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Common Issues in Managing 340B Program Compliance

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Common Issues in Managing 340B Program Compliance

Oct. 26, 2017

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About the Speaker

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Director of Consulting,
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Cynthia is a Pharmacy Consultant with Premier Performance Partners practice based in Charlotte, NC with an office in Cincinnati, Ohio. She provides consultative services to hospital and health-care systems to identify, develop and implement innovative solutions to improve drug utilization, pharmacy supply chain throughput, pharmacy workflow and operations. She focuses on numerous areas including formulary management, medication utilization, improving the effectiveness of the P&T Committee, workforce management, the medication distribution process, and 340B implementation and compliance.

Cynthia joined Premier in 2014 after 15 years experience as a pharmacist consultant for health systems throughout the United States and Canada. Her areas of experience include managing hospital, outpatient, home infusion and nuclear pharmacy operations.

Cynthia graduated from the University of Kentucky with a Bachelor of Science degree in Pharmacy and a Juris Doctor degree in Law. She is a member of the American Society of Health-System Pharmacists.

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Today's topics

- Overview of the 340B Program
- 2017 Published HRSA Audit Results
- 340B Eligibility and Registration
- Prohibition Against Duplicate Discounts
- Diversion
- GPO Prohibition
- Orphan Drug Exclusion

340B drug discount program - overview

- The 340B Drug Discount Program is a section of the Veterans Health Care Act of 1992. The Act requires pharmaceutical manufacturers, participating in the Medicaid program, to provide discounts on outpatient covered drugs purchased by specified public health services and government-supported facilities (called Covered Entities) that serve the nation's most vulnerable patient populations.

- The 340B drug purchasing program is regulated by the Office of Pharmacy Affairs ("OPA") - a division of the department of Health Resources and Services Administration ("HRSA") within the department of Health and Human Services.

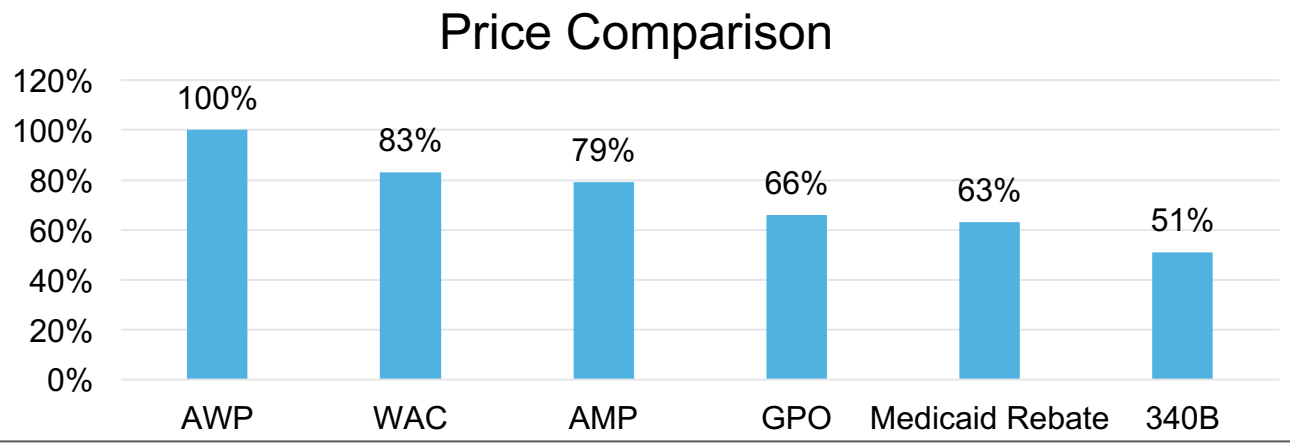
- The Office of Pharmacy Affairs and participating manufacturers have authority to audit Covered Entities for 340B compliance at any given time.

340B drug discount program - overview

- Participation in the 340B program provides significant savings to Covered Entities. The Government Accountability Office reported 340B participants may expect savings of 20-50% off drug costs.

- The pharmaceutical manufacturer agrees to charge a price for covered outpatient drugs that does not exceed the 340B price or “ceiling price”

- “Ceiling price”
  Average manufacturer price (AMP) – Medicaid unit rebate amount (URA)
  340B ceiling price. Calculated quarterly



Categories of entities eligible for 340B

Hospitals

- Acute Care Hospitals, DSH>11.75%
- Children's Hospitals, DSH>11.75%
- Cancer Hospitals
- Rural Referral Centers (RRCs), DSH>8%
- Sole Community Hospitals (SCHs)
- Critical Access Hospitals (CAHs)

Grantees

- Federally Qualified Health Centers (FQHCs)
- Ryan White HIV/AIDS Program Grantees
- Hemophilia Treatment Centers
- Native Hawaiian Health Centers
- Tribal/Urban Health Centers
- Black Lung Clinics
- Title X Family Planning Clinics
- Sexually Transmitted Disease Clinics
- Tuberculosis Clinics
- Title X Family Planning

