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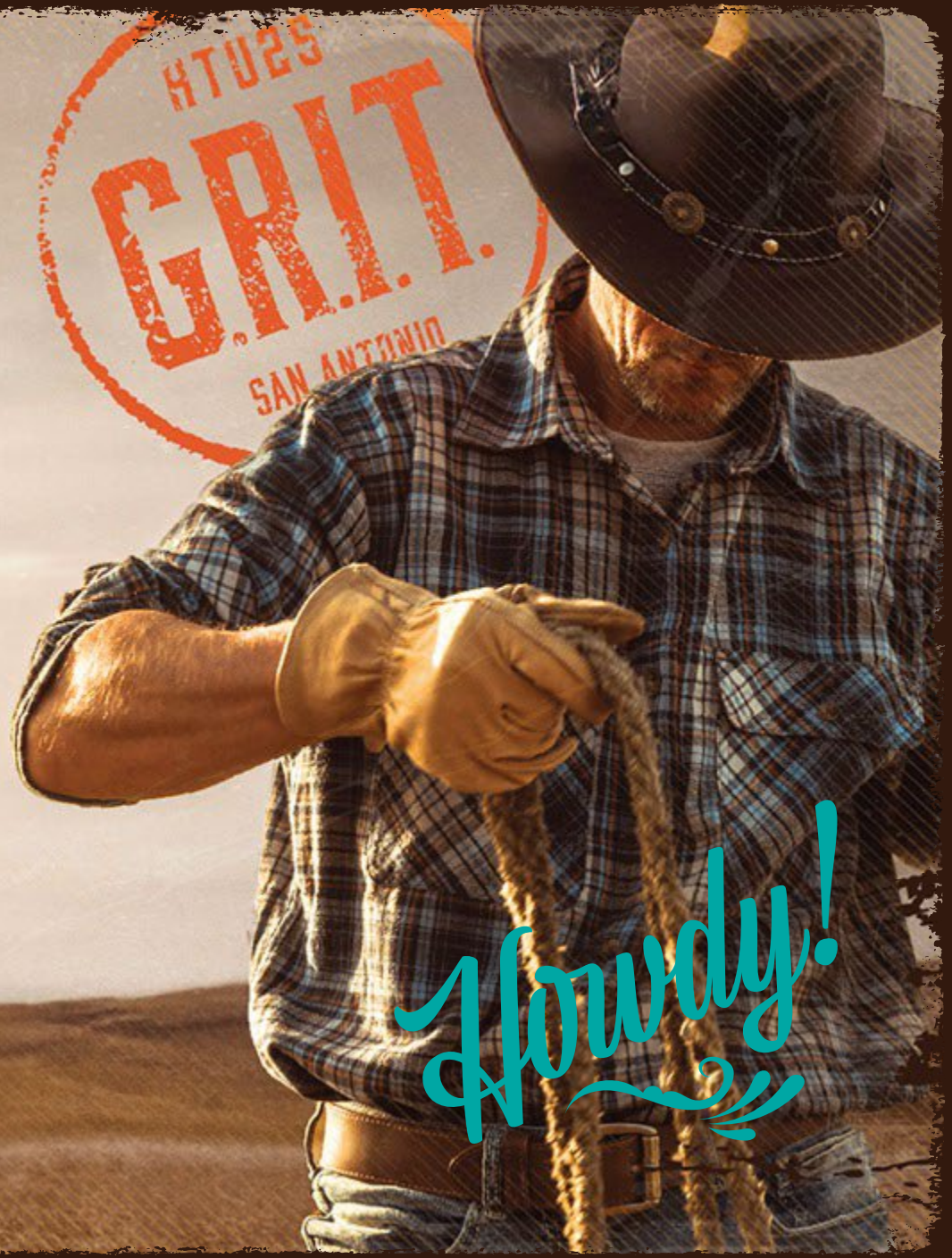
340B – 2025 Legal Landscape



