

Nebraska Hospital Association

340B: The Program, The Environment, A Solution

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Background: SUNRx

- **Wholly Owned Subsidiary of MedImpact Healthcare Systems, Inc.**
- **A Leader in 340B, Serving More Than 160 340B Covered Entities**
 - Federally Qualified Health Centers (FQHC)
 - Disproportionate Share Hospitals (DSH)
 - Critical Access Hospitals (CAH)
 - Sole Community Hospitals (SCH)
- **Solely Dedicated to Maximizing the 340B Contract Pharmacy Model**
- **An Independent Company**
 - No binding ties to wholesalers or chain pharmacies
 - No mail-order pharmacy ownership
- **Nationally Recognized**
 - 22 State Hospital Associations Preferred 340B Provider

Agenda

- 340B Overview and Environment
 - Defining 340B
 - Current Market Perspective
 - Regulatory Insight and Requirements
- Establishing a Solution

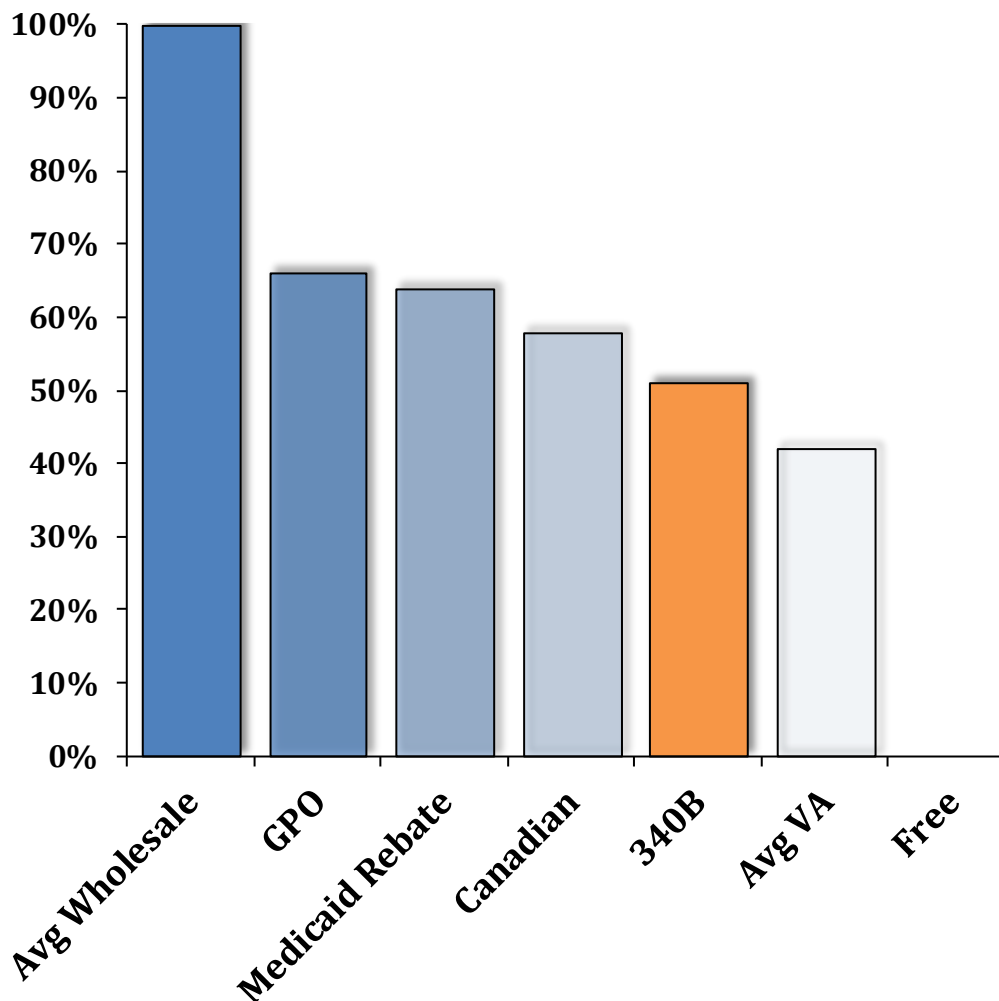
Defining 340B

- **Created in 1992 to:**
 - Expand access to affordable medications for low-income populations
 - Enable hospitals to *manage savings* to better serve the uninsured population
- **Eligibility:**
 - Entities (must be non-profit)
 - Critical Access Hospitals, Federally Qualified Health Centers, Disproportionate Share Hospitals, Critical Access Hospitals, Children's Hospitals and others
 - Medications
 - Outpatient drugs only
 - Patients
 - Only patients of covered entities
- **Oversight Responsibility:**
 - Health Resources and Services Administration (HRSA)
 - Office of Pharmacy Affairs (OPA)

