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340B Financial Compliance

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September 11, 2019

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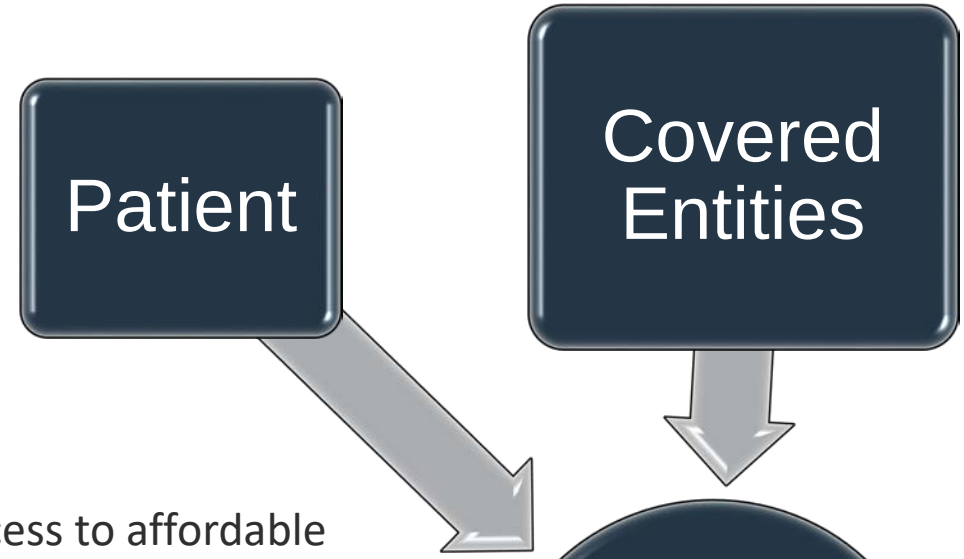
Overview of the 340B Program