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CE Deadline: 09/30/25

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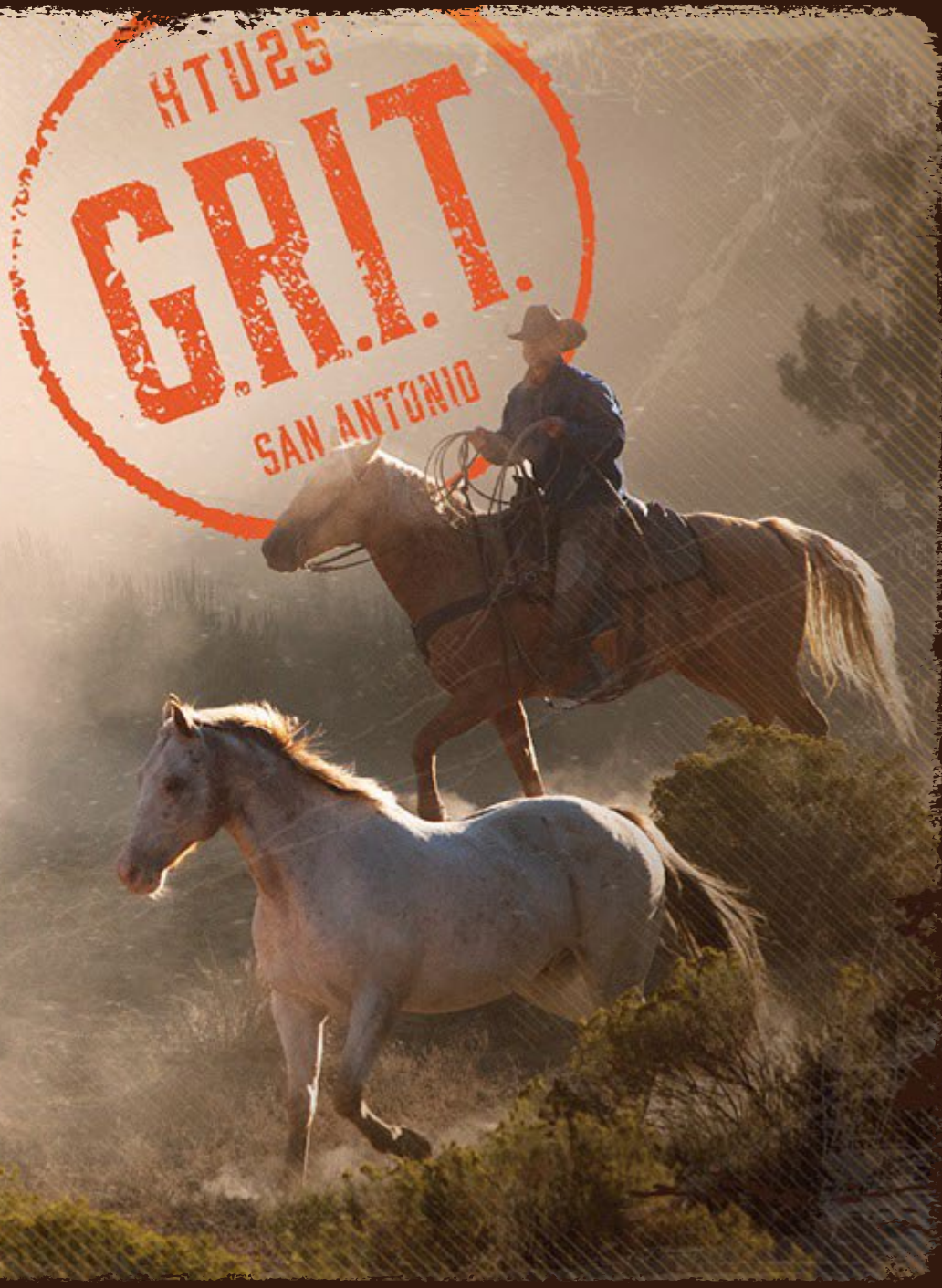

340B – 2025 Legal Landscape

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Disclosures

The presenter has no real or perceived conflicts of interest related to this presentation

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Learning Objectives

At the end of this session, participants should be able to:

1. Recall the 340B Program's unique structure and significant developments in the 340B legal landscape over the prior year.
2. Recognize program growth opportunities and 340B best practices.
3. Identify audit and operational risks of 340B expansion strategies.

Overview

- 340B Program Compliance
- Child Site Eligibility & Updates
- Contract Pharmacy Eligibility & Updates
- Patient Eligibility & Updates
- Billing, Financial Assistance & Reporting
- Inflation Reduction Act
- Looking Ahead

340B PROGRAM COMPLIANCE

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340B Program History & Overview

- Enacted in 1992
- Significant changes in 2010
  - Contract pharmacy expansion
  - Affordable Care Act expansion
- Approximately 13,000 participating entities (“Covered Entities”)
  - Federal grantees & contactors (~80% of Covered Entities)
  - Non-profit & government hospitals (~20% of Covered Entities)
- Approximately $66 Billion in drug purchases
  - Approximately $55 Billion made by hospital Covered Entities

Citations:
- Government Accountability Office: https://www.gao.gov/assets/gao-21-107.pdf
- Health Resources and Services Administration: 2023 340B Covered Entity Purchases | HHS

