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340B In The Field

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Meet the Presenters

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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. Describe the current 340B legal landscape.
2. Recall current manufacturer restrictions on 340B purchases and the impact on 340B covered entities.
3. Recognize 340B program growth opportunities and best practices.
4. Identify solutions to mitigate escalating compliance and oversight issues within the 340B space.

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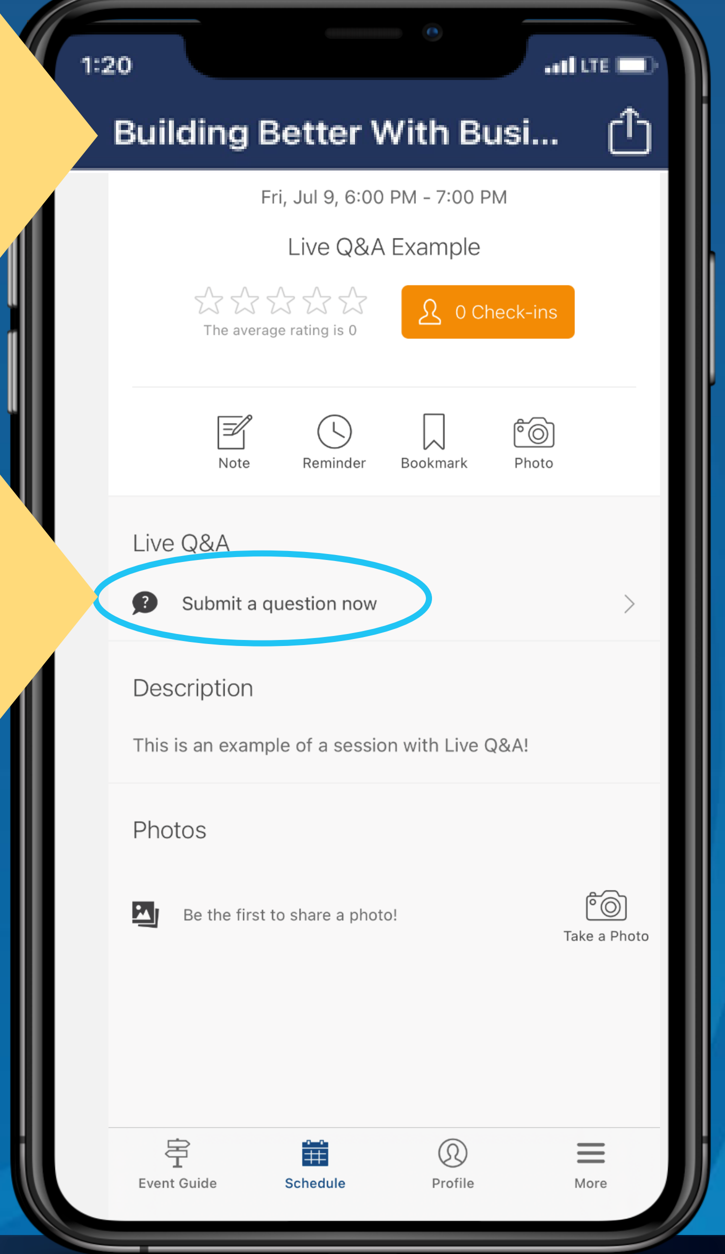

Overview, Current Issue & Opportunities

Emily Jane Cook, MSPH, JD | Partner | McDermott Will & Emery, LLP

Agenda

- Brief history and 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)
- Approximately $44 Billion in drug purchases
  - Approximately $37 Billion made by hospital Covered Entities

Citations:

- 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

Current Litigation

- More than 40 340B-related cases currently in state and federal courts
- Updates occurring almost daily
- Outcomes will determine
  - Remedy for cuts to Medicare payments for 340B drugs
  - Medicaid coverage and payment for 340B drugs
  - Where 340B drugs can be dispensed
  - When Covered Entities can access 340B pricing
  - How Covered Entities and drug manufacturers resolve disputes

Citation: McDermott Plus Consulting 340B Litigation Tracking Tool: https://www.mcdermottplus.com/340b-tracker-tool-registration/

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%
- 340B 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
  - Appeals up to the U.S. Supreme Court
  - 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"
  - D.C. District Court is overseeing CMS proposal of remedy
  - Proposal expected early July

Citation:
- 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

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 21 manufacturers are restricting 340B purchases for Contract Pharmacy dispensing
  - Several manufacturers now refuse to ship 340B drugs to any location other than a registered Covered Entity address
  - Other manufacturers continue to require submission of claim-level data