The Benefits of 340B



-Drug cost savings

-Mission fulfillment

-Outcome optimization

-Care for all community members

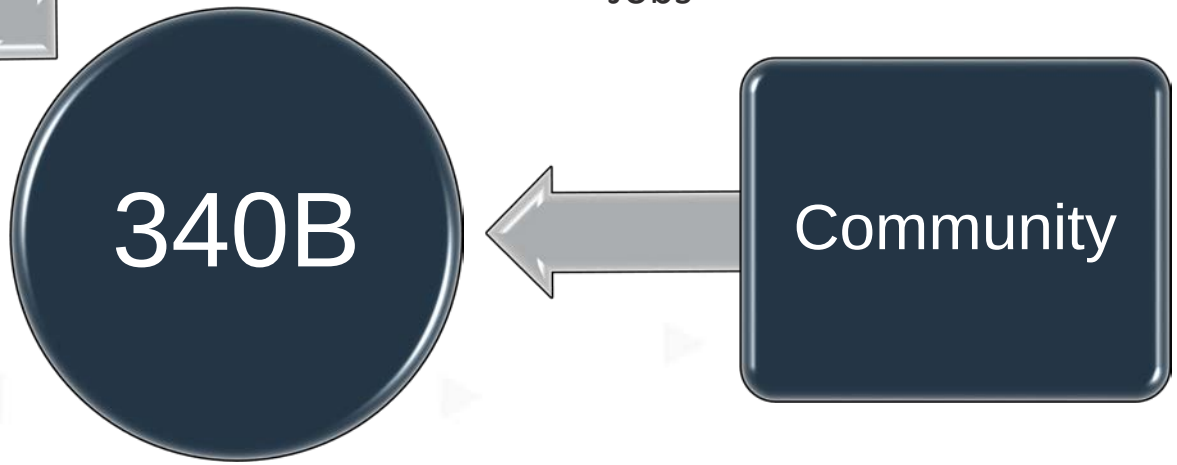
-Local access to medical services

-Jobs

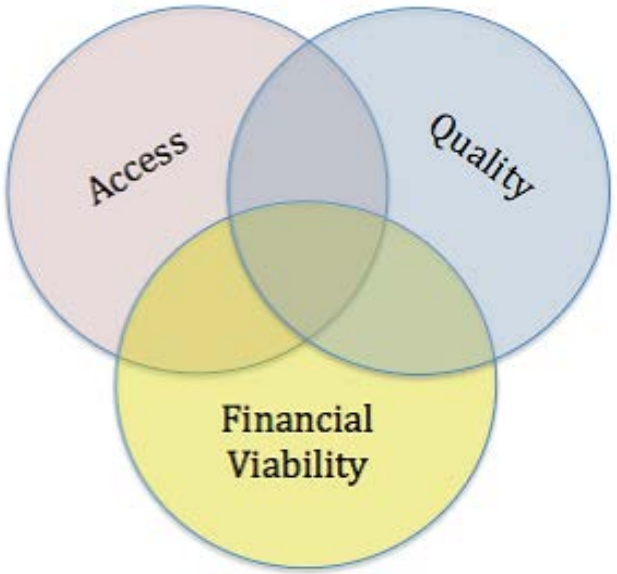
-Access to affordable medications

-Better quality of life

-Improved clinical outcomes through access to services



The Strategic Imperative for 340B



Access

Quality

Financial Viability

Technological Excellence

Efficiency and Effectiveness

Effective Workforce

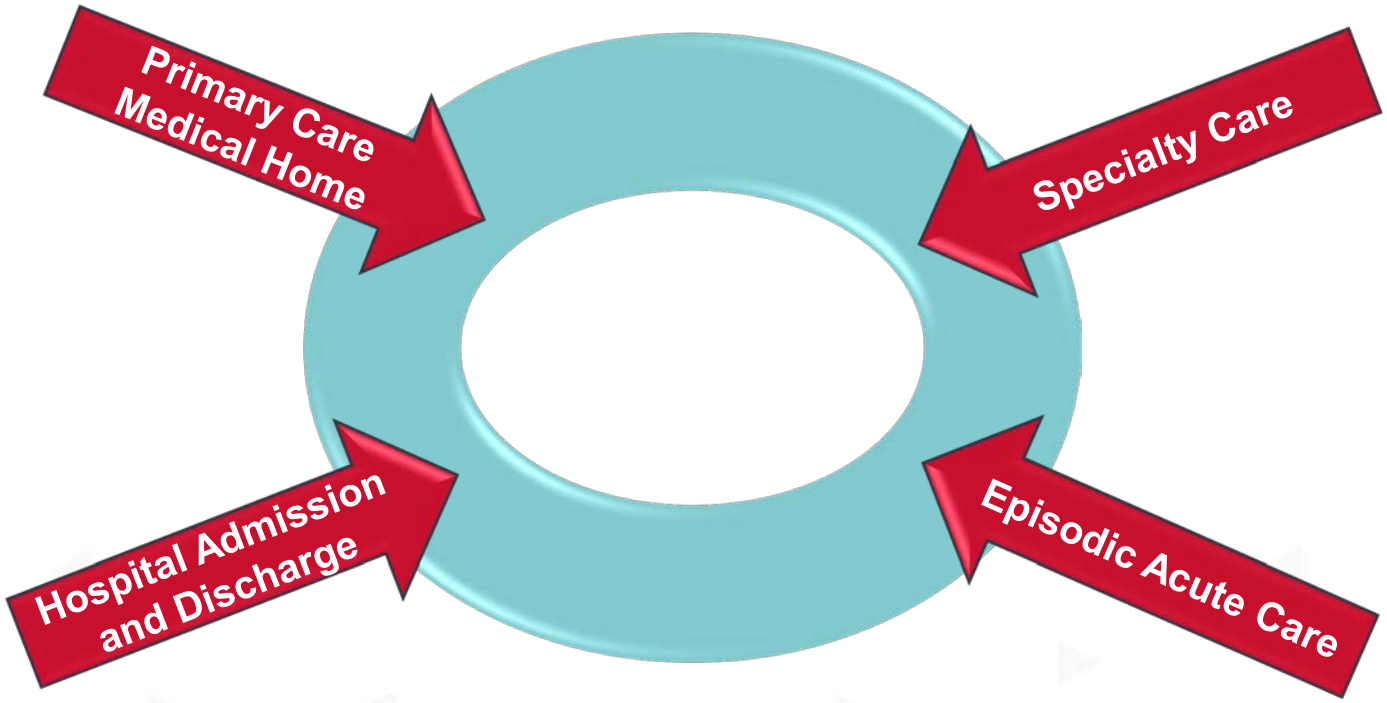
Business Development

Compliance

Advocacy and Social Responsibility

Governance and Leadership

Increased Flexibility to promote access across the continuum of care



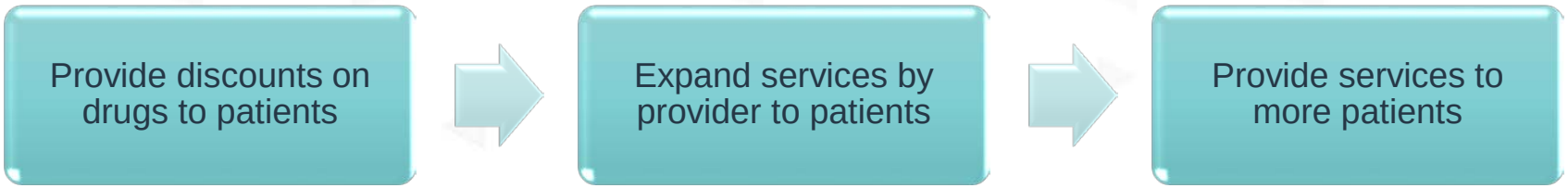
340B Program – Covered Entities

- Health Centers
  - Federally qualified health centers
  - Federally qualified health center look-alikes
  - Ryan White HIV/AIDS Program grantees
  - Comprehensive Hemophilia Diagnostic Treatment Centers
  - Title X Family Planning clinics
  - Sexually transmitted disease clinics

- Disproportionate Share/Critical Access Hospital, Sole Community Hospital, Rural Referral Center, Children's Hospital, Free Standing Cancer Hospital

340B Drug Pricing Program Overview

- Federally mandated drug pricing program created in 1992
- 2017 marked the 25th anniversary of the program
- Part of Public Health Service Act, section 340B & Medicaid rebate program
  - Drug manufacturers must provide front-end discounts on covered outpatient drugs purchased by covered entities
- Provides discounts on outpatient drugs purchased by “safety net” providers for eligible patients
  - Intended to provide financial relief to facilities that provide care to medically underserved
- Average savings of 25 - 50% for eligible covered entities on outpatient drugs
- How are covered entities using 340B savings?