Hospital eligibility criteria

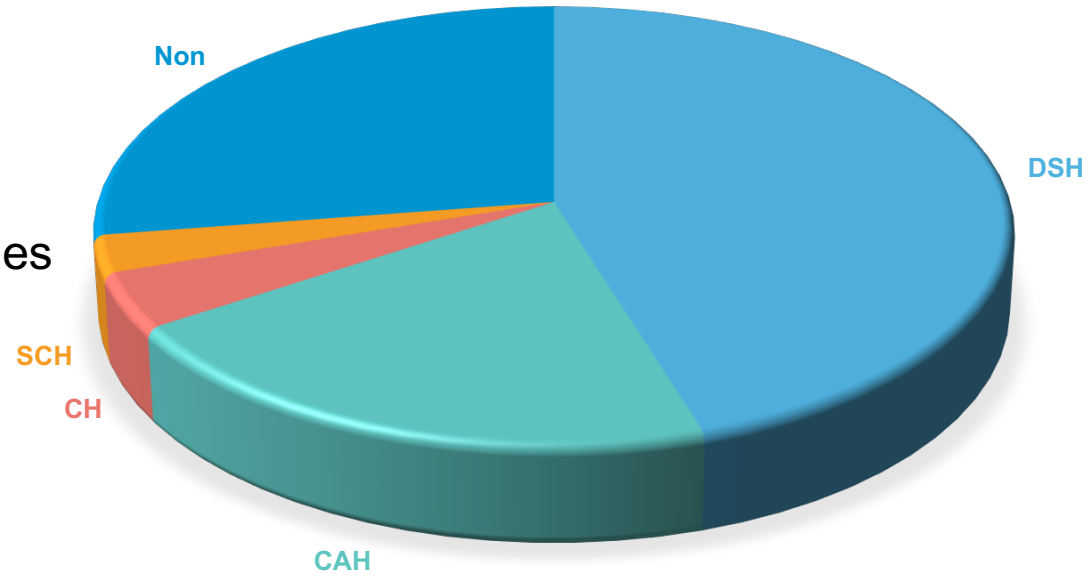
- Owned or operated by a State or local government; OR
- A public or private nonprofit corporation that is formally granted government powers by a State or local government; OR
- A private nonprofit corporation that has a contract with a state or local government to provide health services to low income individuals who are not Medicare or Medicaid beneficiaries
    - The hospital should include a provision specifying the amount of care it will commit to provide to indigent, uninsured and underinsured patients, excluding low income individuals who do not qualify for Medicaid or Medicare
        - Upon registration the OPA will send an email to the government official designated in the contract to certify the existence of the contract
        - The government official must respond within 5 days or the hospital's registration will be canceled
    - OPA requires a certificate of a valid contract signed by the authorizing official and state/local official (42 U.S.C. 256b). AO certifies he/she will notify OPA immediately should the contract become invalid.

340B HRSA audits

- Lack of oversight and regulation of the program has led to increased Congressional scrutiny
- HRSA started auditing Covered Entities in 2012. As of June 2017 HRSA completed total audits of 805 Covered Entities which includes 11,000 offsite outpatient facilities and 18,000 contract pharmacies
- HRSA Covered Entity audits may be random or target.
  - Random audits are selected using a risk stratification methodology, so that entities with higher risk factors are more likely to be selected for audit
  - Risk factors include: number of child sites, volume of purchases, number of contract pharmacies
  - Targeted audits may be triggered by reported violations or allegations

HRSA audits – 2017*

- 73 Covered Entities audited
- 33 Disproportionate Share Hospitals
- 15 Critical Access Hospitals
- 3 Children's Hospitals
- 2 Sole Community Hospitals
- 20 Non-hospital Covered Entities