Citation: 340B ESP: https://www.340besp.com/resources

Current Litigation – Purchase Restrictions, *continued*

As of May 2023

- Four manufacturer cases pending in D.C. District Court
  - Boehringer Ingelheim
  - Merck
  - UCB
  - Amgen
- Two cases pending in federal Appeals Courts
  - D.C. Circuit
    - Novartis
    - United Therapeutics
  - Seventh Circuit
    - Eli Lilly

Current Litigation – Purchase Restrictions, *continued*

- One case decided in Third Circuit — Sanofi, Novo-Nordisk, AstraZeneca
  - Court ruled in favor of manufacturers and found that HHS cannot take enforcement action against manufacturers for imposing 340B sales restrictions that are not prohibited by the statute
  - Notably, AstraZeneca's policy was upheld and since implemented has limited sales of 340B drugs to those shipped to Covered Entity on-site pharmacies (with exception for one Contract Pharmacy if there is no on-site pharmacy)

Citation: *Sanofi Aventis US LLC v. United States HHS*: https://digitalcommons.law.villanova.edu/thirdcircuit_2023/81

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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

Current Litigation – Patient Definition, *continued*

- Following oral arguments in the appeal, HRSA filed documents with the Appeals 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 South Carolina District Court to address the issue of the definition of patient
- The South Carolina District Court appears to be re-auditing the materials provided by Genesis HealthCare to HRSA during the original audit

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

Other Litigation

- Several other 340B-related cases pending in federal District and Appeals Courts
  - *Mosaic Health, Inc. v. Sanofi-Aventis U.S., LLC*, et al.
    - Antitrust case against manufacturers of insulin that are restricting 340B sales
  - *Pharmaceutical Research and Manufacturers of America v. McClain*, et al.
    - Appeal of Arkansas state law prohibiting PBMs from discriminating against 340B Covered Entities and Contract Pharmacies
  - *Heritage Health and Housing, Inc. v. New York State Department of Health*
    - Case against New York for carving 340B drugs out of Medicaid managed care and paying only under Medicaid fee-for-service
  - *AIDS Healthcare Foundation v. Apexus, LLC*
    - Case against the 340B Program Prime Vendor alleging harms to a Covered Entity due to failure to following contractual obligations

Citation: McDermott Plus Consulting 340B Litigation Tracking Tool: https://www.mcdermottplus.com/340b-tracker-tool-registration/

Opportunities – Patient Definition

- 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”
- But, HRSA may be trying to take a more restrictive approach
  - Unexpected reversal of policy to allow use of 340B drugs for patients at unregistered child sites

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

Opportunities – Internal Drug Distribution Models

- Drug manufacturers must still ship 340B drugs to Covered Entities
- Some Covered Entities are developing internal drug distribution models to get 340B drugs to other locations
- Requires understanding of state and federal laws related to drug distribution
- Not an option for all Covered Entities or in all states
- Covered Entities evaluating internal drug distribution models should determine if there no non-340B benefits to implementing such models since they could be blocked by drug manufacturers with little to no warning

Thank you…

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340B – Managing Eligibility Changes: SCH (Sole Community Hospitals) to DSH (Disproportionate Share Hospitals)

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Agenda

- Different types of 340B covered entities
- Focus Hospitals: Disproportionate Share Hospital (DSH) and Sole Community Hospitals (SCH)
- Disproportionate Share Adjustment Percentage (DSH %)
- GPO Prohibition and Medicaid Carve-in implications
    - Medication procurement & proper accumulation
    - GPO purchased non-covered outpatient drugs (bundled charged drugs)
- DSH Benefits: Drugs with Orphan Indications
- Eligibility change process: SCH to DSH
- Budget preparation and communication with leadership

340B Eligibility

Hospitals

- Children's Hospitals
- Critical Access Hospitals
- **Disproportionate Share Hospitals**
- Free Standing Cancer Hospitals
- Rural Referral Centers
- **Sole Community Hospitals**

Federally Qualified Health Center

- Health Center Program Award Recipients
- Health Center Program Look-Alikes
- Native Hawaiian Health Centers
- Tribal / Urban Indian Health Centers

Specialized Clinics

- Black Lung Clinics
- Comprehensive Hemophilia Diagnostic Treatment Centers
- Title X Family Planning Clinics
- Sexually Transmitted Disease Clinics
- Tuberculosis Clinics

