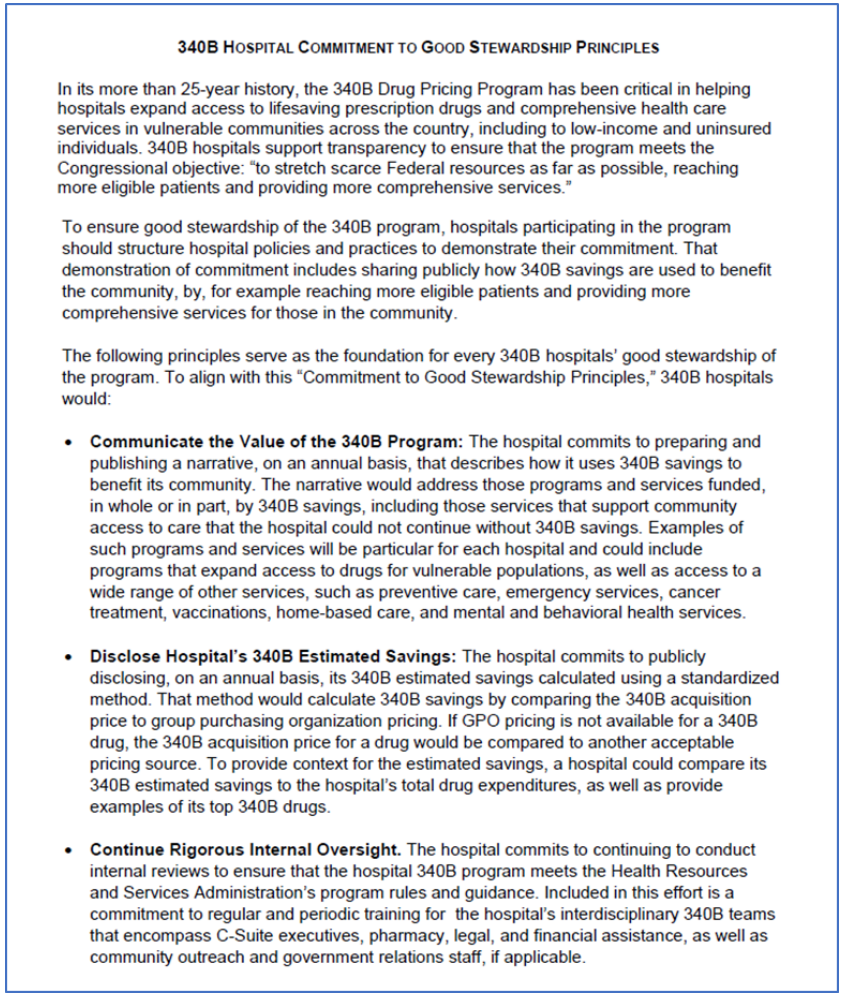
IN THE HOUSE OF REPRESENTATIVES

JANUARY 9, 2023

Mr. ROSENDALE introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

340B Good Stewardship Principles

- AHA is revitalizing these principles in 2023
- Goal: To demonstrate to the Hill and the public that 340B hospitals are willing to be transparent with how they use their savings to serve their patients and communities.
- Three Principles:
  - **Communicate Value of the 340B Program**
  - **Disclose Estimated 340B Program Savings**
  - **Continue to Perform Rigorous Internal Review**



340B Hospital Commitment to Good Stewardship Principles

In its more than 25-year history, the 340B Drug Pricing Program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services in vulnerable communities across the country, including to low-income and uninsured individuals. 340B hospitals support transparency to ensure that the program meets the Congressional objective: "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

To ensure good stewardship of the 340B program, hospitals participating in the program should structure hospital policies and practices to demonstrate their commitment. That demonstration of commitment includes sharing publicly how 340B savings are used to benefit the community, by, for example reaching more eligible patients and providing more comprehensive services for those in the community.

The following principles serve as the foundation for every 340B hospitals' good stewardship of the program. To align with this "Commitment to Good Stewardship Principles," 340B hospitals would:

- **Communicate the Value of the 340B Program:** The hospital commits to preparing and publishing a narrative, on an annual basis, that describes how it uses 340B savings to benefit its community. The narrative would address those programs and services funded, in whole or in part, by 340B savings, including those services that support community access to care that the hospital could not continue without 340B savings. Examples of such programs and services will be particular for each hospital and could include programs that expand access to drugs for vulnerable populations, as well as access to a wide range of other services, such as preventive care, emergency services, cancer treatment, vaccinations, home-based care, and mental and behavioral health services.
- **Disclose Hospital's 340B Estimated Savings:** The hospital commits to publicly disclosing, on an annual basis, its 340B estimated savings calculated using a standardized method. That method would calculate 340B savings by comparing the 340B acquisition price to group purchasing organization pricing. If GPO pricing is not available for a 340B drug, the 340B acquisition price for a drug would be compared to another acceptable pricing source. To provide context for the estimated savings, a hospital could compare its 340B estimated savings to the hospital's total drug expenditures, as well as provide examples of its top 340B drugs.
- **Continue Rigorous Internal Oversight.** The hospital commits to continuing to conduct internal reviews to ensure that the hospital 340B program meets the Health Resources and Services Administration's program rules and guidance. Included in this effort is a commitment to regular and periodic training for the hospital's interdisciplinary 340B teams that encompass C-Suite executives, pharmacy, legal, and financial assistance, as well as community outreach and government relations staff, if applicable.

340B Good Stewardship Principles Guidance

Calculating Estimated 340B Program Savings

(A) GPO or other Estimated Acquisition Costs	Minus -	(B) Actual 340B Acquisition Costs	Plus +	(C) Benefit from Contract Pharmacy Arrangement	Equals =	(D) Estimated Savings of 340B Program
TOTAL						Total Estimated Savings of 340B Program
						Compare 340B Estimated Savings to Total Drug Expenditures

Step (A) Group Purchasing Organization (GPO) or other Estimated Acquisition Costs

Step A establishes what the hospital would have spent on drugs absent the 340B program. In the first column, hospitals should identify GPO prices for drugs purchased through the 340B program. 340B hospitals could work with their wholesale distributors to access the GPO pricing information. The hospital could request that the wholesale distributor provide a report to the 340B hospital that includes GPO pricing for all 340B drugs purchased on a periodic basis. If GPO pricing is not available for comparison, 340B hospitals could use another pricing source such as Wholesale Acquisition Costs (WAC) or another acceptable pricing source to determine the "estimate acquisition costs." Again, the wholesale distributor could provide information for drugs without a comparable GPO price.

Step (B) Actual 340B Acquisition Costs

In **Step B** 340B hospitals determine the actual amount spent on the purchase of 340B drugs. To obtain the actual purchase or acquisition costs for the 340B drugs for **Step B**, the hospital could work with the wholesale distributors and request an invoice report of all the 340B drugs purchased. The amount in **Step B** is subtracted from **Step A**.

Step (C) Benefit from Contract Pharmacy Arrangement

This component of the calculation is intended to capture any benefit the 340B hospital may realize if it utilizes contract pharmacy arrangements. If the 340B hospital **does not** utilize contract pharmacy arrangements, the hospital would **skip Step C**. If the hospital does have a contract pharmacy arrangement, in this step the hospital would add the benefit derived from their contract pharmacy arrangement to the **remainder** from **Step A** and **Step B**. To determine the contract pharmacy benefit, the 340B hospital utilizing such arrangements would look at total prescription drug reimbursement for 340B drugs dispensed through the contract pharmacy minus any dispensing or administrative fees by the contract pharmacy. The hospital could obtain this information from the contract pharmacy entity.

Step (D) Estimated Savings of 340B Program

Step D is the estimated savings the 340B hospital derives from participating in the 340B program. To provide context for the estimated 340B savings, the hospital could compare savings to total estimated hospital drug expenditures as defined by:

Estimated total hospital drug expenditure = total estimated hospital drug expenditures – drug manufacturer rebates and discounts*

**Total estimated drug expenditures include inpatient and outpatient drugs.*

[TEMPLATE TO COMMUNICATE THE VALUE OF THE 340B PROGRAM]

[HOSPITAL NAME, LOCATION]

THE HOSPITAL: [Provide a brief description of your hospital. This is an opportunity to describe your hospital's mission and the community served. Describe any challenges you face in serving your community. You also could consider including some financial metrics such as the amount of uncompensated care your hospital provides and the dollar value of community benefit.]

THE BENEFITS OF THE 340B PROGRAM: [You should include how your hospital uses the 340B program to benefit your patients and community. One source of information the hospital could draw from is any public reporting such as the IRS 990 form or other state or local required reporting. It is most effective to focus on how the program's savings allow your hospital to address identified needs in the community, rather than the financial benefit the program provides to your hospital. However, if the 340B program allows you to maintain vital community services such as access to 24/7 emergency and trauma services, you should include those examples. Consider including examples, such as:

- provide financial assistance to patients unable to afford their prescriptions;
- provide clinical pharmacy services, such as disease management programs or medication therapy management;
- provide transportation to needy patients allowing them access to essential health care services;
- fund other medical services, such as obstetrics, diabetes education, oncology services and other ambulatory services;
- establish additional outpatient clinics to improve access;
- create new community outreach programs;
- provide preventive care and mental and behavioral health services;
- offer free vaccinations for vulnerable populations;
- provide access to specialty care, such as oncology care, not otherwise available to many low-income individuals in the community; and
- provide discharge prescriptions as part of program efforts to reduce avoidable readmissions.