***Published as of 9/5/17**

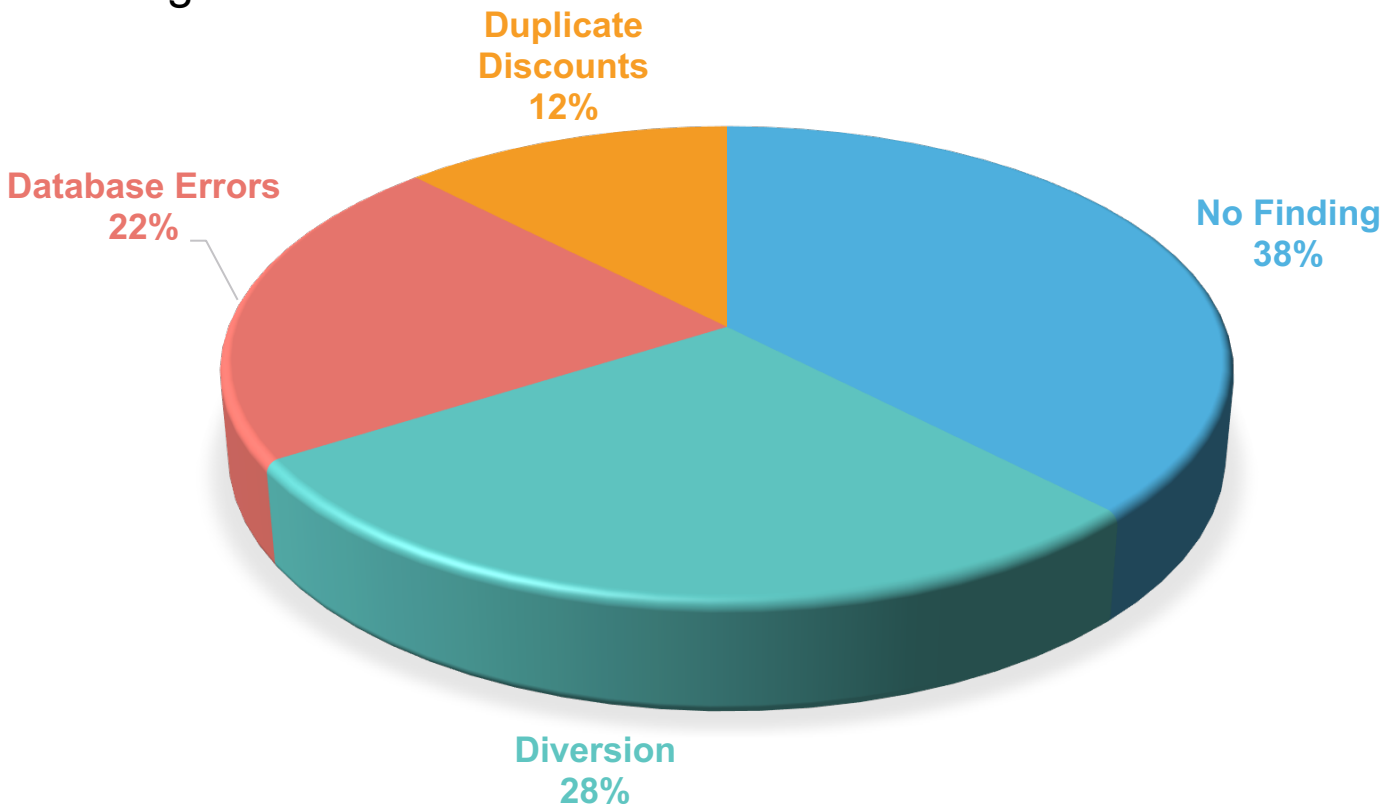
340B HRSA audits

HRSA audit focus includes:

340B Registration – accuracy of information on the OPA 340B database and compliance with recertification requirements
Duplicate Discounts - manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered Entities must accurately report how they bill Medicaid drugs on the Medicaid Exclusion File
Drug Diversion - Covered Entities must not resell or otherwise transfer 340B drugs to ineligible patients
GPO Prohibition - disproportionate share hospitals are prohibited from using GPO acquired drugs for 340B eligible outpatients
Orphan Drug Exclusion - manufacturers are not required to provide orphan drugs at a 340B price to rural referral centers, sole community hospitals, critical access hospitals and free-standing cancer centers