340B Program Compliance

- Provider entity eligibility to participate in the 340B Program
  - Grantee/contractor types
  - Hospital types & Disproportionate Share Hospitals (“DSH”) threshold
- Medicaid duplicate discount prohibition
- Diversion prohibition
- Online database of Covered Entity information
- GPO Prohibition &/or Orphan Drug exclusion

Other Legal/Compliance Considerations

- Child-site eligibility
- Patient eligibility
- Federal healthcare program overpayments
- False Claims Act
- Medicaid billing/coding for 340B drugs
- Medicare billing/coding for 340B drugs
- Terms of hospital contract with state or local government for eligibility
- Scope of federal grant conferring eligibility
- Pharmacy patient financial assistance programs
- State pharmacy laws

What do you think?

Question #1

HHS has published many notices and guidance documents in the Federal Register and on its website explaining how to comply with the 340B Program. Are those notices and guidance documents legally enforceable against covered entities and manufacturers?

A. Yes, covered entities & manufacturers must comply with HHS' compliance instructions.

B. No, this guidance is voluntary and merely advisory.

C. Maybe, depending on a number of factors.

Question #1

Correct Answer

C. Maybe, depending on a number of factors.

- Any HHS enforcement action must be authorized by the 340B Statute.
- HHS can interpret the 340B Statute & issue guidance explaining how it interprets the Statute.
- However, HHS cannot establish entirely new legal standards through guidance, & interpretations that are inconsistent with the plain meaning of the 340B Statute or its intent will be highly scrutinized.

CHILD SITES

Source: Getty Images. Used with permission of HealthTrust.

Criteria to Meet Child Site Eligibility

- 340B Statute does not outline requirements for 340B child-site eligibility
- “Child-site” locations best practices:
  - Must be part of the Medicare-certified & enrolled hospital entity (i.e., must meet Medicare provider-based rules)
  - Must be on a reimbursable line of the hospital’s most-recently filed Medicare cost report to be registered in online 340B database (OPAIS)

Citations: 1. 340B Statute: https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf; 2. 59 Fed. Reg. 47884 (September 19, 1994): https://www.hrsa.gov/sites/default/files/hrsa/opa/outpatient-hospital-facilities.pdf ; 3. Image Source: Getty Images. Used with permission of HealthTrust.

HHS Notice

- In May 2023, HHS unexpectedly revoked a policy that allowed for use of 340B drugs for patients at unregistered child sites of covered entities
- In October, HHS issued a Notice to remind 340B Program covered entities of the child site eligibility criteria
- The notice & current HHS policy are subject to an on-going legal challenge by 44 hospitals

Source: Getty Images. Used with permission of HealthTrust.

Citation:
October 2023 Notice: https://www.govinfo.gov/content/pkg/FR-2023-10-27/pdf/2023-23702.pdf

CONTRACT PHARMACIES

Source: Getty Images. Used with permission of HealthTrust.

340B Contract Pharmacy

340B Covered entities may dispense 340B drugs directly or through contractual arrangements with pharmacies (“contract pharmacies”)

Contract pharmacies typically operate under a “replenishment” or “virtual” inventory model

- Drugs are dispensed from common drug stock & restocked with 340B pricing for eligible drugs
- 340B drugs are invoiced to covered entity & shipped to contract pharmacy (“bill to/ship to”)

Claims for 340B drugs are generally identical to claims for all other drugs

- Eligibility for 340B pricing is typically determined after dispensing

Contract pharmacies bill payors & remit payments back to covered entity less a dispensing fee

Citation: 75 Fed. Reg. 10272 (March 5, 2010): https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf

HHS Guidelines – Best Practices

HHS reviews 340B contract pharmacy arrangements under its 2010 Notice guidelines

- Contract pharmacy must be registered & active in OPAIS
- Covered entity purchases & maintains title to drug
- Patient retains freedom to choose pharmacy provider
- Patient eligibility verification system
- Establish & maintain a tracking system to prevent diversion

Citations: 340B Statute: https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf

Manufacturer Restrictions

- Drug manufacturers are not required to provide a 340B discount & a Medicaid drug rebate on the same drug
- Duplicate discounts are typically prevented by excluding Medicaid claims from contract pharmacy arrangements
- 340B Program does not prohibit contractual duplicate discounts
  - Rebates that are voluntarily offered by manufacturers under commercial payer & PBM agreements

Citation: 340B Statute: https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf

Manufacturer Restrictions, cont'd.