Federal Resources

Resource	Description
HRSA OPA	HRSA Office of Pharmacy Affairs homepage http://www.hrsa.gov/opa/index.html
About 340B Program Audits of Covered Entity	HRSA Program Integrity Page http://www.hrsa.gov/opa/programintegrity/auditscopeandprocess.html
Policy Releases	HRSA Policy releases regarding the 340B Drug Pricing Program http://www.hrsa.gov/opa/programrequirements/policyreleases/index.html
OPA FAQs	HRSA Office of Pharmacy Affairs Frequently Asked Questions (FAQs) http://www.hrsa.gov/opa/faqs/index.html
HRSA 340B Peer-to-Peer Webinars	Register for upcoming 340B Peer-to-Peer Webinars and listen to past webinars http://www.hrsa.gov/opa/peertopeer/webinars.html
340B Prime Vendor Program	Call Center Phone: 1-888-340-2787 ApexusAnswers@340bpvp.com Web: www.340bpvp.com Prime Vendor Program FAQ's https://www.340bpvp.com/resource-center/faqs/
Apexus 340B Medicaid Profiles per State and/or Territory	https://www.340bpvp.com/resource-center/medicaid

Overview of the 330 Program and Program Overlaps

History of the Health Center Program

- Founded in 1965
- Drs. Jack Geiger and Count Gibson
- Dorchester, MA & Mound Bayou, MS
- Fast forward to today
  - ~1,400 health center program participants
  - ~12,000 delivery sites
  - Nearly $6B in grant funding

Benefits of the Health Center Program

- Game-changer for the at-risk/underserved
- Financial benefits as well
  - Enhanced Medicaid reimbursement for encounters
  - Grant funding to subsidize operations
  - Participation in the 340B program
  - Access to FTCA Coverage

Scope of the Health Center Program

- Circle within a circle concept
- Some programs are outside the big circle
  - WIC, child care, other unrelated ventures
- All the small circles get access to HCP benefits
- …
- …
- …and access to the corresponding regulations

Challenges of the Health Center Program

- Regulations, regulations, regulations
- Administrative burden
- Access to care and removing barriers
  - Good thing AND
  - Potential for payer mix to deteriorate
  - Potentially financially constraining
  - NPSR is a great growth engine – unless it isn't

Challenges – Sliding Fee Discounts In-House Pharmacy

- Services within the big circle subject to SFDS
- What does this look like in your shop?
  - Understood? Easy or difficult to apply?
- Goods v. services
  - What do you slide?
- How is it structured?
- Are the drugs accessible and affordable?
  - Barriers to care alleviated?
- Document, document, document

Challenges – Sliding Fee Discounts Contract Pharmacy

- Does the type of pharmacy matter?
- What is our underlying, guiding principle?
  - Increase access and care to the at-risk and underserved patient populations
- Access to 340B drugs and the sliding fee discount
  - In-house AND contract v. contract only
  - Physical distance
- This is a subjective analysis – document your consideration!
- Follow all the cash flow – is there risk there?

Challenges – Sliding Fee Discounts Case Study

- Your clinic has ten locations, three of which have in-house pharmacies.
- The other seven are between five and fifty miles from the nearest in-house pharmacy.
- The in-house pharmacy provides sliding fee discounts on all pharmacy services; consistent with Compliance Manual requirements
- Questions to consider
  - How do you price the 340B drugs for your sliding fee eligible patients?
  - For those receiving services at a location without an in-house pharmacy, is there a barrier to access?
  - If so, where does that barrier start to appear (i.e. how far is too far)?
  - If so, how do you overcome this?

Overlaps between 330 and 340B

- Sliding Fee
  - Dispensing Fee
    - In House
    - Contract
  - Drug Cost
- Charges for Pharmacy - PPS or APM
  - Visit Charge
  - RX Charge – Ancillary
    - Fill Fee
    - Drug Fee
    - In-Kind/Samples
- Pharmacy support staff
- Policy and procedure
  - One Stop Shop Mindset

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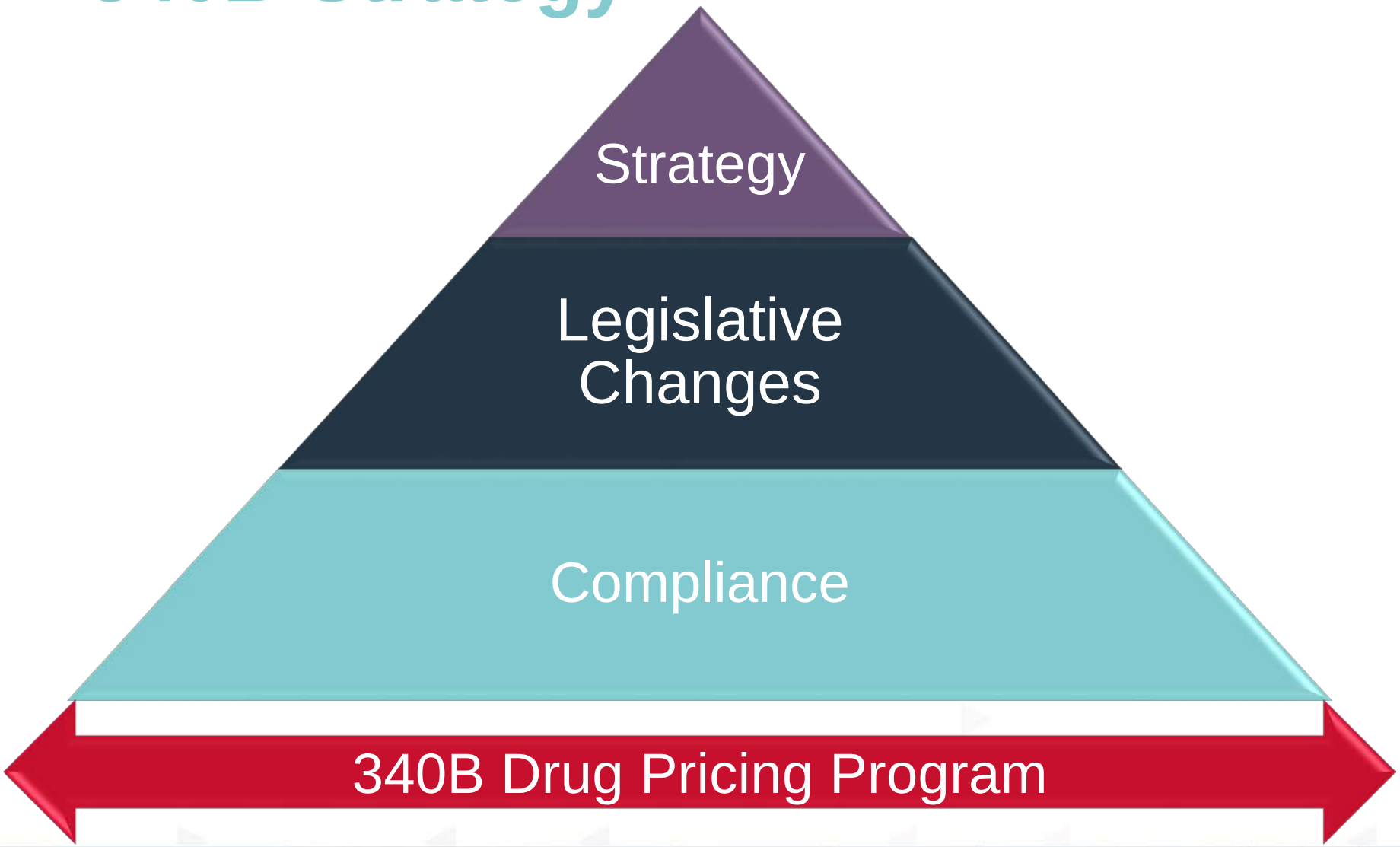
Key 340B Strategy