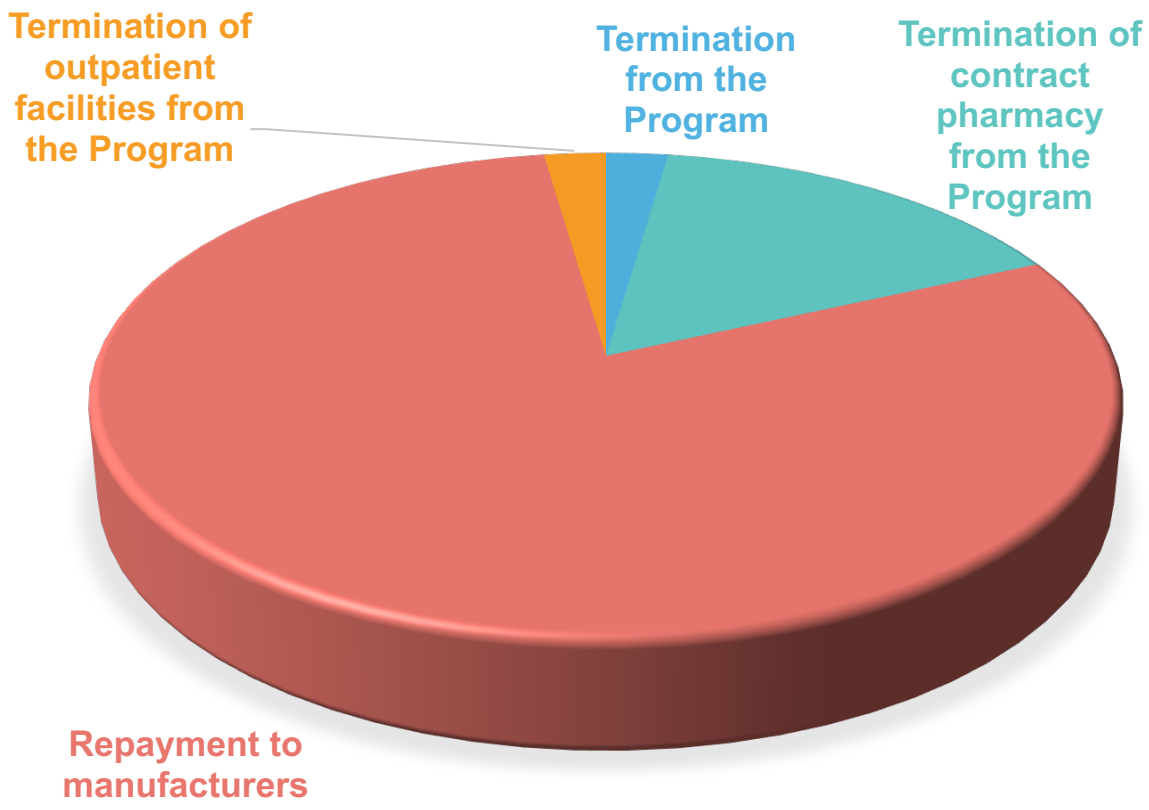
2017 340B audit findings*

66 Findings



* **Published as of 9/5/17**

HRSA audit sanctions



https://340bopais.hrsa.gov/home

OPAIS – Office of Pharmacy Affairs Information System

- Authorizing Officials (AOs) and Primary Contacts (PCs) must create individual user accounts with OPAIS. The functions a user can perform are determined by the user's role. Until a user logs in, the user may only access the public search, reports/files, and login functions
- After establishing an account, the user will be able to register new entities and contract pharmacies during the registration period, make changes to the Covered Entity's (CE's) records, and terminate sites at any time

Information available includes:

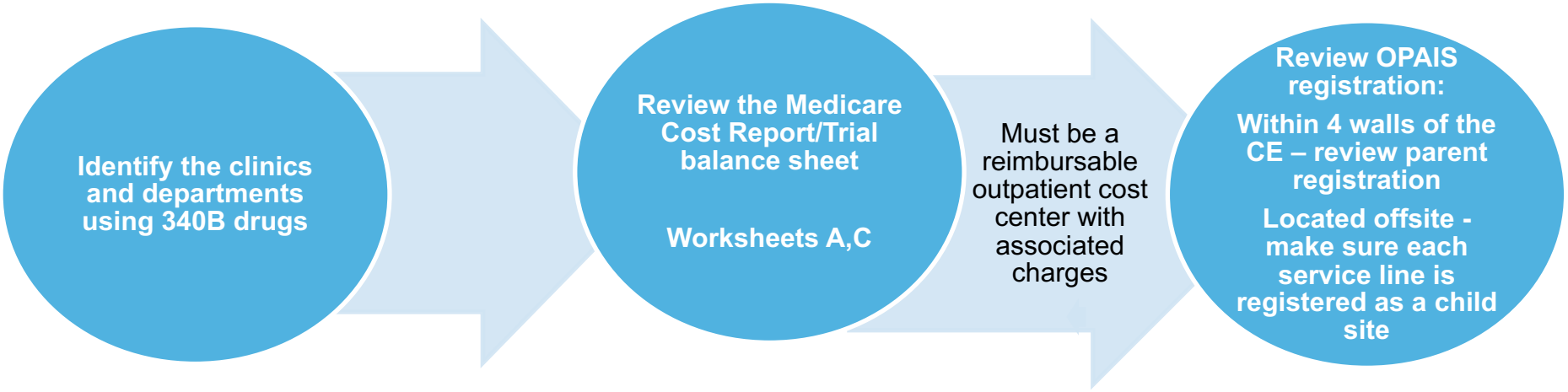
- CE name and type
- 340B identification number
- Authorizing official name and contact information
- Primary contact name and contact information
- Medicare provider number
- Program status
- Registration/recertification date
- Medicaid billing status
- Child sites
- Contract Pharmacy listings

Ensure accuracy of all registration data

All information in the OPAIS system MUST be up to date and accurate

- Validate CE name and address – both physical and ship to addresses
- CE type
- Authorizing official name and contact information
- Primary contact name and contact information
  - AO and PC cannot be the same individual
- Medicare provider number
- Program status
- Registration/recertification date
- Medicaid billing status
- Validate eligibility and status of child sites
- Contract pharmacy details