- Beginning in mid-2020, certain manufacturers began restricting access to 340B drugs dispensed through contract pharmacy arrangements
  - Currently ~40 manufacturers
  - Most require submission of contract pharmacy dispensing data
  - Most allow for exception of designation of a single contract pharmacy
  - Some allow for exception of designation of covered entity-/system-owned retail pharmacy
- Recent effort to move to a "rebate model" to access 340B price
- Expect more manufacturers to add restrictions & the restrictions to become increasingly broad

Citation: National Association of Community Health Centers: https://www.nachc.org/wp-content/uploads/2023/11/340b-restrictions-summary-chart1_.pdf

HHS Advisory Opinion

Litigation

- Following release of HHS Advisory Opinion prohibiting restrictions on sales of 340B drugs & corresponding enforcement letters, 10 manufacturers have brought claims against HHS in federal court
- Four cases pending in D.C. District Court
- One case pending in 7th Circuit (since 2022)
- Two cases decided in federal Court of Appeals
  - Court ruled in favor of three manufacturers & found that HHS cannot take enforcement action against manufacturers for imposing 340B sales restrictions that are not prohibited by the statute

Citation: 340B Litigation Tracker: https://www.mcdermottplus.com/340b-litigation-tracker-registration/

Senate HELP Committee Investigation Report

- On April 24, 2025, Senator Bill Cassidy, ranking member of the Health, Education, Labor & Pensions (HELP) Committee, released a report detailing findings from a year-long investigation into 340B Program revenue use
- Senator Cassidy proposed potential reforms for transparency:
  - Require detailed annual reporting on 340B revenue use
  - Investigate financial benefits received by contract pharmacies & third-party administrators for administering the 340B Program
  - Require transparency & data reporting by contract pharmacies & third-party administrators
  - Provide clear guidelines on “patient” & contract pharmacy utilization

Citation: HELP Committee: Chair Cassidy Releases Report on 340B Re... | Senate Committee on Health, Education, Labor and Pensions

PATIENT ELIGIBILITY

Source: Getty Images. Used with permission of HealthTrust.

Elements of Patient Eligibility

- 340B Statute limits resale & transfer of 340B drugs to “patient[s] of the entity”
- 1996 guidance further defines “patient”
  - Visit with a Covered Entity (CE) provider
  - CE assumes responsibility for & maintains records of the patient’s care
  - For grantee CEs, care must be within scope of their qualifying grant
- Providing 340B drug to anyone other than a “patient” is diversion
  - May be subject to refund of the 340B discount amount to the manufacturer
  - May result in removal from the 340B Program if found to be knowing, intentional, systemic & egregious

Citation: Patient Definition: https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf

Genesis Healthcare vs. Becerra

- Genesis filed suit against HHS following 2017 audit & attempted removal from the 340B Program
- HHS interpreted “patient of the entity” to mean that a covered entity “initiated the healthcare services resulting in the prescription”
- HHS excluded prescriptions written outside of the covered entity
- South Carolina District Court enjoined HHS from enforcing this interpretation against Genesis
- Court applied “plain or common meaning” of the term “patient,” which under all definitions cited requires a healthcare service be provided by the covered entity to the individual qualifying as a “patient” of the covered entity

Citation: *Genesis Healthcare v. Becerra*: https://www.ca4.uscourts.gov/opinions/201701.P.pdf

Genesis Healthcare vs. Becerra, cont'd.

- Decision directly applies only to *Genesis* & HHS
- HHS is not prohibited by the decision from enforcing the narrower "patient" definition against other covered entities
- Other courts may not agree with the South Carolina District Court's reasoning or conclusion

- Reasoning & conclusion may:
  - Be persuasive to other courts
  - Serve as the basis for a covered entity's interpretation of the statutory term "patient"
  - Provide a structure for interpreting other undefined terms in the 340B Statute

Citation: *Genesis Healthcare v. Becerra*: https://www.ca4.uscourts.gov/opinions/201701.P.pdf

Post-*Genesis* HHS Audits

Audits continue in definition of the "patient"

- HHS emphasizes that the *Genesis* decision is applicable solely to *Genesis* Healthcare.
- HHS has resumed audits of the "patient" definition.
- We are already seeing final reports being issued with HHS's pre-*Genesis* interpretation of the definition of "patient" & diversion findings for prescriptions written at non-covered entity locations.

Use of *Genesis* Patient Definition

- Notwithstanding HHS audit enforcement risks, some CEs are continuing to use definitions of "patient" consistent with the reasoning in the *Genesis* case
- CEs taking this approach should understand the legal basis for using the *Genesis* definition & the risk of HHS audit findings
- Following an audit finding, the CE must either:
  - Notify the manufacturers of drugs cited as having been improperly obtained at the 340B price of the audit finding & work with those manufacturers to repay the amount of the discount received
  - Appeal the audit finding

Citation: Program Integrity: Program Integrity | HRSA

What do you think?