340B Program Overview

On average, 340B pricing is:

- 51% Lower Than AWP
- 39% Lower Than AMP
- 15% Lower Than GPO



Source:
Safety Net Hospitals for Pharmaceutical Access

340B: Current Market Perspective

- **340B Models**

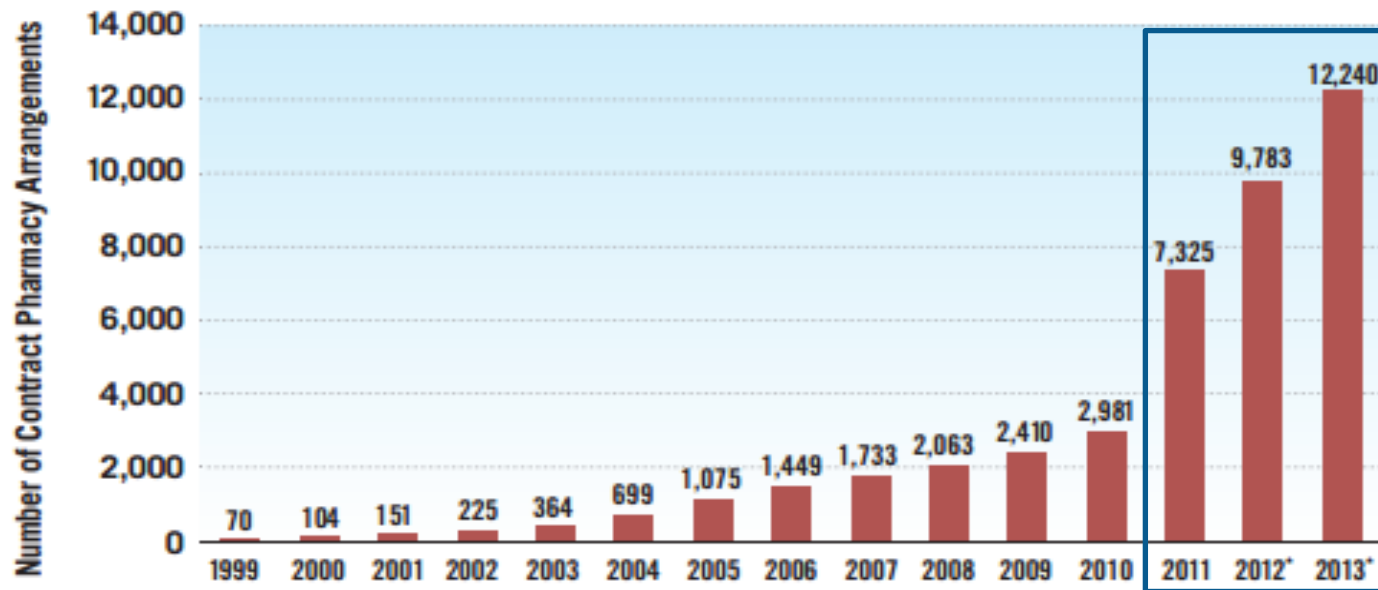
- Contract Pharmacy
 - 340B Administrator Model—Virtual Inventory (i.e., SUNRx)
 - Chain Pharmacy Model (i.e., Walgreens)
- Split Billing (i.e., e-Audit, Sentry, Talyst, MacroHelix)
- Split Billing/Contract Pharmacy (i.e., SUNRx)

- **Pharmacy Participation**

- National Chain Pharmacies (i.e, WAGS, CVS, Rite Aid)
- Regional Chains (Hy-Vee)
- General Merchandising/Food Chains (Walmart, Kroger, HEB, Safeway)
- Independent Pharmacies (including independent chains)

Current Market Perspective: Growth of 340B

Growth in 340B Contract Pharmacy Arrangements, 1999–2013 (as of July of Each Year)



*2012 and 2013 reflect HRSA projections.

Source: Avalere Health analysis of HRSA 340B contract pharmacy arrangements files.

