



HEALTHTRUST[®]
UNIVERSITY CONFERENCE

July 25, 2022

340B in the Field

Emily Cook, John Choi & Chris Yoder

| Disclosures

- The presenters have no real or perceived conflicts of interest related to this presentation

Note: This program may contain the mention of suppliers, brands, products, services or drugs presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and informational purposes and should not be perceived as an endorsement of any particular supplier, brand, product, service or drug.

| Learning Objectives

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

1. Recall the current 340B legal landscape and the effect manufacturer non-participation may impose
2. Identify program growth opportunities and 340B best practices
3. Recognize solutions to mitigate escalating issues within the 340B space

Meet the Panelists



Emily Jane Cook, MSPH, JD
Partner, McDermott Will and Emery, LLP
ecook@mwe.com



John S. Choi, PharmD, MHA
Senior Director of Pharmacy Services, Centra Health
john.choi@centrahealth.com



Chris N. Yoder, MHA
Director 340B MSPS, HealthTrust
chris.yoder@healthtrustpg.com



Overview, Current Issue and Opportunities

Emily Jane Cook, MSPH, J.D. | Partner | McDermott Will & Emery, LLP

| Agenda

- Brief history & overview of the 340B program
- Current litigation – Origin and status
 - 340B payments
 - Manufacturer restrictions on 340B drug sales
 - Patient definition
- Opportunities
 - Patient definition
 - Referral capture
 - Medication therapy management
 - Telehealth

| 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 and contactors (~80% of Covered Entities)
 - Non-profit and government hospitals (~20% of Covered Entities)
- Estimated value of 7.2% of total U.S. drug market
- Discounts vary significantly, but generally estimated at around 25-50%

Citations:

- Government Accountability Office: <https://www.gao.gov/assets/gao-21-107.pdf>
- U.S. Department of Health and Human Services: <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2023.pdf>

| Current Litigation

- More than 30 340B-related cases currently in state and federal courts
- Updates occurring almost daily
- Outcomes will determine
 - Payment rates for 340B drugs
 - Coverage for 340B drugs
 - Where 340B drugs can be dispensed
 - When Covered Entities can access 340B pricing
 - How Covered Entities and drug manufacturers resolve disputes

| Current Litigation, *continued*

- Three issues of most interest
 - Medicare payments for 340B drugs
 - Restrictions on manufacturer sales of 340B drugs
 - How Covered Entities can define “patients” eligible to receive 340B drugs

| Current Litigation – Medicare Payments

- Beginning in 2018, Medicare reduced payments for most 340B drugs paid under the Medicare Outpatient Payment Prospective Payment System (OPPS)
 - Payment reduced from Average Sales Price (ASP) plus 6% to ASP minus 22.5%
- CMS reduced payments under a statutory provision allowing for payment of drugs at acquisition cost if CMS conducted a survey to determine hospital acquisition cost of drugs
- CMS relied on a GAO study of the 340B Program and only reduced payments on 340B drugs billed by certain 340B-participating hospitals

Citation:

- Federal Register: <https://www.govinfo.gov/content/pkg/FR-2020-12-29/pdf/2020-26819.pdf>

| Current Litigation – Medicare Payments, *continued*

- Hospital associations and representative hospitals sued HHS claiming that CMS acted outside of the statute by not conducting a survey and only targeting 340B drugs in the payment reduction
 - Hospitals prevailed in the D.C. District Court, but the decision was overturned by the D.C. Appeals Court
 - Case was appealed to the Supreme Court
- Issue at the Supreme Court was the authority of federal agencies to interpret statutes
 - Supreme Court ruled in favor of the hospitals and sent the case back to the District Court
- Payment cut was implemented in a “budget neutral” manner, making any retroactive corrective action compared to “unscrambling an egg”

Citations:

- Supreme Court Opinion: https://www.supremecourt.gov/opinions/21pdf/20-1114_09m1.pdf

| Current Litigation – Purchase Restrictions

- In mid-2020, certain drug manufacturers began restricting purchases of 340B drugs for dispensing by Covered Entities through third-party pharmacies (“Contract Pharmacies”)
 - Contract Pharmacy dispensing is well-established in the 340B Program as a mechanism for providing 340B drugs to patients of Covered Entities
- Currently 18 manufacturers restricting 340B purchases for Contract Pharmacy dispensing
 - Most condition sales on providing claim-level data to identify 340B-purchased drugs and restrict only purchase by hospital Covered Entities
 - Data is used to enforce contractual rebate provisions with PBMs
 - Specific requirements and exemptions vary by manufacturer

| Current Litigation – Purchase Restrictions, *continued*

- HHS issued an Advisory Opinion in December 2020 stating that the 340B statute does not permit the purchase restrictions
 - Advisory Opinion was later rescinded
 - HRSA has issued warning letters to manufacturers for violating the 340B Ceiling Price rule (requiring sales at the 340B price) and referred manufacturers to HHS Office of Inspector General for imposition of penalties
 - To-date, no penalties have been imposed

Citations:

- Health Resources and Services Administration, Office of Pharmacy Affairs: <https://www.hrsa.gov/opa/program-integrity/index.html>

| Current Litigation – Purchase Restrictions, *continued*

- Manufacturers used Advisory Opinion and later warning letters to sue HHS in federal court
 - Argue that the 340B Statute does not prohibit the purchase restrictions
- Courts have been divided in their rulings to-date
 - In general, Courts have found that manufacturers can impose some restrictions, but that the scope of such restrictions is not specified in the 304B Statute
- As of July 2022, appeals are pending in three different federal Appeals Courts
- Issue may be addressed by legislation before the litigation ends

| Current Litigation – Patient Definition

- Community Health Center Covered Entity (Genesis HealthCare) sued HHS following adverse 340B audit finding
- Genesis HealthCare stocked its on-site pharmacy with only 340B drugs and dispensed 340B drugs to fill all prescriptions
 - HRSA argued this practice violated the 340B Program definition of “patient” and removed Genesis HealthCare from the 340B Program
- HRSA voided its audit findings due to the litigation and the District Court dismissed the case
- Genesis HealthCare appealed arguing that HRSA must provide it with a clear statement of the definition of patient under the 340B statute

Citations:

- Genesis HealthCare v. Becerra: <https://www.ca4.uscourts.gov/opinions/201701.P.pdf>

| Current Litigation – Patient Definition, *continued*

- Following oral arguments in the appeal, HRSA filed documents with the Appeal Court stating that its statements requiring that Genesis HealthCare could only dispense 340B drugs when it “initiat[ed] the healthcare service resulting in the prescription” were not found in the published definition of “patient”
- HRSA has at times required such a relationship between the Covered Entity and the prescription, but appears to have now acknowledged that no such requirement is enforceable
- In July 2022, the federal Appeals Court sided with Genesis HealthCare and remanded the case back to the District Court to address the issue of the definition of patient

Citations:

- Genesis HealthCare v. Becerra: <https://www.ca4.uscourts.gov/opinions/201701.P.pdf>

| Opportunities – Patient Definition, *continued*

- Genesis HealthCare case appears to expand opportunities for Covered Entities to purchase and dispense 340B drugs
- 340B Statute limits sales of 340B drugs to Covered Entities
 - Resale and transfers of 340B drugs are restricted to “patients” of the Covered Entity
 - Patient is not defined by the 340B Statute
- Many Covered Entities are evaluating their current understanding of who is their “patient” and whether to expand dispensing of 340B drugs to additional types of “patients”
- Each Covered Entity must establish its own definition of “patient”

Citations:

- 340B Statute: 42 U.S.C. § 256b
- 340B Patient Definition:
<https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf>

| Opportunities – Referral Capture

- Many vendors have developed software to identify individuals who receive care at a Covered Entity and have prescriptions written by practitioners outside of the Covered Entity
- Some Covered Entities have been using these products to identify individuals who may be eligible to receive 340B drugs purchased by the Covered Entity
- Covered Entities using such products should proceed with caution
 - Taking the position that an individual is a “patient” in such models may result in liability for care provided outside of the oversight of the Covered Entity

| Opportunities – Medication Therapy Management

- Covered Entities are evaluating options for expanding Medication Therapy Management (“MTM”) programs to establish relationships with new patients in order to dispense 340B drugs to such patients
- MTM services are clinical services provided by Covered Entity practitioners (often pharmacists)
- Some similar risks as to referral capture programs
- But, often implemented within health systems where the patient is being referred for MTM services from a system-affiliated practice/practitioner
- Risks of MTM arrangements significantly reduced by Genesis HealthCare case

| Opportunities – Telehealth

- Expansion of telehealth services during the pandemic has caused Covered Entities to explore options for continuing telehealth services post-pandemic in order to enable dispensing of 340B drugs to patients who do not receive services in the Covered Entity itself
- HRSA acknowledged that telehealth could establish patient relationships prior to the COVID-related expansion in coverage for telehealth provided by Covered Entities
- Whether an individual is a “patient” of a Covered Entity is not necessarily dependent on whether the services received are covered by the patient’s insurance or billed to the patient

Thank you...

Emily Jane Cook, MSPH, JD
ecook@mwe.com
310-284-6113



HEALTHTRUST[®]
UNIVERSITY CONFERENCE

340B – Past and Future

John Choi, PharmD, MHA | Senior Director of Pharmacy Services | Centra Health

| Agenda

- 340B Program Narrative as a Covered Entity Pharmacy Director: Past 12 years
- Current Challenges
 - Medicaid Carve In/Out and state audit
 - White Bagging
 - Manufacturer restrictions on 340B drug sales
 - 340B ESP
- Opportunities
 - Specialty Pharmacy
 - Home Infusion
 - Future 340B Revenue Budget, setting the expectation

| 340B for the past 12 years as a Covered Entity Pharmacy Leader

- March, 2010
 - Contract pharmacy expansion – new policy by HRSA-OPA
 - Affordable Care Act expansion:
 - Sec. 7101 Children’s, CAH, RRC, Sec.7102
 - Sec. 7102 340B Program Integrity
 - And the penultimate section of the ACA

“(e) EXCLUSION OF ORPHAN DRUGS FOR CERTAIN COVERED ENTITIES.—For covered entities described in subparagraph (M), (N), or (O) of subsection (a)(4), the term ‘covered outpatient drug’ shall not include a drug designated by the Secretary under section 526 of the

Citations:

<https://www.hhs.gov/guidance/document/340b-drug-pricing-program-orphan-drugs-program-requirements-1>

| 340B for the past 12 years as a Covered Entity Pharmacy Leader, *continued*

- 2011–2018
 - Your CFO

SHOW ME THE MONEY

| 340B for the past 12 years as a Covered Entity Pharmacy Leader, *continued*

2011–2018

- Learned how to decipher Medicare Cost Report
- Safety Net Hospitals for Pharmaceutical Access (SNHPA) – no seats at Coronado Bay
- Love/hate with Third Party Administrators (TPA) of the 340B program
- Fixed accumulator for mixed use area
- Learned to hate Wholesaler Acquisition Cost (WAC) accounts
- Opened 340B infusion centers
- Dreaded legal review of PSAs and Jan 15, April 15, July 15, Oct 15 – register contract pharmacies
- Built 340B Team
- Fear of Health Resources and Services Administration (HRSA) Audit
- Independent external audit
- Specialty Pharmacy

and we delivered...

| 340B for the past 12 years as a Covered Entity Pharmacy Leader, *continued*

2018–Now

- No more winter conference in San Francisco
- Medicare OPPS reduction
- But nimble organizations – biosimilars with passthrough (ASP + 6%)
- P&T formulary review for infusion? Payer driven
- COVID-19
- California Department of Health Care Services (Medicaid) demand for self-audit 340B claims
- White Bag mandate
- 17 Manufacturers impose restrictions on contract pharmacies
- 340B ESP