Question #2

How does a covered entity appeal an HHS audit finding?

A. HHS audit findings are not appealable
B. Submit a Written Notice of Disagreement to HHS
C. File a lawsuit in federal court
D. Both B & C

Question #2

Correct Answer

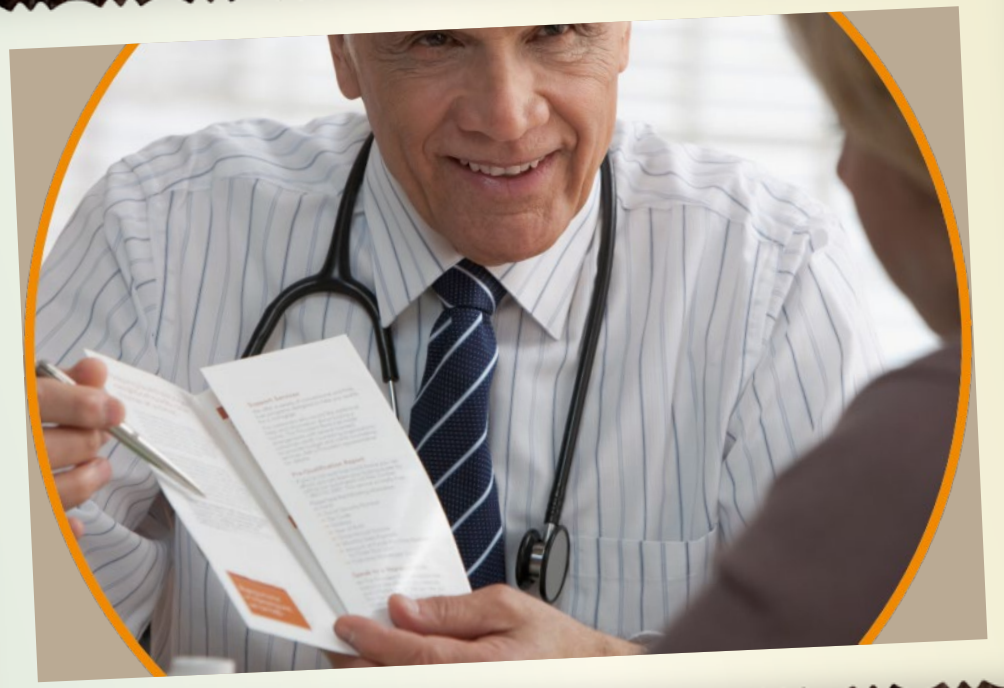
D. Both B & C

HHS audits typically result in a “Final Report” that gives the covered entity an opportunity to submit a Written Notice of Disagreement.

HHS will then issue another Final Report that takes into consideration the covered entity’s comments.

If the covered entity believes the Final Report’s findings are unlawful, it may file a lawsuit in federal court.

BILLING, FINANCIAL ASSISTANCE & REPORTING



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CMS OPPS Repayment

- In November 2023, CMS issued a final rule establishing a remedy to the OPPS payment cuts to 340B drugs from 2018 to 2022
  - Hospitals received lump-sum payments for the total amount due (unless disputed)
  - Budget Neutrality – payments for non-drug items & services to all OPPS hospitals will be reduced by 0.5% starting CY2026 for approx. 16 years
- Payment cut remedy did not remove 340B modifier requirements for Medicare claims – Modifier “TB” required on all claims for 340B drugs, beginning January 1, 2025

Citation: Hospital OPPS Final Rule: https://www.govinfo.gov/content/pkg/FR-2023-07-31/pdf/2023-14768.pdf

Baptist Health vs. Humana

- Baptist Health filed suit against several Humana entities under state contract law for failing to make lump-sum payment similar to CMS
- The underpayments are connected to Humana's mirroring of CMS Medicare fee-for-service payments from 2018 to 2022
- Medicare Advantage (MA) plan payments were "out of the scope of [the OPPS payment remedy] final rule"
- The issue of MA plans was raised in comments to the final rule by various health systems & associations
- CMS references the 340B payment cuts & remedy in the 2025 MA plan year Advance Notice

Citation: Baptist Health v. Humana Docket: https://dockets.justia.com/docket/alabama/almdce/2:2024cv00077/82283

What do you think?

Question #3

Who sets Medicaid reimbursement policy for 340B drugs?