- **Ryan White HIV/AIDS Program Grantees**

Citation: https://www.hrsa.gov/opa/eligibility-and-registration

Disproportionate Share (DSH) vs. Sole Community Hospital (SCH) 340B

DSH

- A private nonprofit hospital under contract with state or local government to provide health care services to low income individuals who are not eligible for Medicare or Medicaid; or
- Owned or operated by a unit of state or local government; or
- A public or private nonprofit corporation that is formally granted governmental powers by a unit of state or local government.
- For-profit hospitals are not eligible to participate in the 340B program.
- **Have a disproportionate share adjustment percentage greater than 11.75% for the most-recently filed cost report**

SCH

- A private nonprofit hospital under contract with state or local government to provide healthcare services to low income individuals who are not eligible for Medicare or Medicaid; or
- Owned or operated by a unit of state or local government; or
- A public or private nonprofit corporation that is formally granted governmental powers by a unit of state or local government.
- For-profit hospitals are not eligible to participate in the 340B program.
- **Have a disproportionate share adjustment percentage greater than 8% for the most-recently filed cost report**

Citation: https://www.hrsa.gov/opa/eligibility-and-registration

Disproportionate Share Adjustment Percentage

- Disproportionate share hospitals (DSHs) serve a significantly disproportionate number of low-income Medicare patients and get additional Medicare payments to cover the costs of providing care to them.
- Based on the hospital's disproportionate patient percentage (DPP).

Example: Hospital A has 62 beds and is in an urban area. It had 5,000 total patient days, 1,000 Medicaid/non-Medicare days, 2,000 Medicare Part A days, and 300 Medicare Part A/SSI days. Hospital A's Medicare DPP is 35%.

$$\text{Medicare DPP} = \frac{\text{300 Medicare Supplemental Security Income Days}}{\text{2,000 Total Medicare Days}} + \frac{\text{1,000 Medicaid, Non-Medicare Days}}{\text{5,000 Total Patient Days}} = .35$$

Citation: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Disproportionate_Share_Hospital.pdf

Disproportionate Share Adjustment Percentage

Medicare DSH Payment Adjustment Formulas for Hospitals Qualifying Under the Primary Method

Status/Location	Number of Beds	Threshold	Adjustment Formula
Urban Hospitals	0–99 Beds	≥15%, ≤20.2%	2.5% + [.65 x (DPP−15%)] **Not to Exceed 12%**
Urban Hospitals	0–99 Beds	≥20.2%	5.88% + [.825 x (DPP−20.2%)] **Not to Exceed 12%**
Urban Hospitals	100 or More Beds	≥15%, ≤20.2%	2.5% + [.65 x (DPP−15%)] **No Cap**
Urban Hospitals	100 or More Beds	≥20.2%	5.88% + [.825 x (DPP−20.2%)] **No Cap**
Rural Referral Centers	N/A	≥15%, ≤20.2%	2.5% + [.65 x (DPP−15%)] **No Cap**
Rural Referral Centers	N/A	≥20.2%	5.88% + [.825 x (DPP−20.2%)] **No Cap**
Other Rural Hospitals	0–499 Beds	≥15%, ≤20.2%	2.5% + [.65 x (DPP−15%)] **Not to Exceed 12%**
Other Rural Hospitals	0–499 Beds	≥20.2%	5.88% + [.825 x (DPP−20.2%)] **Not to Exceed 12%**
Other Rural Hospitals	500 or More Beds	≥15%, ≤20.2%	2.5% + [.65 x (DPP−15%)] **No Cap**
Other Rural Hospitals	500 or More Beds	≥20.2%	5.88% + [.825 x (DPP−20.2%)] **No Cap**

Citation: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Disproportionate_Share_Hospital.pdf