340B Strategy



340B Strategy- Approach

- Approach and goals
- Internal testing
- Internal audit
- Frequency and sample
- 340B team
- Independent external reviews
  - Operational
  - Compliance

Key Strategic Initiatives

- Access and Capture
  - Contract
  - In-house
- Contracting
- Savings generation
- Compliance
- Education

What Are We Doing with the Money?

- Increasing access to more services
- Strengthening financial health
  - Operating Reserves
- Enhancing facilities
- Reducing turnover
- Giving out huge bonuses?

Savings Calculation

Calculating 340B Net Financial Impact and Use of Savings

Apexus | 340B Prime Vendor PROGRAM

TABLE 1: 340B NET FINANCIAL IMPACT					
340B Benefits *Add the following three metrics together for total 340B benefit.* **TOTAL: $**		MINUS **–**	**340B Compliance Maintenance Costs** **TOTAL: $**	EQUALS **=**	**340B Net Financial Impact** **$**
Physician-administered/clinics	$	–		=	
Entity-owned retail pharmacy	$				
Contract pharmacy	$				

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Savings Calculation

Calculating 340B Net Financial Impact and Use of Savings

Apexus 340B Prime Vendor PROGRAM

TABLE 2: USE OF 340B SAVINGS		
Program or Service Provided	**Total Expense**	**Description** (how this aligns with 340B Program intent)

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340B Program Challenges – External influences

- Congressional intent of the Program
  - Debated by some members of Congress
  - Several hospitals have been challenged to respond on use of funds generated from Program savings
  - Monitoring this issue in Congress is important
- Will Medicare want a part of savings?
- Several groups are lobbying to limit providers eligible for the Program
  - Drug manufacturers

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340B Program Challenges – Internal Responses

- Strategy: 340B Compliance Plan for Outpatient, Mixed-Use & Contract Pharmacy programs
  - Demonstrates good-faith commitment to compliance
  - Increases likelihood of identifying & correcting mistakes
  - Includes multiple aspects of the Program & process for responding to concerns identified
- Strategy: Reconsideration of provider-based physicians
  - Eligible to extend 340B savings to provider-based physicians
- Strategy: Publicize benefits as a result of your 340B Program

340B Compliance

Education and Communication

1. The C suite
   - CEO Voice must Set Tone for the Importance of the Program for the Organization, Governance and Community
   - CFO Voice must communicate the financial story of the Savings
   - CRO Voice must highlight the importance of Compliance and Monitoring of Compliance for 340B and impact on other programs
   - CMO Voice must educate Clinical Staff to the importance of program stressing Access and Better quality of patient care
2. Governance
   - Board must be educated on the program
   - Key involvement in the community

Education and Communication

3. Medical Staff
   - Must Understand that program helps patients
   - Must understand enhanced access to discounted drugs
4. The Pharmacies
   - Community relationships
   - PBM pressure
5. The Patients
   - Understand that they are getting better drugs at a discount
6. Billing Department
   - Understand proper billing process to maximize savings