A. HHS
B. CMS
C. State Medicaid Programs
D. B & C
E. All of the above

Question #3

Correct Answer

D. B & C

- HHS is authorized to administer the 340B Program, which fundamentally is a drug purchasing program. However, 340B Program pricing is related to reimbursement due to the duplicate discount prohibition
- CMS has promulgated regulations & guidance establishing Actual Acquisition Cost requirements for Medicaid state agencies to implement
- Medicaid state agencies must implement federal requirements but also have areas of discretion (e.g., coding modifiers for 340B drugs)

Citation: Covered Outpatient Drugs Final Rule: Federal Register: Medicaid Program; Covered Outpatient Drugs

Medicaid Billing for 340B Drugs

- Medicaid “actual acquisition cost” (AAC) billing requires identifying 340B drugs & reporting the “actual” 340B acquisition cost
- Failure to identify drugs as 340B drugs or to accurately report the 340B acquisition cost may result in overpayments
- Suspected Medicaid overpayments must be investigated & refunded within 60 days of quantification
- Failure to investigate or failure to timely refund may result in “reverse” false claims act liability for retained overpayments

Citation: Centers for Medicare and Medicaid Services Bulletin: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf

False Claims Act Settlements

- In 2020, Memorial Care entered into a $30 million settlement agreement with U.S. Department of Justice (DOJ), Health and Human Services Office of Inspector General (HHS OIG) & California Department of Justice (CA DOJ) for over-billing Medi-Cal for 340B drugs & failing to return the overpayments
- In January 2024, Pomona Valley Medical Center reached a settlement of $2.1 million with similar facts
- Expect increased activity in Medicaid 340B overpayment self-disclosures, qui tams & government settlements

Source: Getty Images. Used with permission of HealthTrust.

Citations:
- Memorial Care Settlement: https://www.justice.gov/usao-cdca/pr/oc-based-health-care-organization-agrees-pay-over-315-million-settle-claims-it
- Pomona Valley Medical Center Settlement: https://www.justice.gov/usao-cdca/pr/pomona-hospital-agrees-pay-more-2-million-after-self-reporting-overbilling-medi-cal

Pharmacy Patient Financial Assistance Programs

- Many covered entities are implementing pharmacy-specific patient financial assistance programs
- Often supported by 340B savings or tied to 340B pricing on drugs eligible for assistance
- Present potential risks under the federal anti-kickback statute, the federal beneficiary inducements civil monetary penalty law &/or state equivalent laws
- There are “safe harbors,” but most policies need to be evaluated based on a “facts & circumstances” test

Citations:
- OIG Special Advisory Bulletin: https://oig.hhs.gov/documents/special-advisory-bulletins/880/2005PAPSpecialAdvisoryBulletin.pdf
- OIG Supplemental Special Advisory Bulletin : https://oig.hhs.gov/documents/special-advisory-bulletins/879/independent-charity-bulletin.pdf

Manufacturer Restrictions – Rebate Model

- Late 2024/Early 2025, manufacturers submitted proposals for rebate models to HHS
- Under the rebate models, CEs would initially purchase 340B drugs at commercial prices & subsequently receive rebates as opposed to upfront discounts for 340B drugs
  - CEs would be required to submit claims through a data platform
  - Manufacturers argue that the obligation to guard against duplicate discounts is too opaque without claims submissions data
- HHS has not approved the proposals & stated any such rebate model requires HHS approval

Citations:
- HRSA 340B Drug Pricing Program: https://www.hrsa.gov/opa
- *See, e.g.*, HRSA Correspondence to Stakeholders regarding Rebate Proposals available at https://www.hrsa.gov/opa/program-integrity

Rebate Model – Litigation

- Five manufacturers filed separate lawsuits (four have been consolidated) arguing that preapproval is not required & HHS' failure to approve the rebate models is "arbitrary & capricious"
- In both the consolidated cases and the separate case, the District Court of the District of Columbia found that HHS' requirement of approval is consistent with the 340B Statute
  - The manufacturers have appealed to the D.C. Court of Appeals.
  - The plaintiff-appellant in the separate case has filed to consolidate with the other cases.
  - The cases remain pending.