Validate child site registration



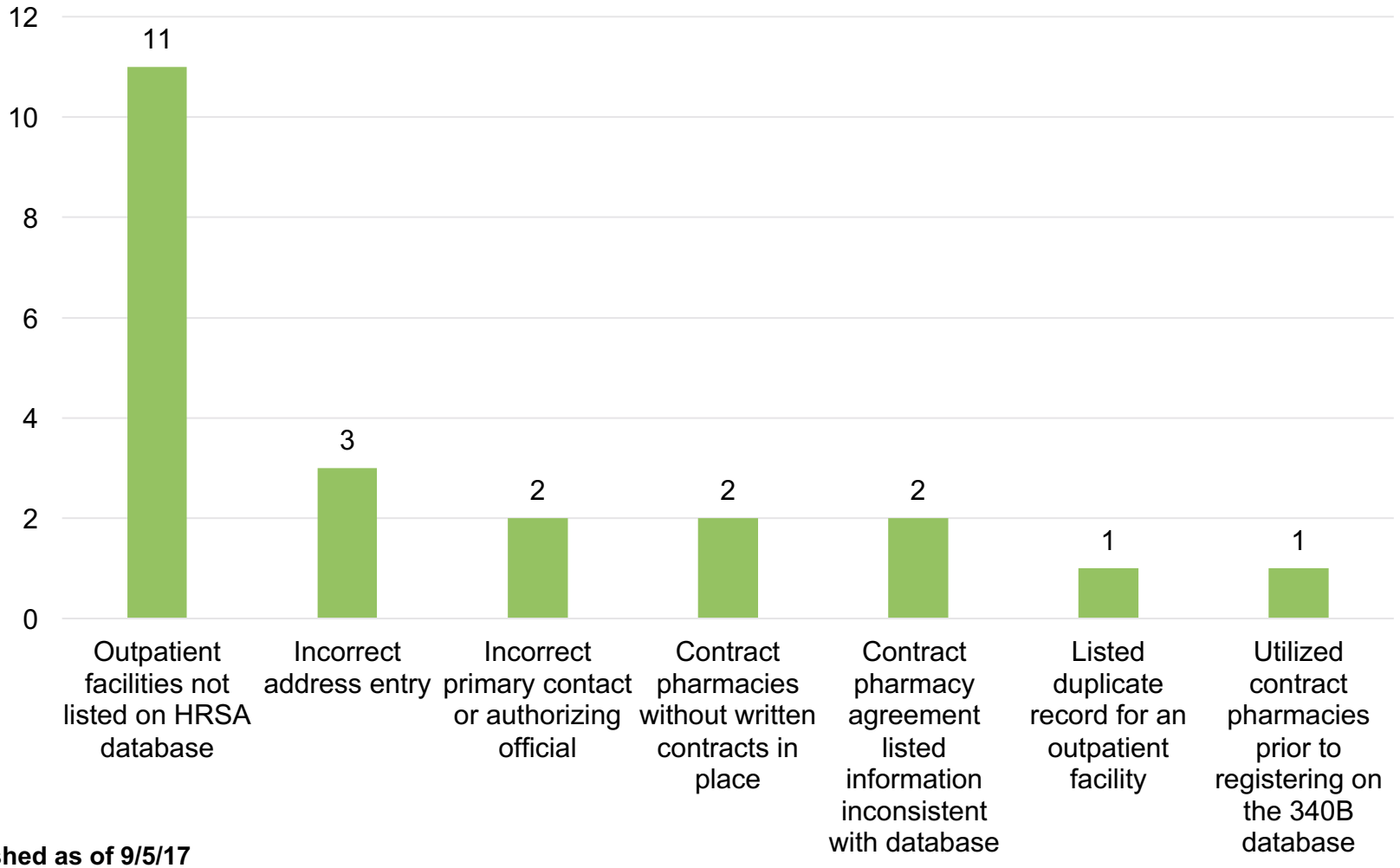
- Ensure eligibility of each child site listed in OPAIS
  - Child site is a reimbursable cost center associated with charges
  - Listed above line 190 on Medicare cost report worksheets A,C
  - Comprised of a single service line

- Review accuracy of listed physical and billing addresses
- Terminate any child sites listed but not current

Validate contract pharmacy registration

- Validate date of registration and “go-live” of each contract pharmacy
- Validate locations and addresses
- Ensure a valid written contract with pharmacy exists prior to registration
    - Full listing of all pharmacy locations that are to be utilized under that agreement
    - A ‘‘ship to, bill to’’ procedure is used in which the Covered Entity purchases the drug – the drug is directly shipped to the contract pharmacy but is billed by the wholesaler to the Covered Entity
    - Include patient freedom to choose a pharmacy provider
- Validate all listed contract pharmacies are utilized, terminate any non-active contract pharmacy relationships and notify HRSA of terminated relationships

2017 audit findings – registration/data base errors*



***Published as of 9/5/17**

Prohibition against duplicate discounts

- Manufacturers are not required to provide both a discounted 340B price and a Medicaid rebate on the same drug*
- Once enrolled in the 340B Program, the Covered Entity must elect to either use 340B drugs for their Medicaid patients (carve-in) or purchase Medicaid drugs through other channels (carve-out)
- The State Medicaid program will seek rebates for drugs dispensed by Covered Entities that choose to carve-out
- Covered Entities must notify the OPA of their decision to carve-in or carve-out. Covered Entities which chose to carve-in will be listed on the Medicaid Exclusion File (MEF)
- The Covered Entity may make a different election for each Medicaid billing number
- Contract pharmacies may not use 340B drugs for Medicaid patients unless an arrangement is made between the contract pharmacy, Covered Entity, and State Medicaid agency to prevent duplicate discounts. HRSA should be notified of this arrangement
- Covered Entities subject to the group purchasing organization (GPO) prohibition cannot use a GPO drugs for Medicaid carve-out prescriptions

*** 42 USC 256(a)(5)(A)(i)**

Prohibition against duplicate discounts

Medicaid Billing

- Medicaid requirements vary state by state with regard to election of carve-in/carve-out status. The status may apply to both Medicaid FFS and MCO

- The MEF is intended by HRSA to be used by states to identify 340B drug claims and avoid duplicate discounts specific to traditional FFS Medicaid