[Where possible, you could include the numbers of patients served in the various programs. You also should consider including at least one specific example of a patient who has benefitted from the hospital's participation in the 340B program consistent with federal and state privacy laws. Some good examples would be a patient who receives access to cancer treatment closer to home; a poor patient who receives prescription drugs at reduced rates or free of charge; a person who receives free treatment at one of your clinics or who is enrolled in one your community health programs made possible in part through the 340B program.]

IMPACT IF THE PROGRAM WAS SCALED BACK: [Describe the programs or services that could have to be reduced or eliminated if the 340B program were scaled back. Explain how reducing or eliminating these programs would decrease access to care for the patients and community your hospital serves.]

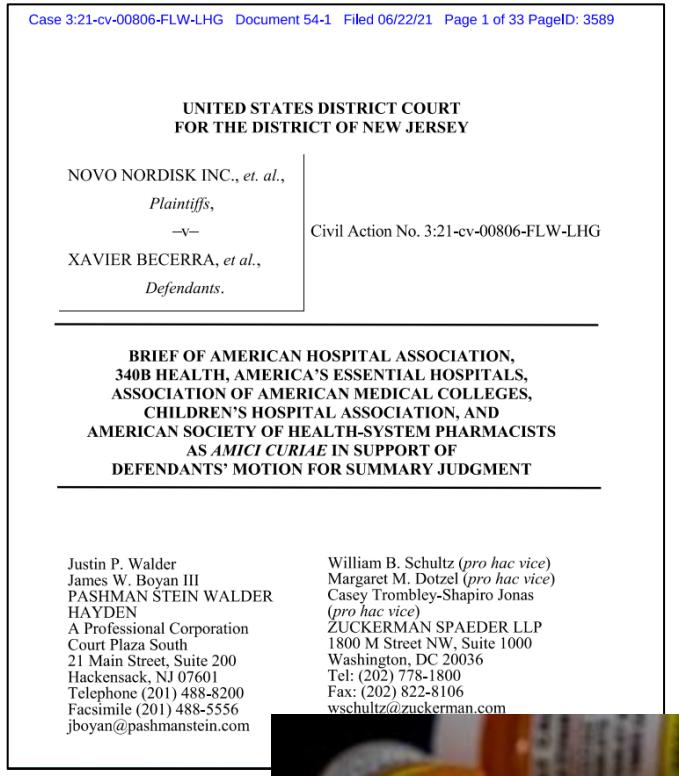
Legal Updates

340B OPPS Litigation

- **June 2022** - U.S. Supreme Court unanimously rules that CMS' 340B payment policy was unlawful and remanded the case back to the district court to resolve an appropriate remedy.
- **September 2022** – U.S. District Court of D.C. rules that CMS must immediately halt 340B payment cuts for 2022
- **January 2023** – U.S. District Court of D.C. rules that the issue of the remedy will be decided by the agency through a proposed rule.
- Next Steps:
  - Await proposed rule on remedy from HHS/CMS slated for April 2023
  - Continue to engage with HHS/CMS on what any remedy should include
  - Selectively engage with members on the Hill to discuss importance of a swift and equitable remedy to all affected hospitals

340B Contract Pharmacy Litigation

- Drug companies sued HHS on OIG civil monetary penalties
  - 2-2 in district court so far
  - 3 appeal (3rd, 7th, DC Cir.); decisions expected this year
- AHA Advocacy:
  - Support HHS in legal challenges (amicus briefs)
  - Supported bipartisan Congressional letter to Becerra
    - Becerra responded, affirming HHS support



Case 3:21-cv-00806-FLW-LHG Document 54-1 Filed 06/22/21 Page 1 of 33 PageID: 3589

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et. al.*,
Plaintiffs,
–v–
XAVIER BECERRA, *et al.*,
Defendants.