- This Growth has spurred recent Congressional Scrutiny
 - Want assurances that the program continues to meet its original intent
 - That contract pharmacies have appropriate oversight

340B: Current Market Perspective

- **Compliance Approach and Adherence**

- Overall responsibility for compliance resides with Covered Entity
- Inconsistency amongst 340B Administrators
 - Program Offerings
 - Fee Schedules
 - Pharmacy Relationships
- Audit Reviews Increase
 - 131 in 2013
 - Findings reported on 51
 - Focus on ensuring the prescription is an “eligible script”
 - Provider Panels
- Manufacturer audits increase
 - Ensure the program is running in accordance with “intent”
- Awaiting “Mega Re-Write”

340B Compliance and Regulatory

Regulatory Insight and Environment

- Hospital Eligibility
- Patient Eligibility
- Regulatory Topics
 - Managed Medicaid
 - Facility Registration
 - Program Audits
 - GPO and Orphan Drugs
- 340B Market Conditions

Hospital Eligibility

Covered Entity Type	Non-Profit, Government Contract	DSH Percentage	GPO Exclusion	Orphan Drug Exclusion
DSH Hospitals	Yes	> 11.75%	Yes	No
Critical Access Hospitals*	Yes	No	No	Yes
Children's Hospitals*	Yes	>11.75%	Yes	No
Sole Community Hospitals*	Yes	>8%	No	Yes
Rural Referral Centers*	Yes	>8%	No	Yes

* Added by the Affordable Care Act

Patient Definition

- HRSA Patient Eligibility

- The covered entity has established a relationship with the individual, such that:
 1. The entity maintains records of the individual's health care
 2. The prescriber is either employed by the covered entity – OR
 3. The prescriber provides health care under contractual or other arrangements (e.g., referral for consultation)
 4. The responsibility for the care remains with the covered entity
- Outpatients Only
- Excludes Fee For Service Medicaid

Managed Medicaid

- Two regulations applicable to Managed Medicaid:

1. 340B Regulation

- Entities must not use 340B for any claim subject to a Medicaid rebate
 - Entity must establish an arrangement with the state to prevent duplicate discounts

2. Affordable Care Act

- ACA - 2010 gave rebates to States for Managed Medicaid claims
- Excludes 340B from rebates
- States are responsible to develop a method to exclude rebates for 340B drugs

- Recommendation

- Since the burden is on the States to exclude 340B from rebates, entities should contact their states to discuss how to ID 340B claims for rebate purposes
- Document all conversations with States or Medicaid MCOs

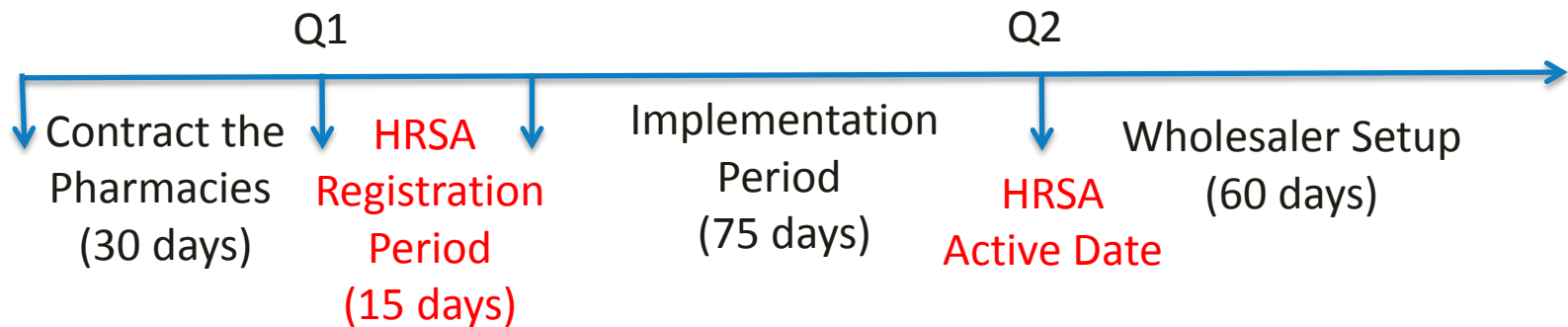
340B Facility and Pharmacy Registration

- HRSA registration periods:

- New covered entities
- Off-site facilities
- Contract pharmacies

<u>Registration Period</u>	<u>Start Date</u>
October 1 st – 15 th	January 1
January 1 st – 15 th	April 1
April 1 st – 15 th	July 1
July 1 st – 15 th	October 1

Implementation Timeline



150 days Minimum (Up to 210 days)

340B Oversight

- HRSA Audits
 - HRSA conducts audits to assure entities are:
 - Preventing diversion of 340B Drugs (use only for eligible patients)
 - Preventing duplicate discounts (Medicaid rebate + 340B discount)
 - Maintaining readily auditable records
 - Adhering to the GPO and Orphan Drug Exclusions
- Internal Audits
 - HRSA expects entities to perform annual “independent” 340B audits
 - Self Audits—random audits of contract pharmacy claims
 - Self-Reporting of program violations to HRSA
- Annual Facility Recertification—Entities should:
 - Assure that their contacts are up to date on the HRSA website
 - Make sure their OP facilities are registered with HRSA
 - Facilities are on their Medicare Cost Report
 - Contracts are in place and annual audits are conducted

GPO and Orphan Drug Exclusion

- GPO Exclusion

- DSH and Children's Hospitals may NOT purchase any outpatient drugs through a GPO (may use either 340B or WAC for outpatients)
- DSH hospitals must have a split billing system for in-hospital administration

- Orphan Drug Exclusion

- Cannot use 340B if the use was for the “original orphan diagnosis”
- Applies to Critical Access, Sole Community and Rural Referral Hospitals
- Must have a tracking system in place
- Entities can opt-in or opt-out of using 340B for orphan drugs

340B Market Conditions in 2014

- **Factor 1: Impact of the Affordable Care Act**
 - Insurance Exchanges have underperformed expectations. It is expected that as many as 40 million will remain uninsured.
- **Factor 2: Safety Net System Impact**
 - Reimbursement remains poor for Medicare and Medicaid. Access to participating providers will be difficult—driving patients to safety net facilities such as DSH hospitals.
 - 2015 federal budget increases reimbursement to community clinics and become more limited for specialty care.
- **Factor 3: HRSA “Mega Reg”**
 - Widely expected that clarity will be provided surrounding the patient definition, rebates, use of economic benefits, variable dispensing fees, and penalties for violation.
- **Conclusion:**
 - Continued expansion of the 340B industry
 - Regulatory clarity coming from the re-write.