| Current Challenges

- Medicaid Carve In
 - Pros:
 - Cost reduction
 - Potential margin with Managed Care Organizations (MCO)
 - Accountable Care Organizations (ACO)
 - Cons:
 - Complexity in billing
 - Compliance concerns
- My experience
 - HRSA audit found drug diversion. Paid back manufacturers
 - California Department of Health Care Services (DHCS) self audit. Paid back \$7.25 dispensing fees for transactions
 - Today, we are carved out but opting to carve in. Evaluating third-party billing vendor

| Current Challenges, *continued*

- White Bagging
 - “is an arrangement between payers and selected pharmacies to ship a patient’s medications directly to the site of care, whose staff must then take whatever steps are needed to prepare and administer the products.”
 - CA Senate Bill 958 Medication and Patient Safety Act of 2022 passed on May 25, 2022. Addresses Brown Bagging, Home Infusion and White Bagging.
- My experience
 - TJC. MM 02.01.01 titled “The hospital selects and procures medications. The policy doesn’t allow white bagging or brown bagging”.
 - Continued to process prior authorization, provide the treatment and bill as usual.
 - Renegotiate with the payers?

Citations:

- <https://www.ashp.org/news/2021/03/22/white-bagging-a-growing-concern-for-health-systems?loginreturnUrl=SSOCheckOnly#:~:text=White%20bagging%20is%20an%20arrangement,prepare%20and%20administer%20the%20products>
- Golightly, Larry & Simendinger, Bonita & Barber, Gerard & Stolpman, Nancy. (2015). Compliance With Hospital Medication Management Standards for Safety and Efficacy Information. *Journal of pharmacy practice*. 28. 135-6. 10.1177/0897190014552725.

| Current Challenges, *continued*

- Manufacturer restrictions on 340B contract pharmacy drug sales & 340B ESP
 - Potential revenue loss > 60% without participation in 340B ESP
- My experience
 - Easy acceptance of 340B ESP by legal, risk and privacy team at one organization
 - Major red flag raised by the privacy team at another as they consider these as PHI identifiers
 - **Rx Number**
 - **prescribed date**
 - **fill date**
 - NDC
 - quantity
 - pharmacy ID
 - prescriber ID
 - wholesaler invoice number
 - 340B covered entity ID

| Opportunities

- Specialty Pharmacy
 - Organization's own to service patients, employees & ACO population
 - Continue to maximize contract pharmacies both national and independent
- Home Infusion
 - 340B?
 - Specialty and Non-Specialty home infusion
 - 300% increase from 2008 to 2019
 - 340B contract pharmacy, own pharmacy with management contract, or self managed
- Setting the expectations
 - Reassess P&L
 - Budget accordingly

References

- Government Accountability Office: <https://www.gao.gov/assets/gao-21-107.pdf>
- U.S. Department of Health and Human Services: <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2023.pdf>
- Federal Register: <https://www.govinfo.gov/content/pkg/FR-2020-12-29/pdf/2020-26819.pdf>
- Supreme Court Opinion: https://www.supremecourt.gov/opinions/21pdf/20-1114_09m1.pdf
- Health Resources and Services Administration, Office of Pharmacy Affairs: <https://www.hrsa.gov/opa/program-integrity/index.html>
- Genesis HealthCare v. Becerra: <https://www.ca4.uscourts.gov/opinions/201701.P.pdf>
- 340B Statute: 42 U.S.C. § 256b

References

- 340B Patient Definition:
<https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf>
- <https://www.hhs.gov/guidance/document/340b-drug-pricing-program-orphan-drugs-program-requirements-1>
- <https://www.ashp.org/news/2021/03/22/white-bagging-a-growing-concern-for-health-systems?loginreturnUrl=SSOCheckOnly#:~:text=White%20bagging%20is%20an%20arrangement,prepare%20and%20administer%20the%20products>
- Golightly, Larry & Simendinger, Bonita & Barber, Gerard & Stolpman, Nancy. (2015). Compliance With Hospital Medication Management Standards for Safety and Efficacy Information. *Journal of pharmacy practice*. 28. 135-6. 10.1177/0897190014552725.

Thank you...

John Choi, PharmD, MHA

john.choi@centrahealth.com

434-200-2161