Civil Action No. 3:21-cv-00806-FLW-LHG

BRIEF OF AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CHILDREN'S HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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340B Contract Pharmacy Litigation

Manufacturer Contract Pharmacy Lawsuits – District Court Actions and Appeals (2021-2022)		
	District Court	**Appeal Filed**
Eli Lilly S. District of Indiana	**March 16** – Courts issues order prohibiting enforcement of ADR against Lilly **Oct. 29** – Decision on merits issued	**Nov. 10** –Lilly filed appeal in Seventh Circuit **Dec. 28** – HHS cross-appealed Oral Argument – **Oct. 31, 2022**
AstraZeneca Delaware	**Feb. 16** – Decision on merits issued	**April 12** – HHS filed appeal in Third Circuit Oral Argument – **Nov. 15, 2022**
Sanofi New Jersey	**Nov. 5**– Decision on merits issued (consolidated with Novo Nordisk)	**Nov. 19** – Sanofi filed appeal in Third Circuit **Dec. 28** – HHS cross-appealed Oral Argument – **Nov. 15, 2022**
Novo Nordisk New Jersey	**Nov. 5**– Decision on merits issued (consolidated with Sanofi)	**Nov. 19** – NNI filed appeal in Third Circuit **Dec. 28** – HHS cross-appealed Oral Argument – **Nov. 15, 2022**
PhRMA Maryland	**Jan. 22** – Complaint filed	N/A
Novartis District of Columbia	**Nov. 5**– Decision on merits issued (consolidated with United Therapeutics)	**Dec. 28** – HHS filed appeal in DC Circuit Oral Argument – **Oct. 24, 2022**
United Therapeutics District of Columbia	**Nov. 5**– Decision on merits issued (consolidated with Novartis)	**Dec. 28** – HHS filed appeal in DC Circuit Oral Argument – **Oct. 24, 2022**
Boehringer Ingelheim District of Columbia	**Oct. 25** – Complaint filed **Nov. 9** – Court granted request for administrative stay	N/A
Merck District of Columbia	**July 8 , 22**– Complaint filed **Sept. 13, 22** – Court granted request for administrative stay	N/A
UCB District of Columbia	**Sept. 23** – Complaint filed	N/A

