HEALTHCARE REGULATORY ROUND-UP #81

340B Update:
Where We Are and Where We're Headed

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Introductions

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Today's Agenda

1. Federal and State Legislative Activity and Regulatory Updates
2. Patient Definition
3. Drug Manufacturer Restrictions and the Administrative Dispute Resolution Process
4. Medicare Advantage Payer Litigation
5. HRSA Audit Activity and Covered Entity Best Practices

1. Federal and State Legislative Activity and Regulatory Updates

340B PATIENTS Act of 2024

Pharmaceutical **A**ccess **t**o **I**nvest in **E**ssential, **N**eeded **T**reatments and **S**upport

- Codifies Covered Entities' (CEs) ability to use contract pharmacy arrangements to dispense covered outpatient drugs
- Supported by AAMC, AHA, 340B Health
- Imposes civil monetary penalties on pharmaceutical manufacturers in violation

340B ACCESS Act

Afording **C**are for **C**ommunities and **E**nsuring a **S**trong **S**afety-net

- Introduced by Indiana, Georgia, and Tennessee representatives
- Bill would define CE patient
- Establish child site eligibility
- Require CEs to use sliding fee scale for drug discounts

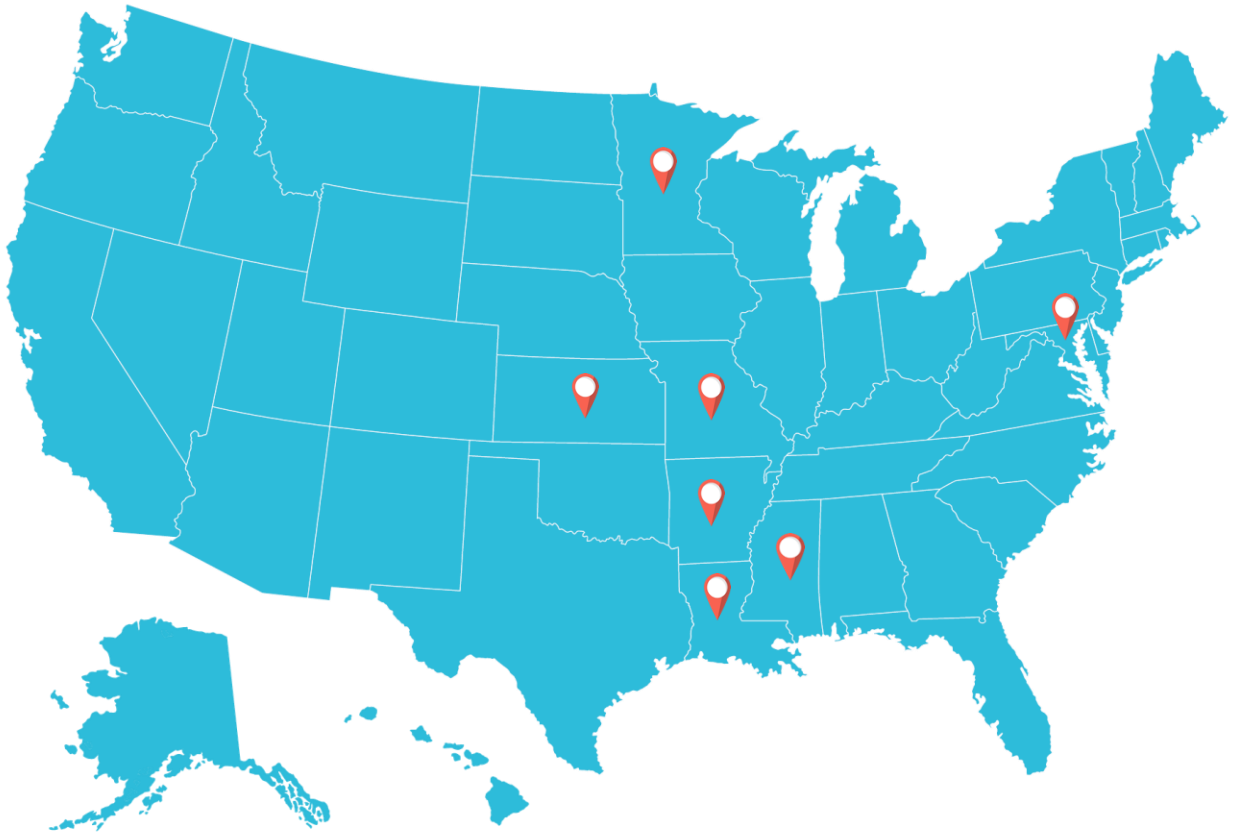
SUSTAIN Act

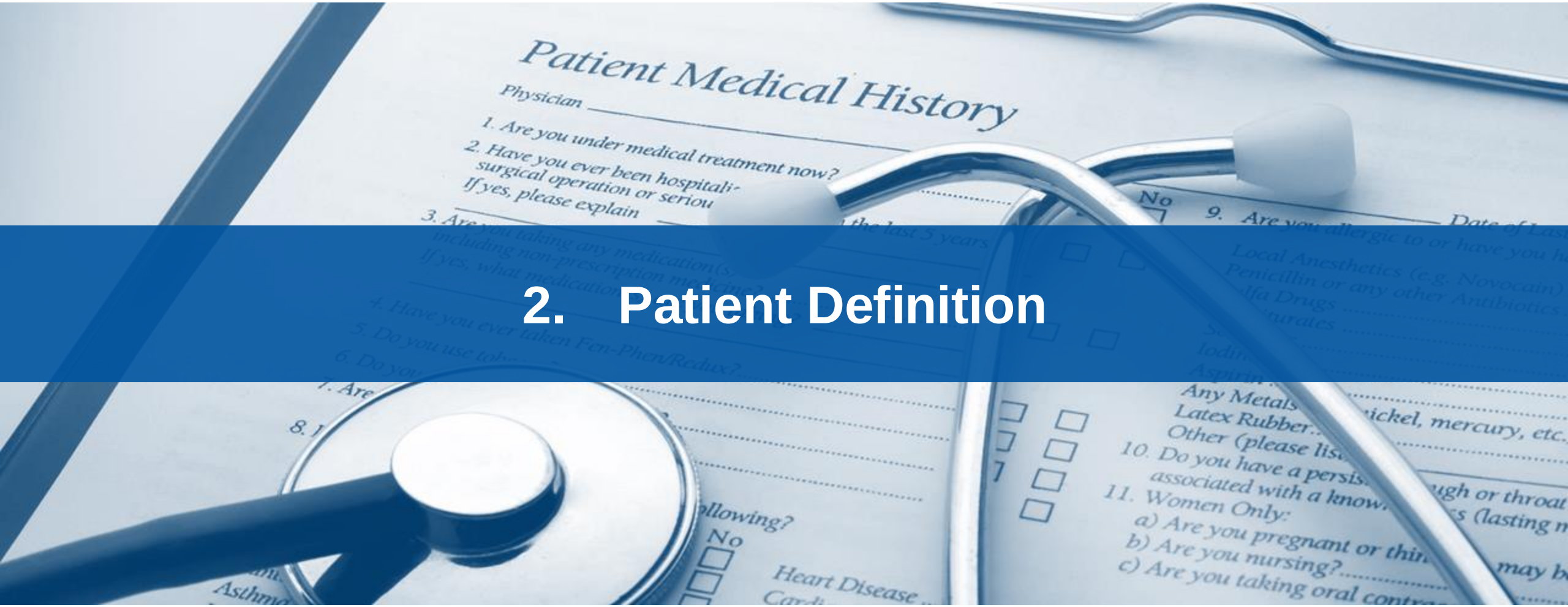
Supporting **U**nderserved and **S**trengthening **T**ransparency, **A**ccountability, and **I**ntegrity **N**ow and for the Future of 340B

- Bill released by “Gang of Six”
- Generally supportive of 340B program as it exists currently

State-Specific Regulatory Updates

- New updates for **Arkansas**, **Kansas**, **Louisiana**, **Maryland**, **Minnesota**, **Mississippi**, **Missouri**, and **West Virginia**





2. Patient Definition

Genesis Case

Varying “schools of thought” within the industry regarding application and/or use of case decision

CEs must consider organizational risk tolerance and program infrastructure in decision making

3. Drug Manufacturer Restrictions and the Administrative Dispute Resolution (ADR) Process

Contract Pharmacy Restrictions

- **Drug companies are restricting access in several ways:**
  - Outright denial of 340B pricing for items shipped to contract pharmacy
  - Restrictions tied to contract pharmacy dispense data (requirement to report de-identified dispensation data to 340B ESP)
  - Restrictions but with certain exceptions (e.g., single contract pharmacy only if without an in-house pharmacy)
- **Impact to CEs:**
  - Face declining contract pharmacy reimbursement
  - Making difficult decisions around data sharing
  - Expending funds pursuing advocacy, 340B ADR, etc.