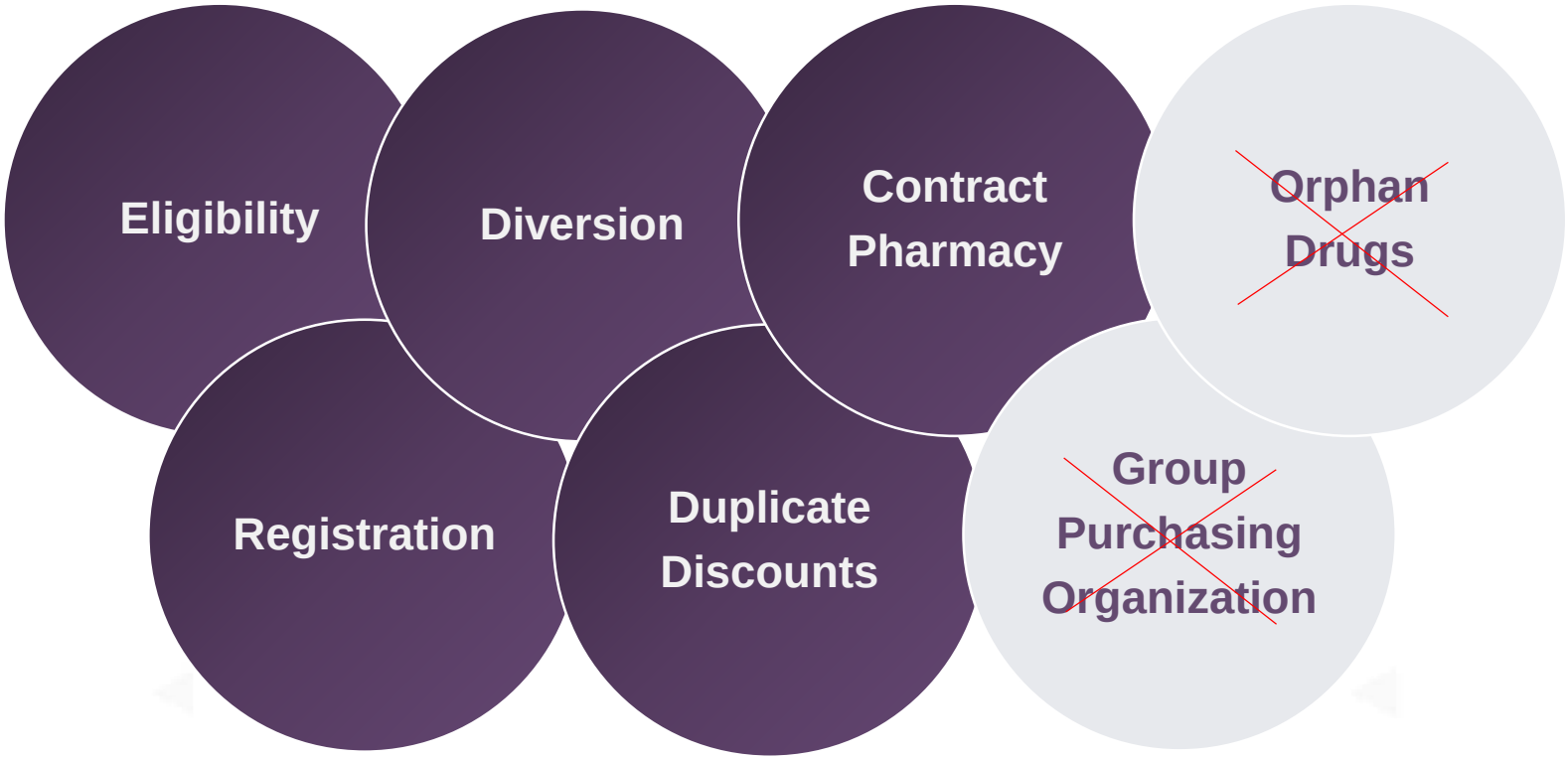
Seven Elements of an Effective Compliance Program

- Developing written Policies & Procedures
- Designating a Compliance Officer & Committee
- Conducting Effective Training
- Developing Effective Lines of Communication
- Enforcing Standards through well publicized Disciplinary Guidelines
- Performing audits & monitoring risk areas
- Responding to detected offenses & developing Corrective Action Initiatives

Sources:

- OIG Hospital Compliance Guide – February 13, 1998
- OIG Supplemental Compliance Guidance- January 31, 2005

340B Compliance



Eligibility

340B participation is limited to only certain non-profit and government affiliated hospitals.

- DSH Hospitals – traditional acute care hospitals that can demonstrate a DSH Adjustment Factor greater than 11.75% on the most recently filed Medicare Cost Report
- Children's Hospitals – pediatric hospitals with a 3300-series Medicare provider number that can perform a DSH calculation based on worksheet S-3 and demonstrate a result greater than 11.75%
- Sole Community Hospitals – hospitals with Sole Community designation that can demonstrate a DSH Adjustment Factor greater than 8.0% on the most recently filed Medicare Cost Report
- Rural Referral Centers – hospitals with Rural Referral Center designation that can demonstrate a DSH Adjustment Factor greater than 8.0% on the most recently filed Medicare Cost Report
- Critical Access Hospitals - All Critical Access Hospitals, regardless of DSH values

Compliance – Registration

- Registration
  - Covered entity must register with HRSA
  - Each eligible entity location that plans to use 340B drugs (clinic or offsite outpatient department) must be separately registered
  - Information should be collected by the authorizing official during the annual recertification process

Recertification

- 340B covered entities must annually recertify their 340B eligibility
- Notifications are sent to Primary Contact & Authorizing Official
- Once recertification period begins the Authorizing Official only has access via their user accounts to attest their covered entity's compliance with 340B requirements & complete recertification
- Contacts listed in the 340B database must be accurate at all times to receive all notifications

Contract Pharmacy

- HRSA allows providers to enter into arrangements with multiple contract pharmacies to dispense 340B drugs to qualifying patients of providers
- Covered entity is responsible for compliance and must monitor contract pharmacies
- HRSA recommends independent audits
- Child sites, outpatient clinics
- Retail pharmacy split-billing software
- Brand vs. generic
- Do you periodically review your contract pharmacy arrangements?
- What about Medicaid? – Later slide on duplicate discount risk

Compliance – Recertification Process

1. **All** information listed on the 340B Program database for the covered entity is complete, accurate & correct;
2. The covered entity meets **all** 340B Program eligibility requirements…
3. The covered entity is complying with **all** requirements & restrictions of Section 340B of the Public Health Service Act…

IS YOUR AUTHORIZING OFFICIAL READY TO ATTEST TO THESE 3 QUESTIONS?