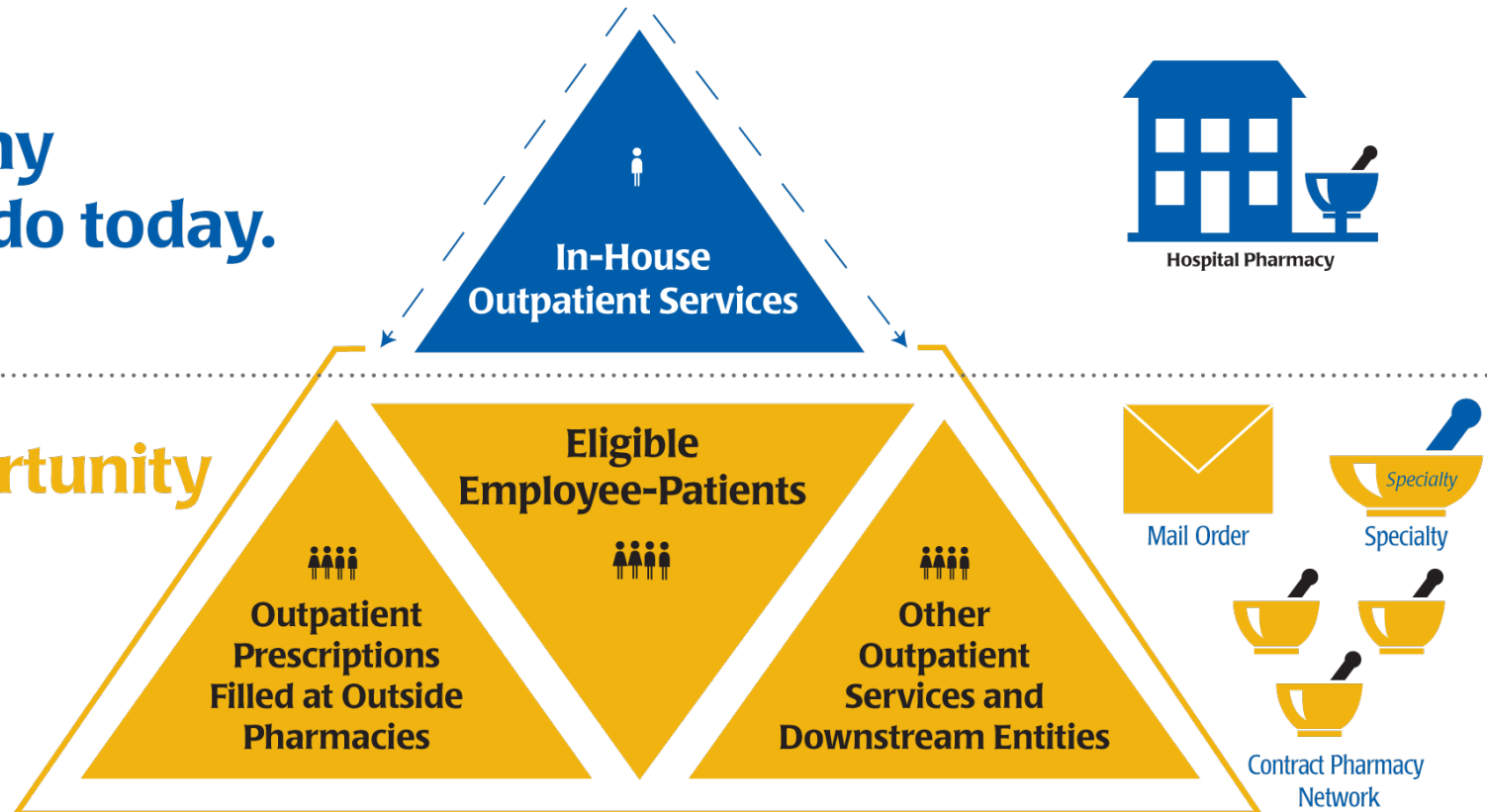
Establishing a Solution

The Hospital 340B Opportunity

What many hospitals do today.