Contract Pharmacy Restrictions (*cont.*)

- **Manufacturer restrictions on 340B drug sales:**
  - 30+ manufacturers restricting sales despite statute requiring manufacturers to offer drugs to 340B hospitals at the 340B ceiling price
  - Both federal district courts and federal appeals court have determined these restrictions are allowed under the 340B statute

HRSA's Response to Johnson & Johnson (J&J)

- J&J published plans to offer a rebate program for 340B CEs for certain drugs (e.g., anticoagulant, Xarelto; and Crohn's disease medication, Stelara)…
  - August 14: HRSA sends initial notice to J&J to inform of Secretarial approval requirement.
  - September 17: HRSA sends letter to J&J noting it violates section 340B(a)(1) of the Public Health Service Act.
  - September 19: J&J responds to HRSA with plans to proceed.
  - September 27: HRSA responds with a written warning requesting response by 9/30.
  - September 30: J&J informed HRSA that it plans to cease its formerly announced rebate program.

https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-27-24-hrsa-letter-johnson-johnson.pdf

ADR Process

- **New rules this year (effective June 18, 2024)**
  - **Key differences from prior (2020) guidelines:**
    - Elimination of legal proceeding rules
    - Reduction of panel size and expectations
    - Good Faith Effort required for ADR claim
    - Removal of $25K minimum threshold
    - Final decisions published on HRSA's website
    - Manufacturers may bring Medicaid managed care duplicate discount claims

Medicare Advantage (MA) Payer Litigation

MA Impact from New Guidance

- **Medicare activity**
  - U.S. Supreme Court found that HHS violated federal law when it reduced Medicare payment rates in 2018.
  - Medicare reverted back to prior payment policy and is reimbursing 340B hospitals for Part B drugs at the same rate used for non-340B hospitals (ASP + 6% rates).
  - Lump sum payments issued earlier this year to “remedy” the prior cuts (2018 – September 2022).

Source: CMS Billing 340B Modifiers Under the Hospital Outpatient Prospective Payment System (OPPS), March 2023

MA Impact (*cont.*)

- **CMS – No formal instruction given to MA payers:**
  - The Final Rule did not specify how CE Hospitals should handle MA claims or instruct MA payers to follow CMS with establishing a repayment “remedy”.
  - MA plans with rates tied to traditional Medicare rates benefited from the payment reduction on drugs from 2018 – 2022.
  - Future alignment between Medicare and MA plans may result in further adjustments.
  - Historically, CMS has not interfered on matters between MA payers and providers.
  - Contractual provider agreements dictate terms.
  - Impacted CE Hospitals should evaluate and initiate repayment.