Disproportionate Share Adjustment Percentage

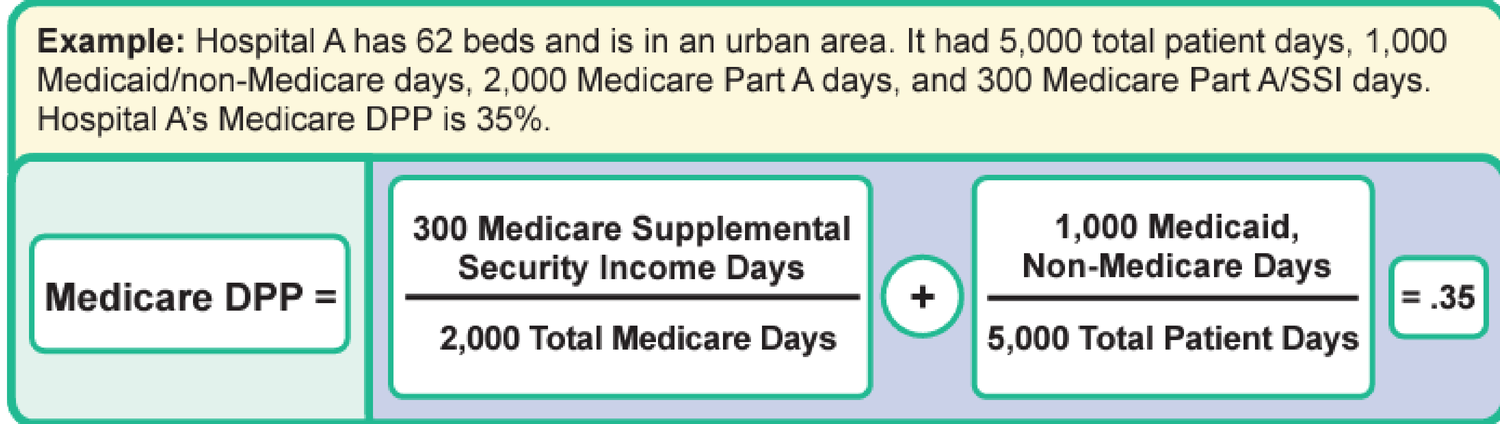


Figure 2. Medicare DPP Calculation & Corresponding Payment Adjustment Calculation Under the Primary Qualifying Method

Because Hospital A is located in an urban area, has fewer than 100 beds, and has a DPP of more than 20.2%, the formula for determining the Medicare DSH adjustment is:

5.88% + [.825 x (DPP–20.2%)]

5.88% + [.825 x (35%–20.2%)]

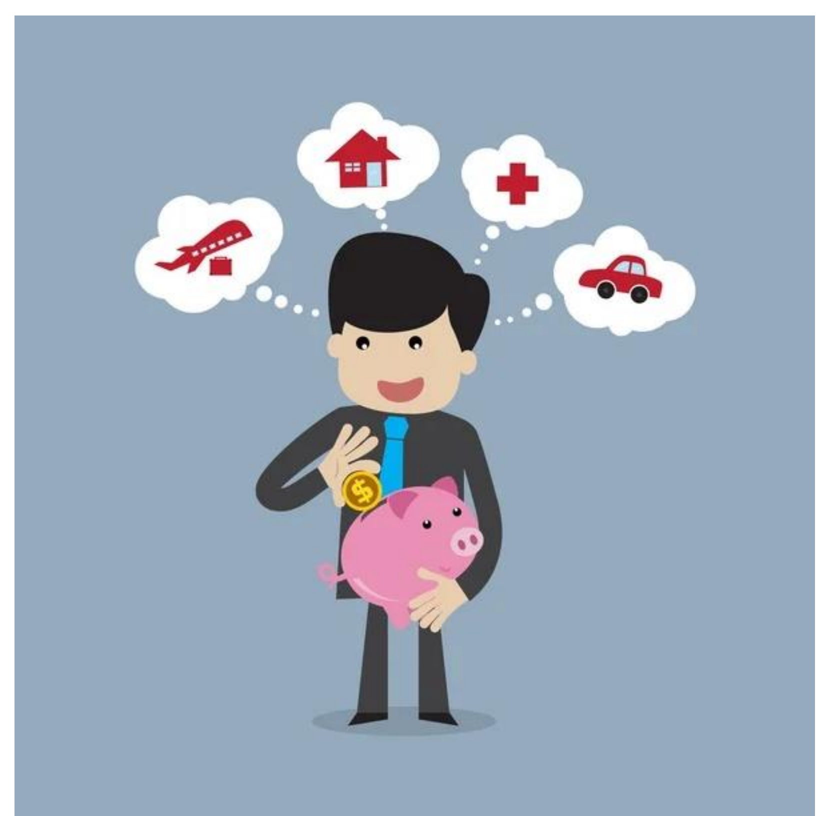
5.88% + 12.21% = 18.09%

Urban hospitals with fewer than 100 beds are subject to a maximum DSH adjustment of 12%; therefore, Hospital A's Medicare DSH adjustment is 12%. DSHs may also qualify for a low-volume hospital payment adjustment.

Citation: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Disproportionate_Share_Hospital.pdf

Disproportionate Share Adjustment Percentage > 11.75%

Now What??