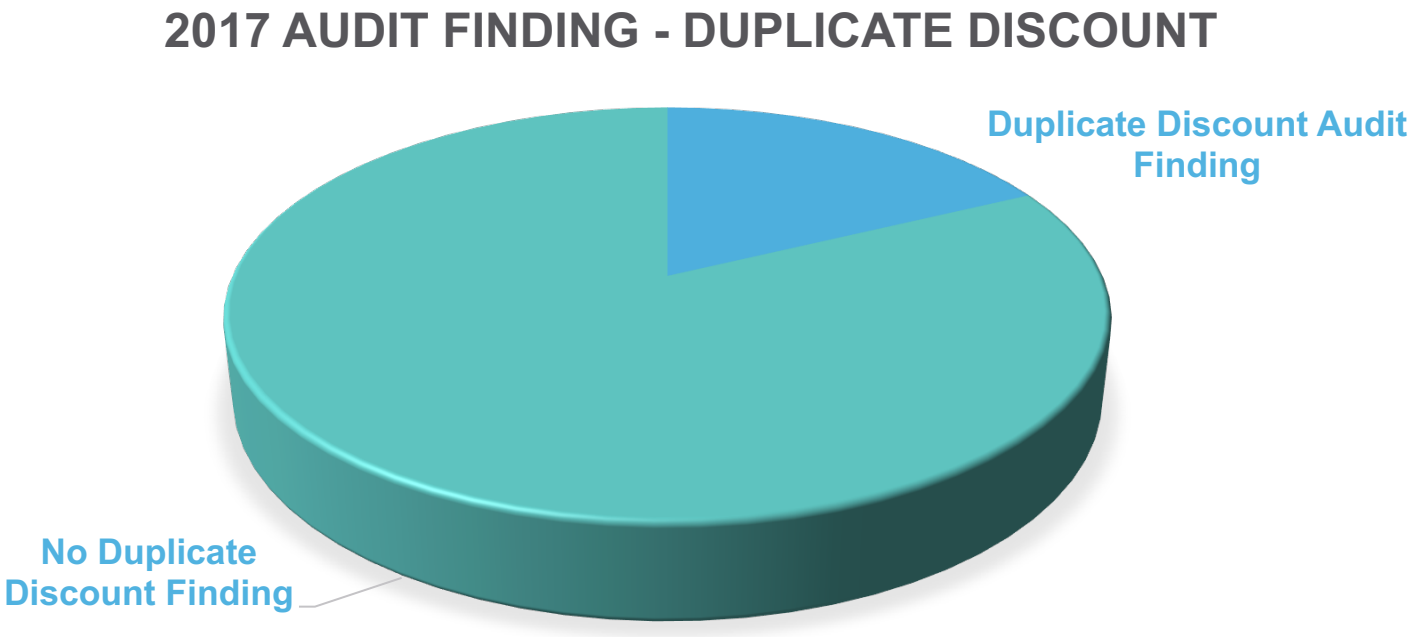
- Based on a CMS ruling in April 2016, MCOs must identify and exclude 340B claims data from the utilization reports they submit to states to collect Medicaid rebates. As an alternative the Covered Entity must submit 340B claims data directly to the state prior to the state submitting invoices for Medicaid rebates to manufacturers.

- As of April 1, 2017, CMS ruled that states must establish retail 340B FFS Medicaid reimbursement policies in which payment for 340B Medicaid FFS drugs will be based upon actual acquisition cost along with a dispensing fee

- Many states require a billing modifier or unique Bank Identification Number (BIN)/Processor Control Number (PCN)/Group number to identify 340B drugs when billing Medicaid (carve-in)

Prohibition against duplicate discounts

18% of Covered Entities audited in 2017* had incomplete or inaccurate data in the Medicaid exclusion file



- **The Covered Entity bears the responsibility to ensure the information contained in the MEF is accurate**
- **Covered Entities must have mechanisms in place to prevent duplicate discounts**

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Prohibition against duplicate discounts

- Review your carve-in carve-out status
  - Carve-in: your CE should be registered on the MEF. Ensure all appropriate Medicare/NPI numbers are listed
  - Carve-out: no listing in the MEF

- Contact the Medicaid agencies for the states in which your CE submits claims. Verify requirements for carve-in or carve-out status. Do the same requirements apply to Medicaid MCO? Obtain associated BIN/PCN/Group numbers

- Work with your reimbursement specialist to identify all the Medicaid FFS and MCO plans for which the hospital submits claims. Ensure the payer feeds into the split billing software are accurate

- If carving out, review split billing audit extract/qualified utilization report with payer fields. Review all payers to ensure no Medicaid FFS is listed. Repeat for Medicaid MCO if carve-out status is required by the state

- Review Medicaid managed care contracts to ensure that your 340B billing practices comply with the contracts

- Outline the methods employed to prevent duplicate discounts in your policy and procedures

Diversion

- Covered Entities cannot resell or otherwise transfer 340B drugs to ineligible patients. Diversion occurs when a CE uses 340B drugs in patients that fail to meet eligible patient criteria or in patients of an excluded service of the CE. 340B drugs must be used only in connection with outpatient services.

- Definition of an eligible patient in the hospital setting:

    - Must establish a relationship with the CE such that the CE maintains records of the individual's care AND

    - Must receive care from a professional employed by the Covered Entity or under contract or other arrangement with the Covered Entity such that responsibility for the care remains with the Covered Entity

Diversion

Based on audit results, “responsibility for care” requirement met if:

- The outpatient prescription is written within the four walls of the hospital or at a 340B registered offsite location as a result of the care provided in that location
- The outpatient prescription is written outside the hospital, but care is provided at the hospital and drugs are administered in conjunction with that care and the CE maintains responsibility for the patient’s care (infusion center)
- The “patient care” must occur in a provider based location – must be a reimbursable cost center on the most recently filed Medicare cost report

Diversion

Who is an eligible patient?