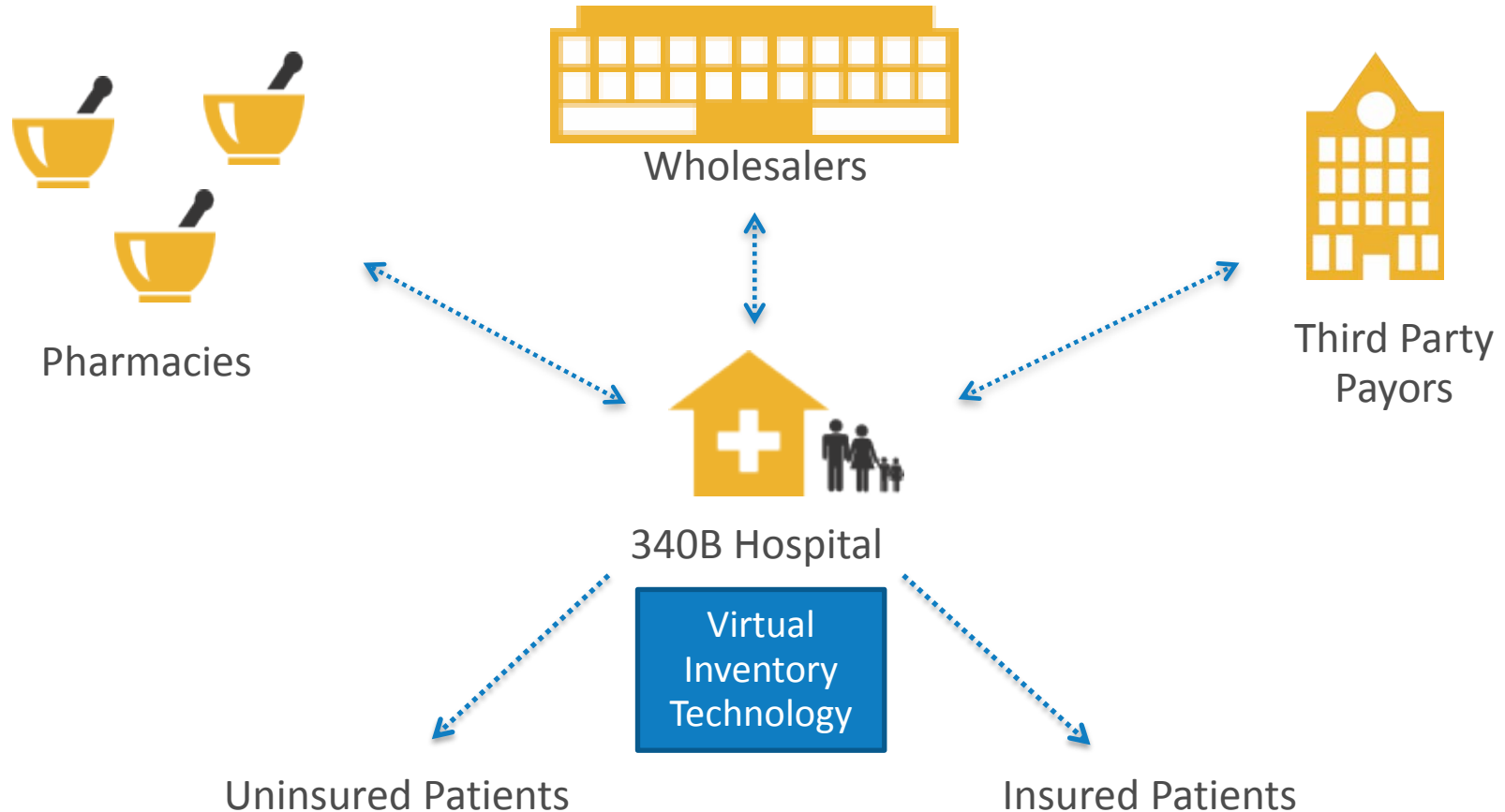
The Opportunity



Contract Pharmacies

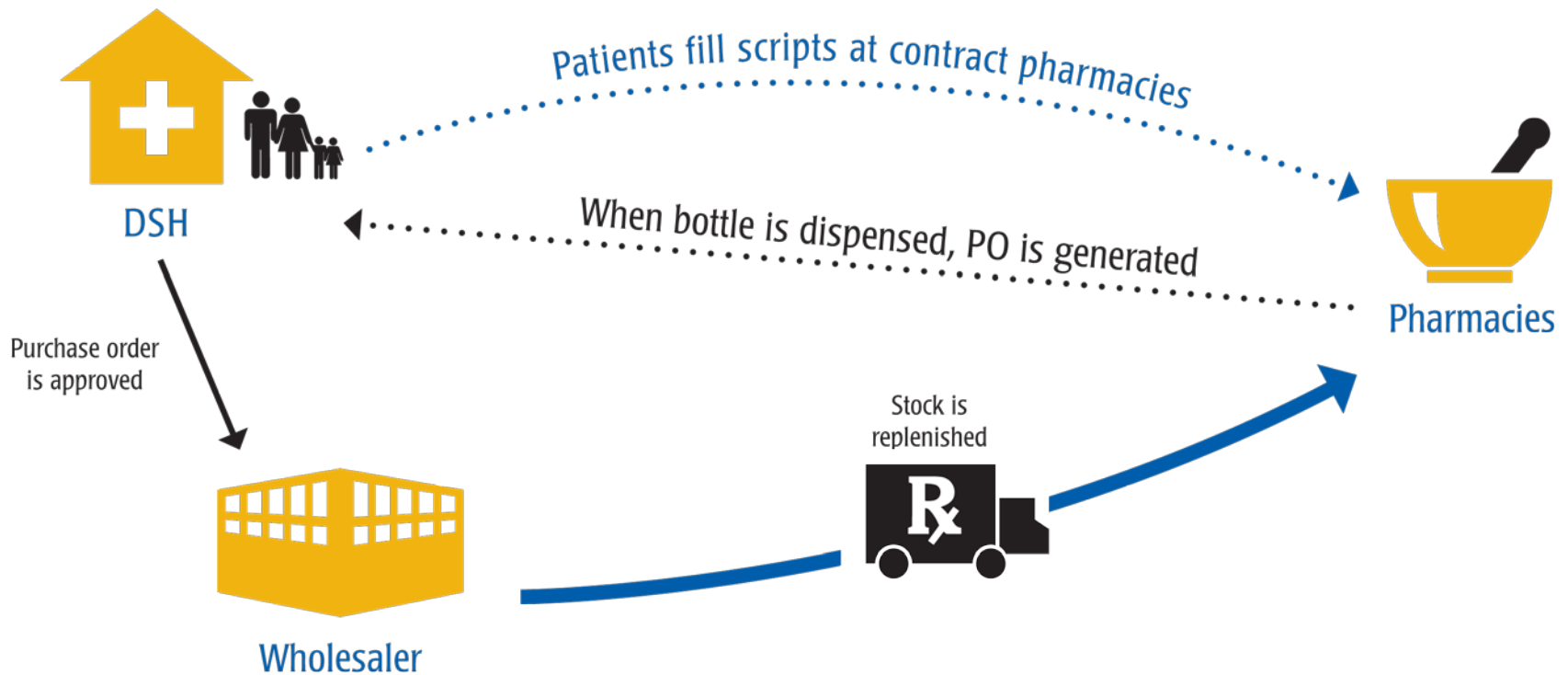
- Hospitals may set up a contract pharmacy network to serve their patients:
 - Contract pharmacies (all types) supplement your outpatient pharmacy
 - Keep outpatient prescriptions “within the system” that are now being “lost to the community”
 - Convenient pharmacy locations to expand access to the uninsured
 - Working with a pharmacy chain will create efficiencies and greater access
- Pharmacy Contracts
 - Serving both cash and third-party patients
 - Paid a dispensing fee (prefer fixed), and drugs are “replenished” by the hospital (bill-to, ship-to)
 - Strict diversion and inventory control management