Happy Wife = Happy Wife

Happy CFO = Happy Life

Source: https://www.shutterstock.com/image-vector/businessman-planning-save-money-good-future-187312721

340B GPO Prohibition

- STATUTORY PROHIBITION ON GROUP PURCHASING ORGANIZATION PARTICIPATION
  - ***Disproportionate share hospitals (DSH)***, ***children's hospitals***, and ***free-standing cancer hospitals*** participating in the 340B Program under 42 U.S.C. 256b(a)(4)(L) and (M) are subject to 42 U.S.C. 256b(a)(4)(L)(iii), which states that in order to participate in the 340B Program, these entities ***may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement."***
  - Since the GPO prohibition is an eligibility requirement, covered entities found in violation will be **considered ineligible and immediately removed from the 340B Program**. Covered entities may also be subject to repayment to manufacturers for the time period for which the violation occurred.

340B GPO Prohibition: Operational Change Requirements

Covered Outpatient Drugs purchased under GPO account:

- Hospital can use a GPO for covered outpatient drugs that are part of/incident to another service and payment is not made as direct reimbursement of the drug ("bundled drugs"). For example, diluents for infusions, large volume parenterals purchased by materials management and used as diluents, etc.
- Minimal reimbursement for inpatient IV Fluid utilization even if itemized billed.
- Pharmacy to manage the procurement of Miscellaneous Drugs purchased by MM and IV Contrasts purchased by Imaging. Proper purchase split and accumulation of IV Contrast with correct billing (bill on administration).
- Collaborate with Revenue Cycle, Finance, and Information Technology to properly manage the Charge Description Master for bundle charging of covered outpatient drugs purchased under GPO.
- Under SCH 340B: Medicaid Carve-Out uses GPO Drugs.
- Under DSH 340B: Medicaid Carve-Out must use WAC purchased drugs. Major increase in cost
- Convert to Medicaid Carve-In.

Orphan Drugs: Cost Savings Opportunity SCH to DSH Conversion

- For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals participating in the 340B Program, the term “covered outpatient drug” doesn't include a drug designated by the Secretary under section 526 of the Federal Food, Drug and Cosmetic Act for a rare disease or condition.
- Therefore, manufacturers aren’t required to provide these covered entities’ orphan drugs under the 340B Program. A manufacturer may, at its sole discretion, offer discounts on orphan drugs to these hospitals.
- https://www.hrsa.gov/opa/program-requirements/orphan-drug-exclusion

Citation: https://www.hrsa.gov/opa/program-requirements/orphan-drug-exclusion

Orphan Drugs: Number of Orphan Drug Designations

Fig. 1

Decade	Count
1980s	307
1990s	660
2000s	1,153
2010s	2,979

Count of FDA orphan drug designations by decade, 1983—2019. 1980s includes 1983–1989

Citation: https://ojrd.biomedcentral.com/articles/10.1186/s13023-021-01901-6

DSH Conversion Check List

- ✓ Check Medicare Cost Report: Worksheet E, Section A, Line 33. 2nd quarter
- ✓ Cost Saving Analysis: Orphan drug conversion to 340B and cost of loss of 340B for a quarter if conversion back to SCH
- ✓ Leadership approval to change Eligibility to DSH
- ✓ Prepare for GPO exclusion compliance
  - Bundle Charge IV fluids managed by MM
  - All other drug procurement process to follow mixed use setting split and accumulation
  - Medicaid Carve-In and prevention of duplicate discount compliance
- ✓ HRSA Registration July 1–July 15 for October 1, go live as DSH
- ✓ Notify wholesaler of the conversion and create WAC accounts
- ✓ Notify 340B Third-Party Administrators of the change for mixed use setting procurement process change and contract pharmacy for inclusion of orphan drugs
- ✓ Make appropriate changes to 340B Policy and Procedure
- ✓ Monitor DSH % Adjustment monthly/quarterly

Thank you…

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340B In The Field

Q&A With The Panel

Assessment Question #1:

There is on-going litigation that may result in a federal court establishing the definition of “patient” under the 340B Program.

A. True

B. False

Assessment Question #1 | Answer…

There is on-going litigation that may result in a federal court establishing the definition of “patient” under the 340B Program.

A. **True**

B. False

Assessment Question #2:

In which way(s) does the 340B GPO Prohibition impact 340B covered entities?

A. Covered entities found in violation will be considered ineligible and immediately removed from the 340B Program.

B. Covered entities may be subject to repayment to manufacturers for the time period for which the violation occurred.

C. It only impacts Disproportionate Share Hospitals (DSH).

D. Both A & B

Assessment Question #2 | Answer…

In which way(s) does the 340B GPO Prohibition impact 340B covered entities?