- Dispensing of a drug for subsequent self-administration or administration in the home setting is insufficient to qualify an individual as an eligible patient
- Must be a patient of the CE – not merely a beneficiary of the hospital PBM. An employer or insurer relationship by itself will not qualify 340B patient eligibility
- Must be an outpatient – what about observation patients?
- HRSA proposed to outline new patient definition guidelines in the 2105 proposed 340B Drug Pricing Program Omnibus Guidance or “Mega-Guidance”. The Mega-Guidance was withdrawn from White House Office of Management and Budget review on January 30, 2017.

Who is an eligible provider?

- Per Apexus FAQ 1442: “A provider that has admitting privileges with the Covered Entity may provide health care services to a patient of the Covered Entity as long as all other patient definition criteria are met”
- Admitting privileges of a provider alone are insufficient for qualifying eligibility of a patient (of that provider) to receive 340b drugs
- Definition of an eligible provider should be outlined in the CE’s 340B policy and procedures

Maintain an updated eligible provider list in your split billing software!!

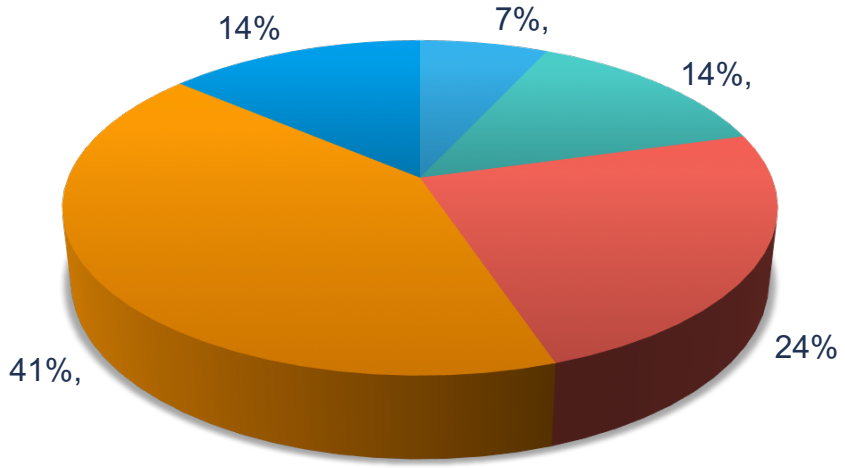
Improper Accumulations

- The Covered Entity accumulates 340B drugs differently than what was dispensed to the eligible patient as a result of a CDM linked to multiple NDCs
- Accumulations are based on improper billing units per drug package
  - Review the split billing utilization report for errors in the billing unit multiplier (number of billing units per package)
  - The billing units and drug dose are in the same unit of measure (i.e., ml, mg, etc.)

As the NDC denotes a box of 10, the billing unit multiplier is 10

NDC	Description-Brand	Description Generic	Strength	Form	Size	Hosp Usage	Hosp Billing Units (size)	Billing Units/ea PKG
55513054610	NEUPOGEN	FILGRASTIM	480MCG/1.6ML	SDV	10X1.6ML	115	1.6ml	16
67457022005	ISOSULFAN BLUE	ISOSULFAN BLUE	5ml/vial	SDPF	6X5ML	110	5ml	30
00023114501	BOTOX THERAPEUTIC DSHP	ONABOTULINUMTOXINA	100U	PWVL	1 EA	5	1	1