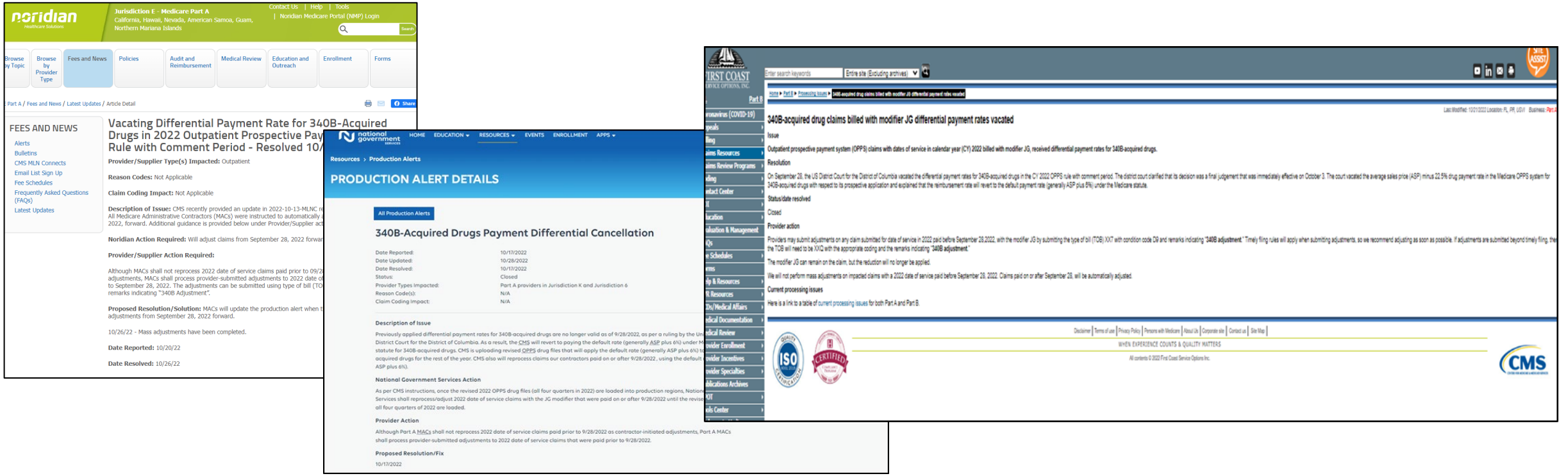
Source: Powers Law

www.340breport.com

Regulatory Updates

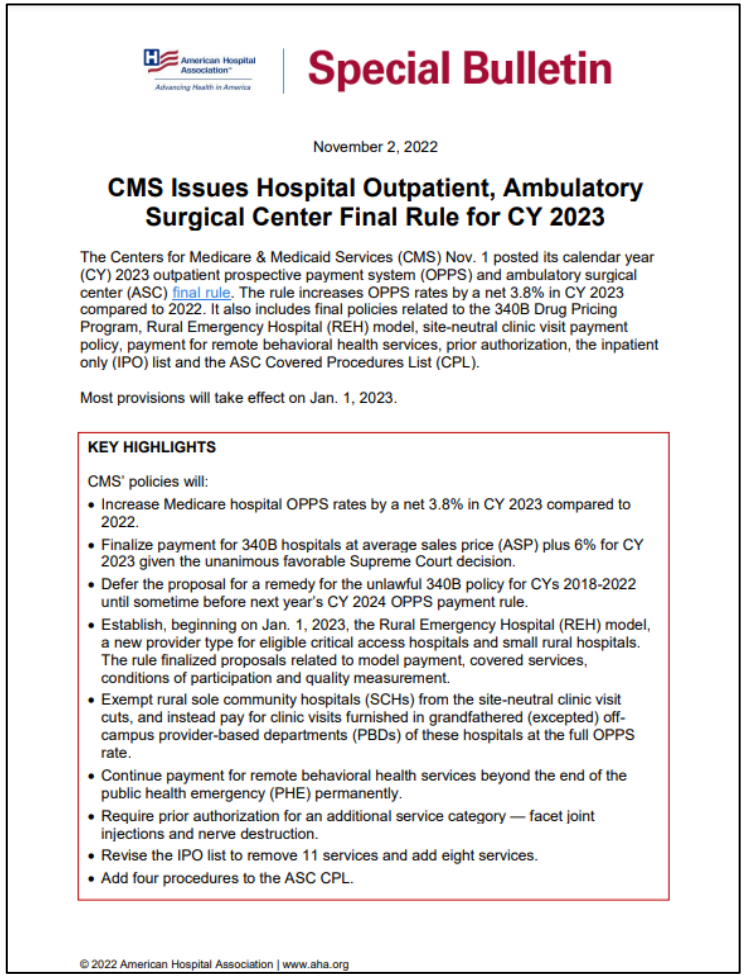
CY 2022 OPPS 340B Payments

- For rural 340B hospitals that are seeking relief from 340B OPPS underpayments, contact your individual MAC(s) for guidance on submitting claims for repayment.



CY 2023 OPPS Final Rule

- All 340B hospitals will be paid ASP + 6% for CY 2023
- Budget neutrality adjustment for non-drug services was modified to account for the increase in the 340B payment rate
- Continues to require 340B hospitals to report either the “JG” or “TB” modifier depending on what type of 340B hospital you are
- Awaiting proposed rule (est. April 2023) on remedy for prior unlawful policy



American Hospital Association
Advancing Health in America

Special Bulletin

November 2, 2022

CMS Issues Hospital Outpatient, Ambulatory Surgical Center Final Rule for CY 2023

The Centers for Medicare & Medicaid Services (CMS) Nov. 1 posted its calendar year (CY) 2023 outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) final rule. The rule increases OPPS rates by a net 3.8% in CY 2023 compared to 2022. It also includes final policies related to the 340B Drug Pricing Program, Rural Emergency Hospital (REH) model, site-neutral clinic visit payment policy, payment for remote behavioral health services, prior authorization, the inpatient only (IPO) list and the ASC Covered Procedures List (CPL).

Most provisions will take effect on Jan. 1, 2023.

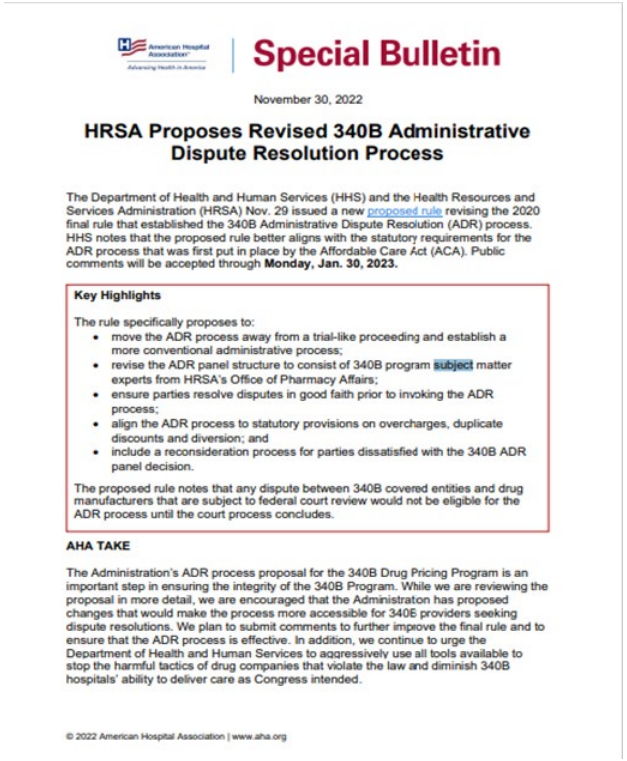
KEY HIGHLIGHTS

CMS' policies will:

- Increase Medicare hospital OPPS rates by a net 3.8% in CY 2023 compared to 2022.
- Finalize payment for 340B hospitals at average sales price (ASP) plus 6% for CY 2023 given the unanimous favorable Supreme Court decision.
- Defer the proposal for a remedy for the unlawful 340B policy for CYs 2018-2022 until sometime before next year's CY 2024 OPPS payment rule.
- Establish, beginning on Jan. 1, 2023, the Rural Emergency Hospital (REH) model, a new provider type for eligible critical access hospitals and small rural hospitals. The rule finalized proposals related to model payment, covered services, conditions of participation and quality measurement.
- Exempt rural sole community hospitals (SCHs) from the site-neutral clinic visit cuts, and instead pay for clinic visits furnished in grandfathered (excepted) off-campus provider-based departments (PBDs) of these hospitals at the full OPPS rate.
- Continue payment for remote behavioral health services beyond the end of the public health emergency (PHE) permanently.
- Require prior authorization for an additional service category — facet joint injections and nerve destruction.
- Revise the IPO list to remove 11 services and add eight services.
- Add four procedures to the ASC CPL.

340B ADR Proposed Rule

- Updates old rule and defines a new process for 340B administrative dispute resolutions (ADR)
- Makes ADR process more accessible for all 340B hospitals to raise claims by:
  - Removing the $25,000 claim value for threshold
  - Reforming the process to be more administrative rather than “trial-like”
  - Reducing the burden on providers for documentation, etc.
- AHA also advocated for:
  - Explicit language in the rule to include contract pharmacy cases
  - Defining a timeline for ADR decisions with a recommendation for a 6-month decision timeframe
  - Not halting consideration of ADR cases that involve issues that are the subject of litigation in Court



American Hospital Association | Special Bulletin

November 30, 2022

HRSA Proposes Revised 340B Administrative Dispute Resolution Process

The Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) Nov. 29 issued a new proposed rule revising the 2020 final rule that established the 340B Administrative Dispute Resolution (ADR) process. HHS notes that the proposed rule better aligns with the statutory requirements for the ADR process that was first put in place by the Affordable Care Act (ACA). Public comments will be accepted through **Monday, Jan. 30, 2023.**

Key Highlights

The rule specifically proposes to:

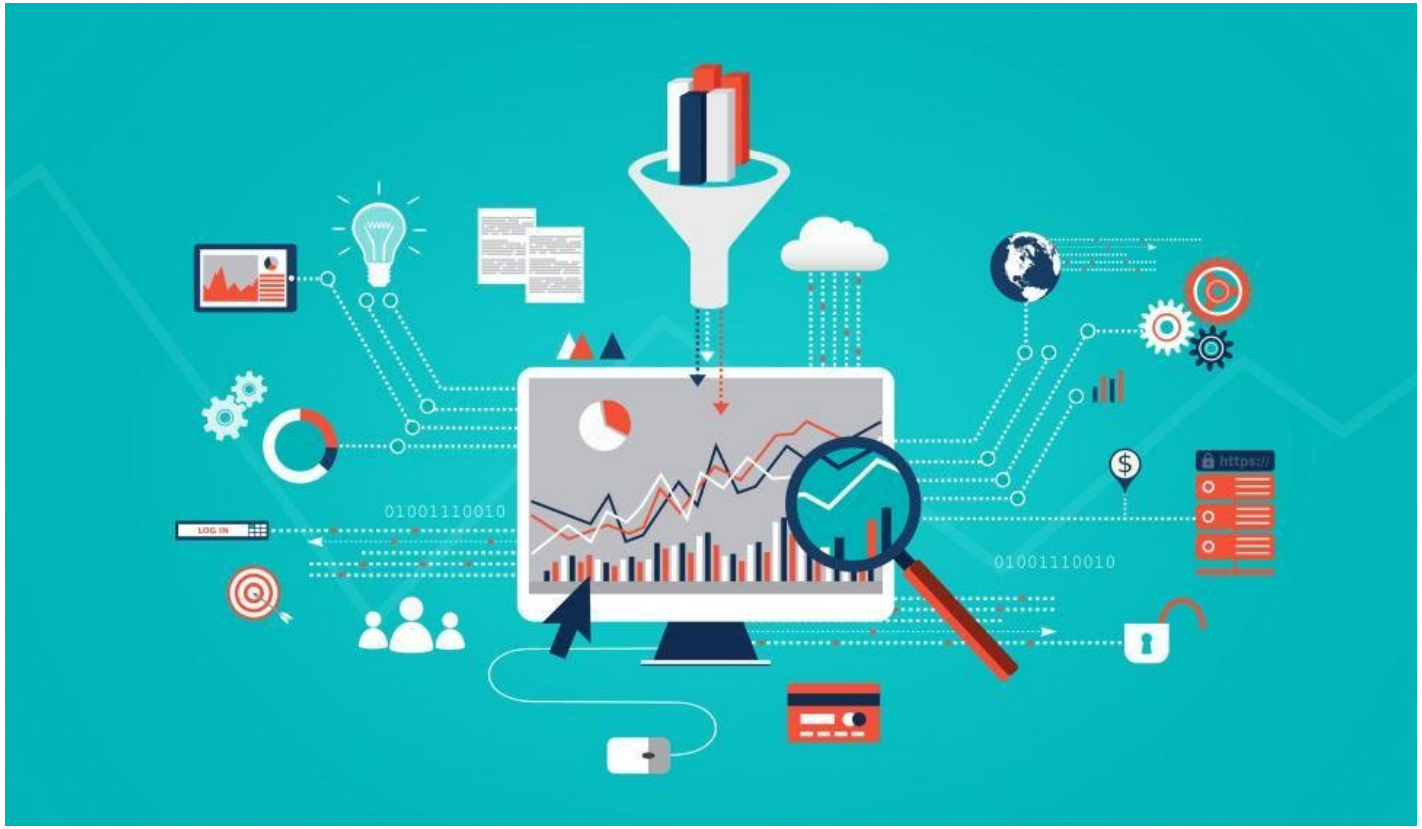
- move the ADR process away from a trial-like proceeding and establish a more conventional administrative process;
- revise the ADR panel structure to consist of 340B program subject matter experts from HRSA's Office of Pharmacy Affairs;
- ensure parties resolve disputes in good faith prior to invoking the ADR process;
- align the ADR process to statutory provisions on overcharges, duplicate discounts and diversion; and
- include a reconsideration process for parties dissatisfied with the 340B ADR panel decision.

The proposed rule notes that any dispute between 340B covered entities and drug manufacturers that are subject to federal court review would not be eligible for the ADR process until the court process concludes.

AHA TAKE

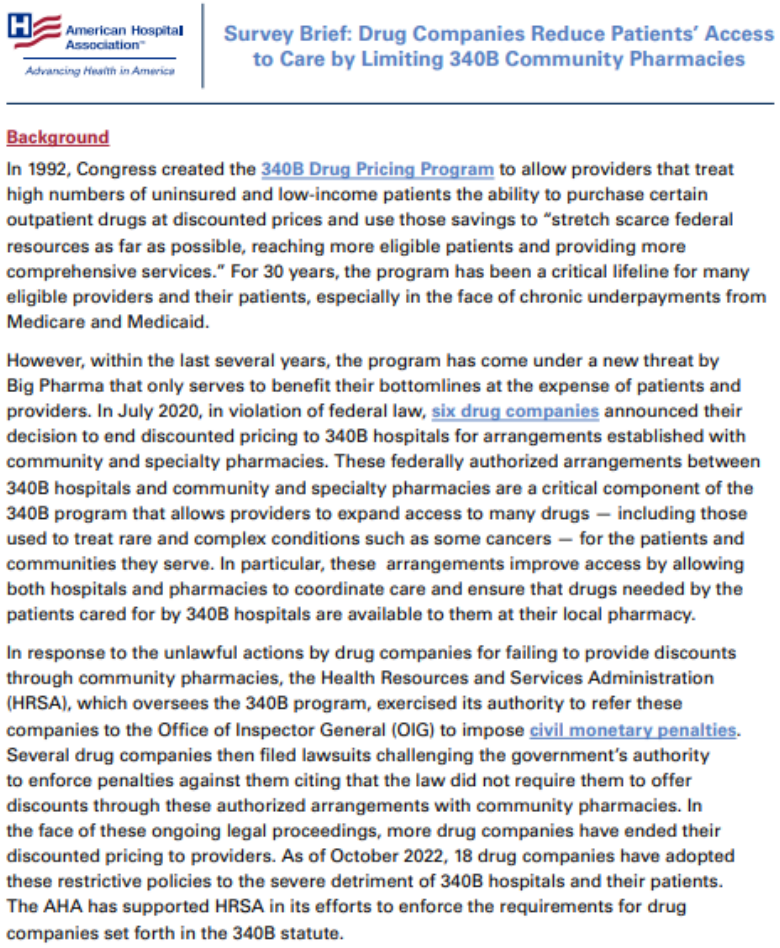
The Administration's ADR process proposal for the 340B Drug Pricing Program is an important step in ensuring the integrity of the 340B Program. While we are reviewing the proposal in more detail, we are encouraged that the Administraton has proposed changes that would make the process more accessible for 340E providers seeking dispute resolutions. We plan to submit comments to further improve the final rule and to ensure that the ADR process is effective. In addition, we continue to urge the Department of Health and Human Services to aggressively use all tools available to stop the harmful tactics of drug companies that violate the law and diminish 340B hospitals' ability to deliver care as Congress intended.