Citations: McDermott+ 340B Litigation Tracker: https://www.mcdermottplus.com/340b-tracker-tool-registration/

INFLATION REDUCTION ACT

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Inflation Reduction Act (IRA)

- The IRA introduces a “Maximum Fair Price” (“MFP”) for certain prescription drugs under Medicare Part B and Part D
- MFP will be negotiated between CMS and drug manufacturers under the Medicare Drug Price Negotiation Program for certain selected drug products determined by CMS
- Under the IRA drug prices should be set to the lower of the 340B ceiling price or the MFP
- For drugs subject to both 340B and MFP discounts, the IRA requires manufacturers to ensure non-duplication of discounts for 340B covered entities

Citation: Inflation Reduction Act of 2022: https://www.irs.gov/inflation-reduction-act-of-2022

Drugs Subject to MFP in 2026

1. **Eliquis** (Prevention & treatment of blood clots)
2. **Jardiance** (Diabetes; Heart failure)
3. **Xarelto** (Prevention & treatment of blood clots)
4. **Januvia** (Diabetes)
5. **Farxiga** (Diabetes; Heart failure; Chronic kidney disease)
6. **Entresto** (Heart failure)
7. **Enbrel** (Rheumatoid arthritis; Psoriasis; Psoriatic arthritis)
8. **Imbruvica** (Blood cancers)
9. **Stelara** (Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis)
10. **Fiasp**; **Fiasp FlexTouch**; **Fiasp PenFill**; **NovoLog**; **NovoLog FlexPen**; **NovoLog PenFill** (Diabetes)

Citation: Centers for Medicare and Medicaid Services Medicare Drug Price Negotiation Program: Factsheet: Medicare Drug Price Negotiation Program

Additional Drugs Subject to MFP in 2027

1. **Ozempic; Rybelsus; Wegovy** (Type 2 diabetes; Type 2 diabetes & cardiovascular disease; Obesity/overweight & cardiovascular disease)
2. **Trelegy Ellipta** (Asthma; Chronic obstructive pulmonary disease)
3. **Xtandi** (Prostate cancer)
4. **Pomalyst** (Kaposi sarcoma; Multiple myeloma)
5. **Ibrance** (Breast cancer)
6. **Ofev** (Idiopathic pulmonary fibrosis)
7. **Linzess** (Chronic idiopathic constipation; Irritable bowel syndrome with constipation)
8. **Calquence** (Chronic lymphocytic leukemia/small lymphocytic lymphoma; Mantle cell lymphoma)
9. **Austedo; Austedo XR** (Chorea in Huntington's disease; Tardive dyskinesia)
10. **Breo Ellipta** (Asthma; Chronic obstructive pulmonary disease)
11. **Tradjenta** (Type 2 diabetes)
12. **Xifaxan** (Hepatic encephalopathy; Irritable bowel syndrome with diarrhea)
13. **Vraylar** (Bipolar I disorder; Major depressive disorder; Schizophrenia)
14. **Janumet; Janumet XR** (Type 2 diabetes)
15. **Otezla** (Oral ulcers in Behçet's Disease; Plaque psoriasis; Psoriatic arthritis)

Citation: Centers for Medicare and Medicaid Services Medicare Drug Price Negotiation Program: Fact Sheet: Medicare Drug Price Negotiation Program

LOOKING AHEAD

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Restrictions on 340B

- **Manufacturers**
  - Currently ~40 manufacturers restrict 340B purchases
  - Recent efforts to convert 340B to a rebate program (6 appeals pending in federal court)
  - Relief not expected without additional legislation or litigation
- **Congress**
  - 340B ACCESS Act – Viewed as more pharma-friendly
  - SUSTAIN 340B Act – Viewed as more covered entity-friendly
  - Unclear path under new Congress
- **HHS**
  - Continued requests for regulatory authority, including oversight of savings
  - History of policy decisions that are not covered entity-friendly

Citation: AmerisourceBergen Manufacturers Restriction List: https://www.amerisourcebergen.com/provider-solutions/hospitals-and-health-systems/340b-manufacturer-updates

Department of Health & Human Services Budget FY 2026

- Proposed formation of new “Administration for a Health America” (AHA)
- Combines functions of the following agencies:
  - HHS
  - Substance Abuse & Mental Health Services Administration (SAMHSA)
  - Office of the Assistant Secretary for Health (OASH)
  - National Institute for Environmental Health Sciences (NIEHS)
  - Certain programs from the Centers for Disease Control & Prevention (CDC)
- Shifts responsibility of 340B Program to CMS
  - Budget maintained at $12 million for oversight & auditing activities

Citation: Fiscal Year 2026 Budget in Brief: https://www.hhs.gov/sites/default/files/fy-2026-budget-in-brief.pdf

State Laws

- 21 states have enacted laws prohibiting manufacturer 340B contract pharmacy restrictions
- All of the state laws passed to-date are subject to on-going litigation
  - Laws to-date have been upheld on appeal
  - Kansas & WV have said they will not enforce the laws in their states
- 31 states have laws that bar pharmacy benefit managers from discriminating based on 340B status
- 3 states have passed laws requiring CE data reporting/transparency