2017 Audit Finding – Diversion*

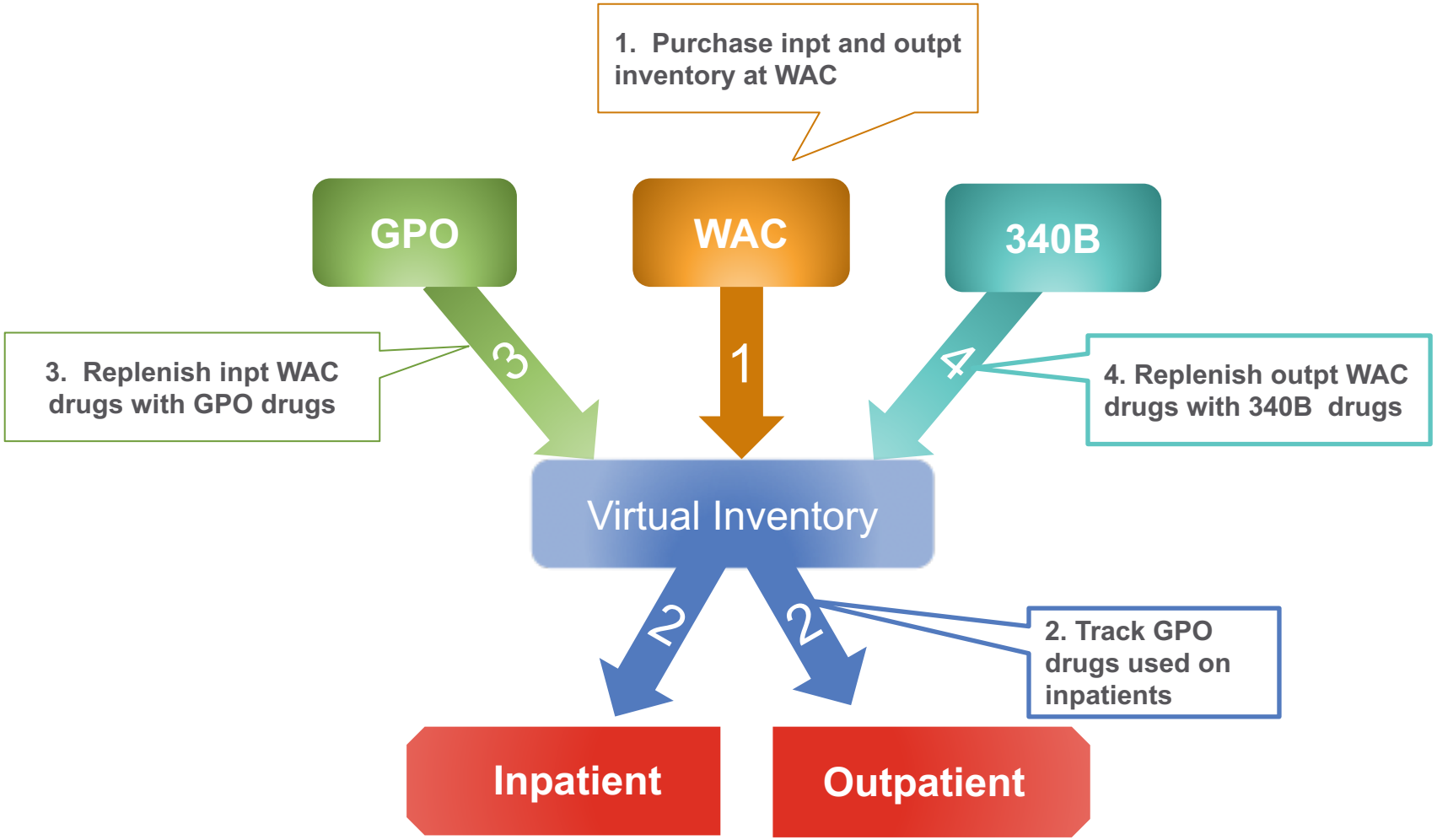


* Published as of 9/5/17

GPO prohibition

- Applies to DSH, Children's and free-standing Cancer Hospitals.
- Per 42 U.S.C. 256b(a)(4)(L)(iii), these Covered Entity types may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement."
- The GPO prohibition applies to off-site outpatient facilities registered on the OPA 340B Database
- Based upon the HRSA issued Program notice 2013-1, off-site outpatient facilities may use a GPO for covered outpatient drugs if the following criteria are met:
  - The facility is located at a different physical address than the parent;
  - The facility is not registered on the OPA 340B database as participating in the 340B Program;
  - The facility purchases drugs through a separate pharmacy wholesaler account than the 340B participating parent;
  - The parent Covered Entity maintains records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on the OPA 340B database.

GPO prohibition



GPO prohibition

340B	Covered Outpatient Drug Eligible Patient, Location, and Provider
GPO	Inpatient or Offsite Location Bundled Drug?
WAC	Ineligible Patient Lost Charges Wasted Drug

- **The GPO prohibition is a requirement for eligibility!**
- **Violation = immediate termination from the 340B program**
- **The Covered Entity "parent" must ensure compliance with all outpatient clinics, contract pharmacies, and sites that participate in the 340B Program.**

Orphan drug exclusion

- In 2010, the 340B program was expanded to include sole community hospitals. Rural referral centers, critical access hospitals and free standing cancer hospitals.

- The Obama administration amended Section 340B of the Public Health Service Act (42 U.S.C. 256b) to exclude orphan drugs from the definition of ‘covered outpatient drug’.

- Orphan drug:
  - A drug that is intended to treat a disease or condition with fewer than 200,000 patients in the U.S. or
  - A drug used to treat a disease or condition with more than 200,000 patients in the U.S., but one in which the manufacturer does not expect the drug revenues to cover research-related expenses

- Manufacturers are not required to provide orphan drugs at a 340B price to the hospital types listed above. The manufacturer may voluntarily offer such discounts on a case by case basis.

Orphan drug exclusion

- HRSA publishes a list of orphan drugs based on the orphan drug designations provided by the U.S. FDA, Office of Orphan Products Development. This list is updated quarterly and may be accessed at
  https://www.hrsa.gov/opa/program-requirements/orphan-drug-exclusion/index.html

- In 2013, HRSA ruled that the Orphan Drug Exclusion applied only when the drug was used to treat the specific indication for which it received the orphan drug designation

- A U.S. District Court held that HRSA's ruling was invalid. Subsequently, orphan drugs must be excluded from the 340B program in their entirety, regardless of the usage.

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Download the HRSA orphan drug list on a quarterly basis
Routinely compare the list to contract pharmacy prescriptions and in-house /in-clinic drug use

Industry references

HRSA

https://www.hrsa.gov/

Apexus

https://www.apexus.com/home/

888.340.2787

340B Health

https://www.340bhealth.org/

202-552-5850

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Question & Answer Session