A. Covered entities found in violation could be considered ineligible and immediately removed from the 340B Program.

B. Covered entities may be subject to repayment to manufacturers for the time period for which the violation occurred.

C. It only impacts Disproportionate Share Hospitals (DSH).

D. Both A & B

Assessment Question #3:

In which of the following areas could covered entities find potential growth opportunities?

A. Changes to the definition of "patient"

B. Use of software to identify individuals who may be eligible to receive 340B drugs

C. Expanding MTM programs

D. All of the above

Assessment Question #3 | Answer…

In which of the following areas could covered entities find potential growth opportunities?

A. Changes to the definition of "patient"

B. Use of software to identify individuals who may be eligible to receive 340B drugs

C. Expanding MTM programs

D. All of the above

Assessment Question #4:

Solutions to mitigate escalating compliance and oversight issues within the 340B space may include which of the following:

A. Working closely with your 340B Oversight Committee

B. Ask for 340B guidance from a for-profit health system

C. Don't worry about 340B compliance

Assessment Question #4 | Answer…

Solutions to mitigate escalating compliance and oversight issues within the 340B space may include which of the following:

A. **Working closely with your 340B Oversight Committee**

B. Ask for 340B guidance from a for-profit health system

C. Don’t worry about 340B compliance

References

- Government Accountability Office: https://www.gao.gov/assets/gao-21-107.pdf
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- 340B Statute: 42 U.S.C. § 256b

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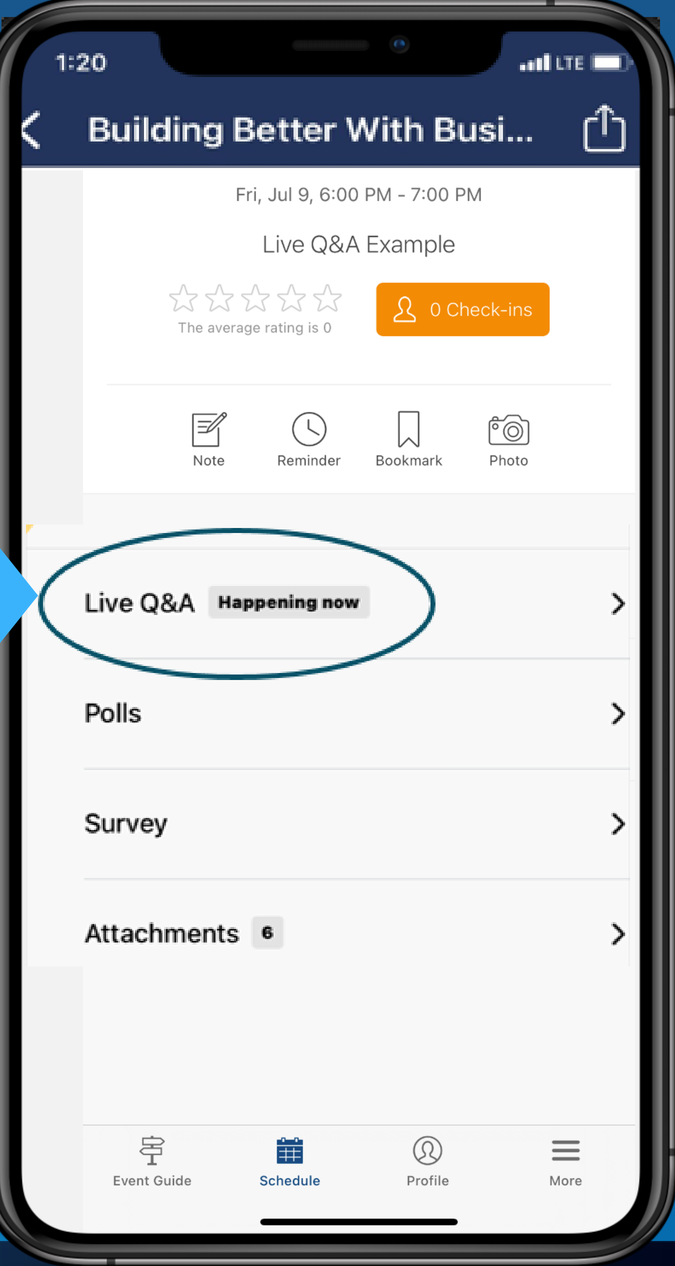

Thank you…

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