Diversion

Diversion

- Drugs can only be used on an outpatient basis for covered entity's patients as defined by HRSA
- Use for other individuals constitutes prohibited diversion
- Focus on defining **"patient**" & **"covered entity"**

What is **"covered entity"**?

- Where services are provided
- Physicians must be employed or under a contractual or other arrangement
- Entity should maintain a listing of approved 340B physicians

Duplicate Discount for Medicaid & Medicaid Managed Care

- Covered entities are now able to make a determination for both Medicaid Fee for Service & Medicaid Managed Care Organizations when determining to carve in or carve out Medicaid
- Prevention of duplicate discounts remains requirement of covered entity
- Contract Pharmacy Carve In? Know your State!
- Covered entities should have mechanisms in place to identify Medicaid MCO patients
- Urges covered entities, state Medicaid programs and Medicaid MCOs to work together on a process to identify 340B claims
- Alternate mechanisms to supplement the 340B Medicaid Exclusion File
- Critical for covered entity to maintain dialogue with state Medicaid agencies to prevent duplicate discounts

State 340b - Medicaid

- How does State track HRSA Medicaid Exclusion File for both FFS and MCO claims
- Contract pharmacies are not permitted to bill Medicaid FFS or MCO for 340B drugs
- For covered entities that carve-in Medicaid, they should bill a drug's actual acquisition cost
- Dispensing fees, supply fees and admin fees should be billed using appropriate revenue codes
- Cost report
  - Key is whether it is carved into or out of your cost settlement or PPS rate

Compliance – Consequences of Not Complying

Repayment of discount to manufacturer

Removal from 340B Program

Possible Civil Monetary Penalties for knowing & intentional violations

Potentially false claim liability (ripe for *qui tam* actions?)

340B Compliance Summary

- Compliance risks are a reality to be monitored closely
- 340B Program & related multiple contract pharmacy relationships can be very beneficial but complicated to ensure compliance
- Regardless of 340B Program administrator selected, make sure covered entity is comfortable with definitions & policies applied to Program
- Critical to stay abreast of communications
- Mega-guidance to come

340B Audit

HRSA 340B Compliance Audits

HRSA Audits

HRSA believes that covered entities that do not regularly review & audit contract pharmacy operations are at increased risk for compliance issues

Annual audit of each location will provide covered entities

- Regular opportunity to review & reconcile 340B patient eligibility information
- Prevent diversion

Covered entity should compare 340B prescribing records with contract pharmacy's dispensing records at least on a quarterly basis to prevent

- Diversion
- Duplicate discounts

Conducting these audits using an independent auditor will test if the pharmacy is following all 340B program requirements & provide the covered entity with ability to timely report any violations, if applicable

A Closer Look at OIG Report and Contract Pharmacy Complications

Scenario 1: Nonexclusive physician

A physician practices part time at a covered entity, but also has a private practice. The physician first sees an individual at the covered entity. On a separate occasion, the physician sees the same individual at the private practice & writes a prescription for the individual. The individual fills the prescription at the covered entity's contract pharmacy.

Scenario 2: Time limit after patient’s visit

A physician sees an individual at a covered entity & writes a prescription for the individual. Four months after filling the original prescription, the individual refills the prescription at the covered entity's contract pharmacy. The individual is not seen at the covered entity during those 4 months.

Scenario 3: Prescription from a referred physician

A physician sees an individual at a covered entity & refers the individual to a specialist who is not affiliated with the covered entity. The specialist writes a prescription for the individual, & the individual fills the prescription at the covered entity's contract pharmacy.

Scenario 4: Matching prescription to clinical information

A physician sees an individual at a covered entity for chest pain & writes the individual a prescription for a blood pressure medication (related to the chest pain). During that visit, the physician also writes the individual a prescription for a sleep medication (related to a previously diagnosed condition).

- OIG interviewed 30 covered entities and eight administrators with 199 unique contract pharmacies relationships
- For each scenario there was not a clea consensus of the proper handling
  - How do you define your provider list?
  - Do you have a time restriction?
  - Do you match to clinical information?
  - How do you handle referrals?
  - Do you have visiting specialists?

2018 Audit Results

- HRSA has conducted approximately 200 audits annually since 2015
- 198 publically available for 2018
- Audits initially had a collaborative/educational tone but the tone has changed when HRSA began instituting punitive penalties to ensure compliance
- HRSA's budget will remain the same for FY 2019
  - 340B program has grown to 22 FTEs in 2018 from 4 FTEs in 2014
- HRSA will continue to focus on contract pharmacy arrangements, diversion, duplicate discounts & 340B database records

2018 Audit Results

- Diversion – 17 findings
- Duplicate Discounts – 15 findings
- Did not provide contract pharmacy oversight – 3 findings
- Incorrect OPAIS record – 18 findings
- No adverse findings – 36 covered entities

Manufacturer Audits

Manufacturer Audit Guidelines			
May only conduct after showing of "reasonable cause"	Manufacturer inquiries to covered entity may help support "reasonable cause"	Important for covered entities to respond to manufacturer inquiries, failure to respond could result in audit	Details are not publicly available

Falling Through the Cracks

- Clinic administered 340 drugs
  - Tracking it to avoid appearance of diversion
- Patient/self-administered 340B drugs
- Rarely stored in the pharmacy
- Tracking and auditable records?

Clinic/Self-Administered 340B Drugs

- Key components to maintaining compliance
  - Auditable
  - Complete
  - Accessible
  - Cost effective

- Reasonable tracking methods?