Source: https://www.pyapc.com/insights/pya-qa-340b-repayments-from-maos/

HRSA Audit Activity and CE Best Practices

HRSA Audit Activity

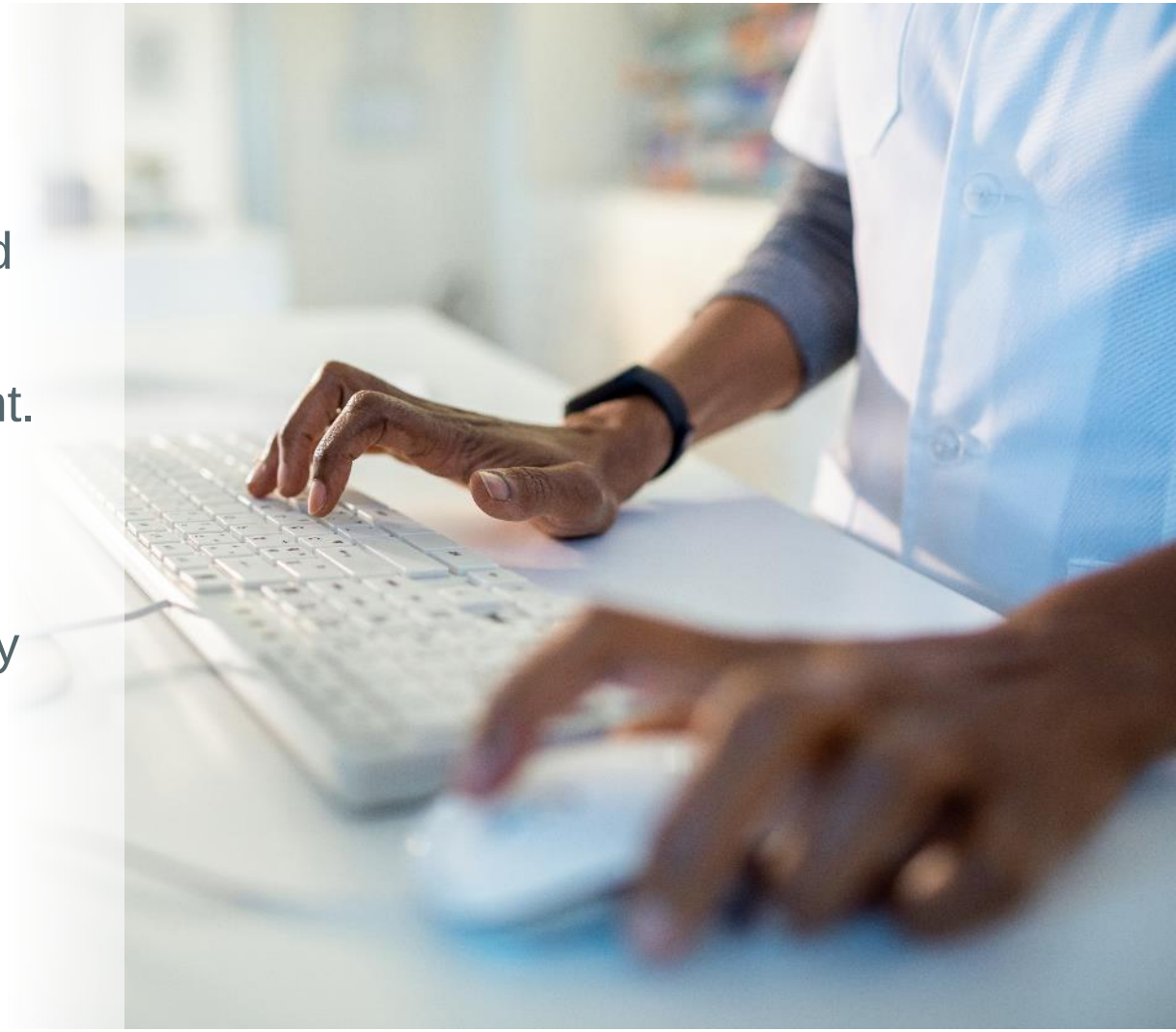
FY 2022	FY 2023	FY 2024
199 audits	159 audits	63 audits

- **Findings:**
  - Incorrect OPAIS record
    - Incorrect address or incorrect cost report filing date/reporting period
    - Child sites not listed/ineligible offsite outpatient facilities
    - Contract pharmacies not current (closed but not removed)
  - Diversion
    - Ineligible site
    - Inpatient dispensing
  - Duplicate discounts
    - Medicaid exclusion file errors

CE Best Practices

Auditing and Monitoring Importance

- Policies and procedures should include any child site changes.
- OPA database information should be kept current.
- Any changes that may have occurred should be monitored (*e.g., new providers, etc*.)
- Billing requirements should be reviewed routinely to ensure billing processes and procedures are current and up-to-date.



Source: https://www.hrsa.gov/opa/

340B Program Infrastructure

- All policies and procedures should be written and address compliance with the areas that are noted in the annual recertification attestation.
- A strong 340B Program infrastructure includes the following internal controls:
  - Detailed policies and procedures
  - Retention of applicable records
  - Appropriate oversight, including formal auditing and monitoring processes
  - Well-documented and defined patient definition

Annual Recertification Attestation

- All information on OPA database is accurate
- All contract pharmacy arrangements are in compliance
- The CE:
  - Meets all 340B program eligibility requirements
  - Will comply with all 340B program requirements
  - Maintains auditable records
  - Has systems in place to ensure ongoing compliance
  - Will notify OPA with any significant changes
  - Understands they may be liable for any breaches

Source: https://www.hrsa.gov/opa/

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November 13: 2025 OPPS Final Rule

November 20
December 4
December 11
} **2025 MPFS Final Rule, 3-Part Series**

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