340B Data & Research



Contract Pharmacy Restrictions Impact Survey – Nov. 2022

- CAHs accounted for 45% of respondents
- $507K average annualized losses for CAHs from contract pharmacy restrictions
- $117K average annualized losses per arrangement
- 20% of contract pharmacies were “no volume on the books” pharmacies
- Forced many hospitals to cut programs and services, exacerbated existing financial challenges, and made it more difficult to fill staffing gaps



American Hospital Association
Advancing Health in America

Survey Brief: Drug Companies Reduce Patients' Access to Care by Limiting 340B Community Pharmacies

Background

In 1992, Congress created the 340B Drug Pricing Program to allow providers that treat high numbers of uninsured and low-income patients the ability to purchase certain outpatient drugs at discounted prices and use those savings to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." For 30 years, the program has been a critical lifeline for many eligible providers and their patients, especially in the face of chronic underpayments from Medicare and Medicaid.

However, within the last several years, the program has come under a new threat by Big Pharma that only serves to benefit their bottomlines at the expense of patients and providers. In July 2020, in violation of federal law, six drug companies announced their decision to end discounted pricing to 340B hospitals for arrangements established with community and specialty pharmacies. These federally authorized arrangements between 340B hospitals and community and specialty pharmacies are a critical component of the 340B program that allows providers to expand access to many drugs — including those used to treat rare and complex conditions such as some cancers — for the patients and communities they serve. In particular, these arrangements improve access by allowing both hospitals and pharmacies to coordinate care and ensure that drugs needed by the patients cared for by 340B hospitals are available to them at their local pharmacy.

In response to the unlawful actions by drug companies for failing to provide discounts through community pharmacies, the Health Resources and Services Administration (HRSA), which oversees the 340B program, exercised its authority to refer these companies to the Office of Inspector General (OIG) to impose civil monetary penalties. Several drug companies then filed lawsuits challenging the government's authority to enforce penalties against them citing that the law did not require them to offer discounts through these authorized arrangements with community pharmacies. In the face of these ongoing legal proceedings, more drug companies have ended their discounted pricing to providers. As of October 2022, 18 drug companies have adopted these restrictive policies to the severe detriment of 340B hospitals and their patients. The AHA has supported HRSA in its efforts to enforce the requirements for drug companies set forth in the 340B statute.

New Contract Pharmacy Study

- **66%** of the uninsured population and **67%** of the Medicaid population live in zip codes with at least one 340B contract pharmacy
- **73%** of Black population, **73%** of Asian population, and **66%** Hispanic population living in zip codes with at least one 340B contract pharmacy
- The number of contract pharmacy agreements among rural 340B hospitals increased by **51%** between 2020 and 2022
- The number of specialty contract pharmacy agreements among CAH and SCH 340B hospitals increased by **63%** and **73%**, respectively, from 2020 to 2022, compared to **52%** among DSH 340B hospitals
- Several rural states such as Mississippi (119%), Montana (167%), and Wyoming (244%) more than doubled their number of specialty contract pharmacy agreements during the pandemic

Research in the Pipeline

- Case studies on how 340B brings value to patients and communities
- Contextualizing the size and scope of the 340B program
- 340B impact on underserved patient populations
- 340B “child site” locations and service to underserved patient populations

Hear from the Field!

Karen Cheeseman, President & CEO

Mackinac Straits Health System