Split Billing Software

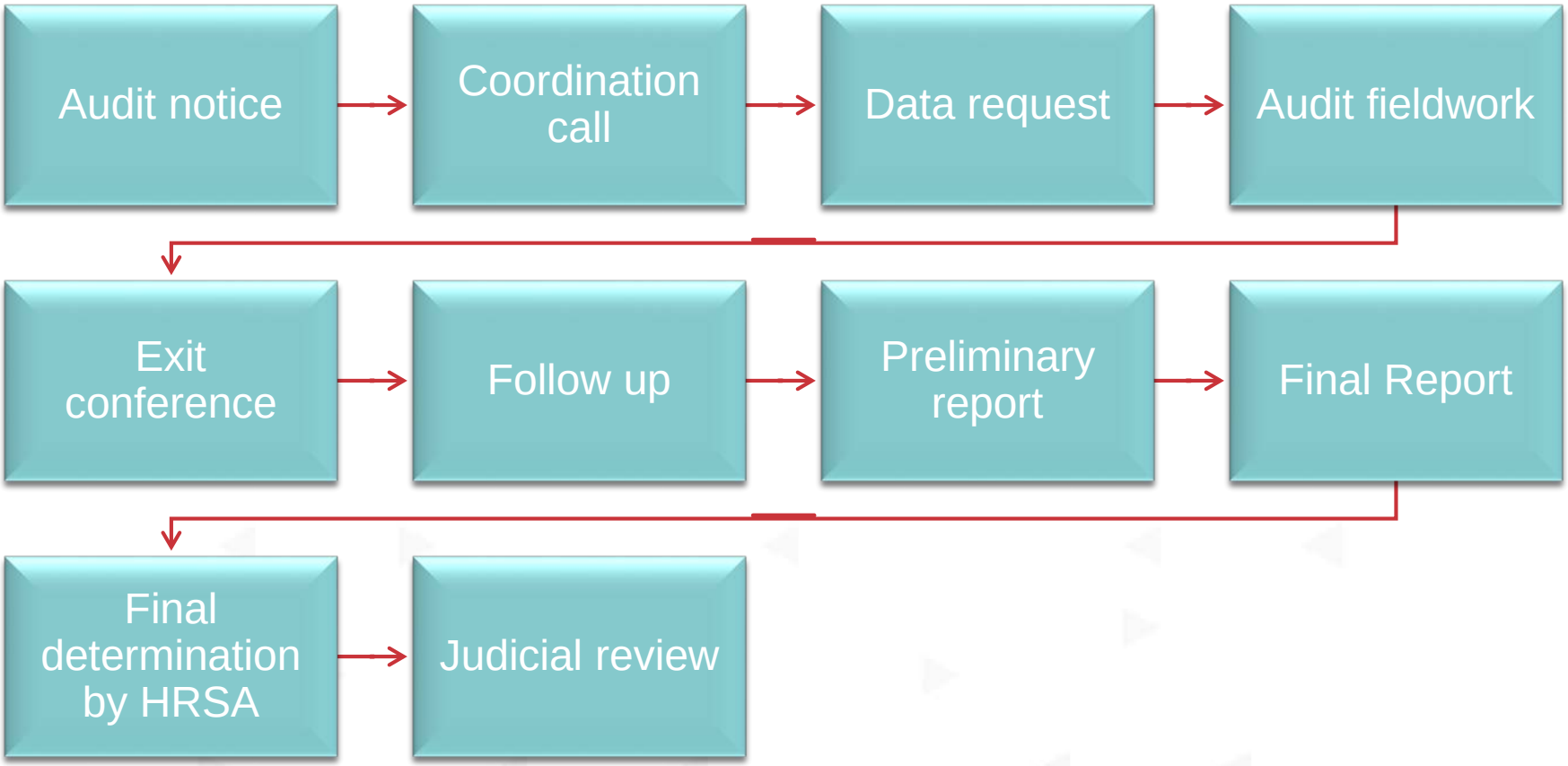
- Virtual Inventory
- Receive discounts based on the drug utilization by covered outpatients
- Retrospective procurement is used to realize the discounts based on utilization
- Example vendors:
  - CaptureRx, EAudit Solutions, MacroHelix, PSG, Rx Strategies, Sentry, SunRx, Verity Solutions, Wellpartner

340B Strategy - Split Billing Software

- Accumulator maintenance
  - Crosswalk
  - Utilization data sources and queries
  - Purchasing trends
  - Rules and filters
  - Reports
  - Multiple contract pharmacy split-billing vendors
  - EHR billing conversions

Audit Preparation and Findings

HRSA – Audit Process



Preparation for Audits

- Based on common findings from HRSA audits, being prepared is critical
- Recommended to perform internal review procedures throughout the year (there are sample audit guides available, including from APEXUS)
- Is an internal review enough? Covered entities should consider independent mock reviews performed by independent third party
- New compliance challenges, including “expectation of” annual independent audits, especially surrounding contract pharmacy relationships

Preparation for Audits – Example of Internal procedure

Interview personnel involved in 340B Program processes and procedures	• Finance, Pharmacy Director, Purchasing Coordinator & Administration
Gather all policies and procedures related to 340B	• Obtain data policies for any vendor software • Obtain copies of all 340B contracts with pharmacies &/or other 340B service providers

Preparation for Audits – Example of Internal procedure

Obtain all Medicaid ID numbers, provider numbers & NPIs for all entity sites billing	• Medicaid (including Medicaid managed care) for 340B drugs • Point of contact with State Medicaid agency • Could represent multiple states and Medicaid contracts
Review decision for purchasing orphan drugs & verify accuracy on 340B database	• Review National Drug Code (NDC) used for OP drugs
Obtain population of all 340B dispensations for a specified period of time (typically six months)	• Select sample based on high-cost drugs, Medicaid transactions & Orphan drugs • Include each 340B service area (main pharmacy, outpatient clinics, contract pharmacy, retail pharmacy, etc.)