Citation: 340B Report Bills & Laws Trackers: https://340breport.com/

SUSTAIN 340B Act

- Bipartisan group of six senators released a discussion draft of proposed 340B legislation – “SUSTAIN 340B Act”
- The draft seeks to clarify the use of contract pharmacies & the definition of “child site” & “patient,” among other changes
- Would require additional data reporting & impose a “user fee”
- The draft was accompanied by a supplemental Request for Information (RFI), including several questions & topics for 340B stakeholder input
- The bipartisan working group underwent a membership change earlier this year and a bill is not anticipated until Fall 2025 at the earliest

Citation: SUSTAIN 340B Act Discussion Draft: https://www.thune.senate.gov/public/_cache/files/5e99f492-7a5e-428d-a25e-f4722cfd4b38/26132C0D072A3EF9EB32FB58CFEF5819.340b-discussion-draft-explanatory-document-and-subsequent-rfi.pdf

340B Access Act

(Reps. Bucshon, Carter & Harshbarger)

- 340B Affording Care for Communities & Ensuring a Strong Safety-Net Act (340B ACCESS Act) introduced on May 28, 2024
- The bill attempts to
  - Clarify the intent of the 340B Program
  - Codify a prescription-by-prescription patient definition
  - Impose restrictions on contract pharmacies & child site eligibility
  - Increase transparency
- Described as a “pharmaceutical industry wish list”
- Referred to the Committee on Energy & Commerce

Citation: 340B Access Act: https://www.nachc.org/wp-content/uploads/2024/05/340B-ACCESS-Act-Text.pdf

Solutions – Best Practices to Mitigate Issues

- Regularly monitor updates in the 340B Program
- Monitor compliance of internal programs with guidance from government agencies & courts
- Confer with third parties to review & audit internal programs for compliance
- Keep Policies & Procedures up to date with current practices
- Provide periodic internal education to ensure leadership & staff with 340B responsibilities are aware of current guidelines & internal policies

Solutions – Resources

- Internal Resources
  - Internal 340B Program Compliance Team
  - Update Policies & Procedures
- External Resources
  - Public Sources (340B Health, 340B Report, etc.)
  - Government (HHS, 340B Prime Vendor Program, etc.)
- Legal Consultative Services
  - Third-party expert consultants (law firms, consultants, etc.)

Assessment Question #1

Which of the following best describes a significant development in the 340B legal landscape over the last year?

A. Manufacturers have begun implementing rebate models

B. The *Genesis* patient definition now applies to all covered entities

C. The SUSTAIN 340B Act passed

Assessment Question #1: Correct Response

Which of the following best describes a significant development in the 340B legal landscape over the last year?

A. Manufacturers have begun implementing rebate models

B. The *Genesis* patient definition now applies to all covered entities

C. The SUSTAIN 340B Act passed

Assessment Question #2

Which of the following is a best practice around 340B program growth?

A. Regularly monitor updates in the 340B Program
B. Keep Policies & Procedures up to date with current practices
C. Confer with third parties' expert consultants on trends and compliance
D. All of the above

Assessment Question #2: Correct Response

Which of the following is a best practice around 340B program growth?

A. Regularly monitor updates in the 340B Program

B. Keep Policies & Procedures up to date with current practices

C. Confer with third parties' expert consultants on trends and compliance

D. All of the above

Assessment Question #3

Which of the following are audit and operational risks of 340B expansion strategies?

A. Risk of overpayments due to use of unregistered child sites

B. Risk of duplicate discounts between MFP and 340B prices

C. Risk of HRSA audit due to reliance on *Genesis* patient definition

D. All of the above

Assessment Question #3: Correct Response

Which of the following are audit and operational risks of 340B expansion strategies?

A. Risk of overpayments due to use of unregistered child sites

B. Risk of duplicate discounts between MFP and 340B prices

C. Risk of HRSA audit due to reliance on *Genesis* patient definition

D. All of the above

References

- Government Accountability Office: https://www.gao.gov/assets/gao-21-107.pdf
- Health Resources and Services Administration: https://www.hrsa.gov/opa/updates/2021-340b-covered-entity-purchases
- 340B Patient Definition: https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf
- *Genesis HealthCare v. Becerra*: https://www.ca4.uscourts.gov/opinions/201701.P.pdf
- Program Integrity: https://www.hrsa.gov/opa/program-integrity
- Covered Outpatient Drugs Final Rule: https://www.federalregister.gov/documents/2016/02/01/2016-01274/medicaid-program-covered-outpatient-drugs
- Inflation Reduction Act of 2022: https://www.irs.gov/inflation-reduction-act-of-2022
- Centers for Medicare and Medicaid Services Medicare Drug Price Negotiation Program: https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf
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