340B Program Development and Setup



340B Virtual Inventory

THE VIRTUAL INVENTORY



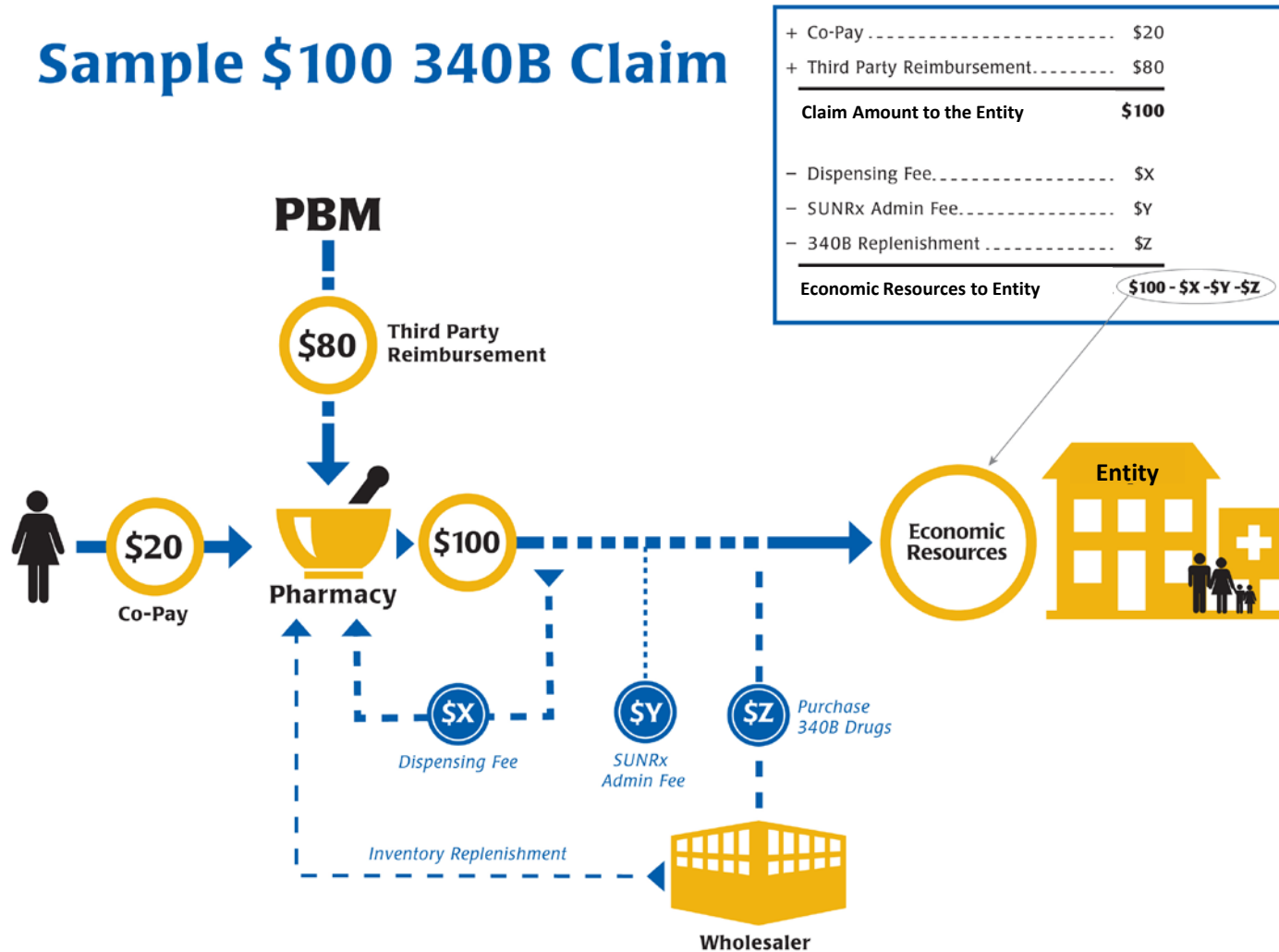
Cash Solution for Uninsured Patients

- Issue 340B prescription cards
- Real-time adjudication
- Determine patient eligibility
- Calculate “lowest price” patient copay
- The Lowest Price...Every Time
- Fact: For nearly 50% of prescriptions 340B is NOT the lowest available price



Third Party Example

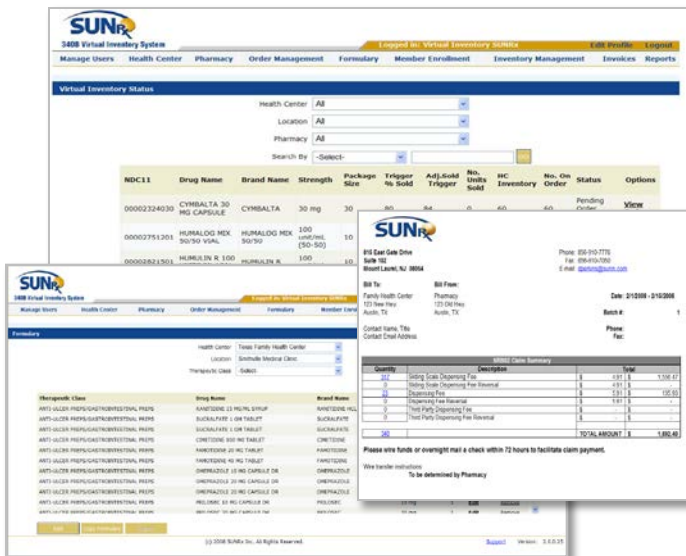
Sample \$100 340B Claim



Monitoring and Compliance

- Every transaction should be tracked, creating a fully auditable records:
 - Eligibility
 - Medication dispensing history
 - Reversals, re-bills
 - Replenishment orders
 - Pharmacy Receipts

Compliance Reporting



Dashboard Monitoring

- Program Performance Monitoring:
 - Captured claims by pharmacy
 - Program utilization
 - Financial performance

Marketing Your Program

Medications are expensive. We can help.

Take your ABC Health Center's 340B card and your prescription to one of our pharmacy partners and begin saving today!

Las Medicinas Son Caras. Nosotros le Podemos Ayudar.
Lleve su tarjeta 340B ABC Health Center y su receta medica a nuestra farmacia colaboradora y comience a ahorrar hoy.

Pharmacy A
Anywhere Street
Suite 0
Everywhere, ZZ 00000
XXX-XXX-XXXX

Pharmacy B
Anywhere Street
Everywhere, ZZ 00000
XXX-XXX-XXXX

We accept ABC Health Center's 340B prescription card.

Aceptamos la tarjeta 340B ofrecida por ABC Health Center

Present your card to the pharmacist with your prescription and start saving today!

Presente su tarjeta al farmaceutico con su receta medica y comience a ahorrar hoy!

For more information, contact ABC Health Center or ask the pharmacist.

Para mas informacion, contacte a ABC Health Center o pregunte a su farmaceutico.

Did you tell your patients to take their 340B card and prescription to a participating pharmacy?

Medications are expensive. We can help.

SUNRx

Conclusion

- Participate in a 340B Program
 - Understand the requirements
 - Engage a partner who will:
 - Maximize the benefit and adhere to compliance
 - Partner with Best Practice Hospitals
 - Utilize Nebraska State Hospital Association relationships

Thank You