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Preparation for Audits – Example of Internal procedure

Inventory disposition reconciliation from beginning of sample time frame to end of sample time frame	• Review of GPO purchases & exclusion of 340B drugs if applicable
Contract Pharmacy	• Additional procedures should be developed around contract pharmacy relationships
Internal Reviews	• Who internally should perform this self-monitoring? • Is internal review enough based on expectation of independent audits?

340B Compliance Issues Found During BKD Reviews

BKD Review Findings

- Overall similar to HRSA audit findings
  - Contract Pharmacy
  - Diversion
  - Duplicate Discounts
  - Registration
  - Program Compliance

BKD & HRSA Audit Findings

Contract Pharmacy

- Pharmacy incorrectly registered as child site entity was shipping 340B drugs to a pharmacy not listed on the 340B database
- Registered contact pharmacies without written contract in place

Diversion

- 340B drugs dispensed to inpatients
- 340B drugs dispensed for prescriptions written at ineligible sites
- 340B drugs dispensed for prescription written at ineligible site by ineligible provider
- 340B drugs dispensed to non-patient at contract pharmacy

BKD & HRSA Audit Findings (Cont'D)

Duplicate Discounts

- 340B drugs dispensed to Medicaid patients by contract pharmacy, absent arrangement to prevent duplicate discounts
- Entity billed Medicaid for a patient at a contract pharmacy contrary to information contained in the Medicaid Exclusion File
- Entity was billing Medicaid contrary to information included in the Medicaid Exclusion File

BKD & HRSA Audit Findings (Cont'D)

Registration

- Incorrect entries for primary location & contact information
- Closed outpatient facilities remained registered on the 340B database
- Incorrect name listed for an outpatient facility
- Outpatient facility of the hospital was not listed on the 340B database
- Entity was using a contract pharmacy not listed on the 340B database even though there was a written contract in place.
- Incorrect 340B database record – Incorrect authorizing official

BKD & HRSA Audit Findings (Cont'D)

Compliance

- Internal monitoring & audit procedures for 340B Program are not completed or followed
- Inadequate documentation from contract pharmacy to produce a report detailing dispensations to agree with the contract pharmacy accumulator
- Listing of eligible providers provided to contract pharmacy included all medical professionals who have credentials with the hospital rather than those with contracts
- Physicians not included on the listing of approved 340B physicians employed, under contractual or other arrangement

Independent Audit Expectation

- Mega Guidance emphasizes the continued importance and **expectation** of an annual independent audit being perform
- HRSA is proposing standards for audits and quarterly reviews of contract pharmacy arrangements to ensure that compliance efforts result in
  - Early identification of problems
  - Implementation of corrections
  - Corrective action plans
  - Prevention of future compliance issues

- Maintain auditable data for a period of not less than 5 years

Independent Audits – Hrsa's View

- HRSA believes that covered entities that do not regularly review and audit contract pharmacy operations are at increased risk for compliance issues
- Annual audit of each location will provide covered entities:
  - Regular opportunity to review and reconcile 340B patient eligibility information
  - Prevent diversion
- Covered entity should compare 340B prescribing records with contract pharmacy's dispensing records at least on a quarterly basis to prevent:
  - Diversion
  - Duplicate discounts
- Conducting these audits using an independent auditor will ensure the pharmacy is following all 340B program requirements and provide the covered entity with ability to timely report any violations if applicable

Independent Audit – Agreed Upon Procedures

- We will compare eligible 340B locations as listed on the HRSA Office of Pharmacy Affairs database to a listing of sites utilizing Covered Entity's 340B program provided by the Health Center and note whether there are any differences. We will also agree each 340B site to a listing of sites within scope of the HRSA Notice of Grant Award.
- We will obtain lists of patients receiving 340B eligible drugs during the period from January 1, 20xx to December 31, 20xx. We will select 75 patients from the lists and agree them to the medical record at the Health Center.
- We will obtain the medical records of the patients selected in item #2 and agree the services that were provided to the patient to the scope of eligible services for which funding was awarded to the Health Center.

Independent Audit – Agreed Upon Procedures

- From the patient's medical records viewed in item #3 above, we will compare the prescribing physician to the list of eligible employed or contracted providers determined by the Health Center's policies and procedures related to the 340B Drug Pricing Program.
- We will obtain a listing of all contract pharmacy locations for the Health Center and agree the location of each contract pharmacy to the approved location list maintained on the HRSA Office of Pharmacy Affairs website.
- We will obtain the Health Center's financial class records for the patients selected in item #2 to determine if the patient accounts were billed to Medicaid or Medicaid Managed Care organizations.
- If Medicaid or Medicaid Managed Care was billed in item #6, we will compare the amount billed for pharmacy claims to instructions received from Medicaid for proper treatment for avoidance of a duplicate discount.

Independent Audit – Agreed Upon Procedures

- We will obtain the Health Center's policy and procedures documentation for the 340B Drug Pricing Program and compare the medical records of the patients selected in item #2 to the definition of covered patients eligible for participation in the 340B program as outlined in the Health Center's policy and procedures documentation and report patients that do not meet the stated eligibility criteria.
- We will clerically test four monthly reconciliation reports for amounts owed to the Health Center and amounts owed to the Contract Pharmacy.
- We will agree the reimbursement received for the patients selected in Item #2 (contract arrangement patients only) to remittance advices and cash receipts listings and agree this total to the amount remitted to the Health Center from the Contract Pharmacy.

Independent Audit – Agreed Upon Procedures

- We will select 20 individual drugs from a detailed listing of replenishments, and report items that are included in the detail in excess of quantities included in dispensing reports.

Questions?

Thank You!