Pharmaceutical Summit on Business and Compliance Issues in Managed Markets

TRACK A: 340B PROGRAM CONSIDERATIONS

A Panel Discussion By:

Agenda

- Panel Introductions
- Overview of 340B Program
- Compliance Considerations of the 340B Program
- Remediation of 340B Compliance Risk
- Emerging Issues within 340B Program
- Conclusion

Introductions:

Anthony Greco
Director, PwC

Anthony S. Greco is a Director in the Advisory practice. He is a member of Pharmaceutical & Life Sciences sector with a focus on Governance Risk and Compliance with over 15 years of experience. He provides financial and business advice in connection with complex compliance and regulatory issues.

Ray Schroeder
Director, PwC

Ray is a Director in the Risk Assurance practice with extensive experience in business and IT process and controls as well as advanced data analytics and visualization. He has more than 12 years of industry experience spanning across both audit and IT. Ray's clients include Fortune 50's with large scale system implementations and data migrations.

Aaron Vandervelde
Managing Director, BRG

Aaron Vandervelde has over 12 years of experience providing strategy, health policy and litigation consulting services to clients in the healthcare industry. He specializes in financial and economic analysis of health policy and provides litigation consulting services related to issues arising from contracts and transactions between healthcare entities and with the federal government.

Overview of 340B Program

What is the PHS Program?

- Created in 1992 after the adoption of the Medicaid Drug Rebate program and is named for the provision in the **Public Health Service Act** which authorizes it (340B)

- Commonly known as a **“PHS”** or **“340B” price**

- Allows **eligible federally funded grantees** and other safety net health care providers to **purchase prescription medication at significantly reduced price**

- Administered by the **Office of Pharmacy Affairs (OPA)** within the Dept. of Health & Human Services

Program Eligibility

Organizations

- Nonprofit health care organizations that **have certain Federal designations or receive funding from specific Federal programs**
- Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and certain types of hospitals and specialized clinics.

Patients

- Patients **must receive health care services other than drugs** from the 340B covered entity

Drugs

- Generally, the 340B Program covers the following **outpatient** drugs:
  - FDA-approved prescription drugs;
  - Over-the-counter (OTC) drugs written on a prescription;
  - Biological products that can be dispensed only by a prescription (other than vaccines); or
  - FDA-approved insulin.

Source: http://www.hrsa.gov/opa/eligibilityandregistration/index.html

How is this price calculated?

Medicaid Drug Rebate Program data drives PHS price calculation:

AMP = Average Manufacturer Price

URA = Unit Rebate Amount

PHS Price = AMP – URA

340B price is a "ceiling price"

- Covered entities receive a minimum discount of approx. 23.1% on name-brand prescription drugs & 13% for generic and OTC drugs.
- Covered entities are free to negotiate discounts that are lower than the maximum allowable statutory price (i.e., sub-ceiling prices) or use a "Prime Vendor."

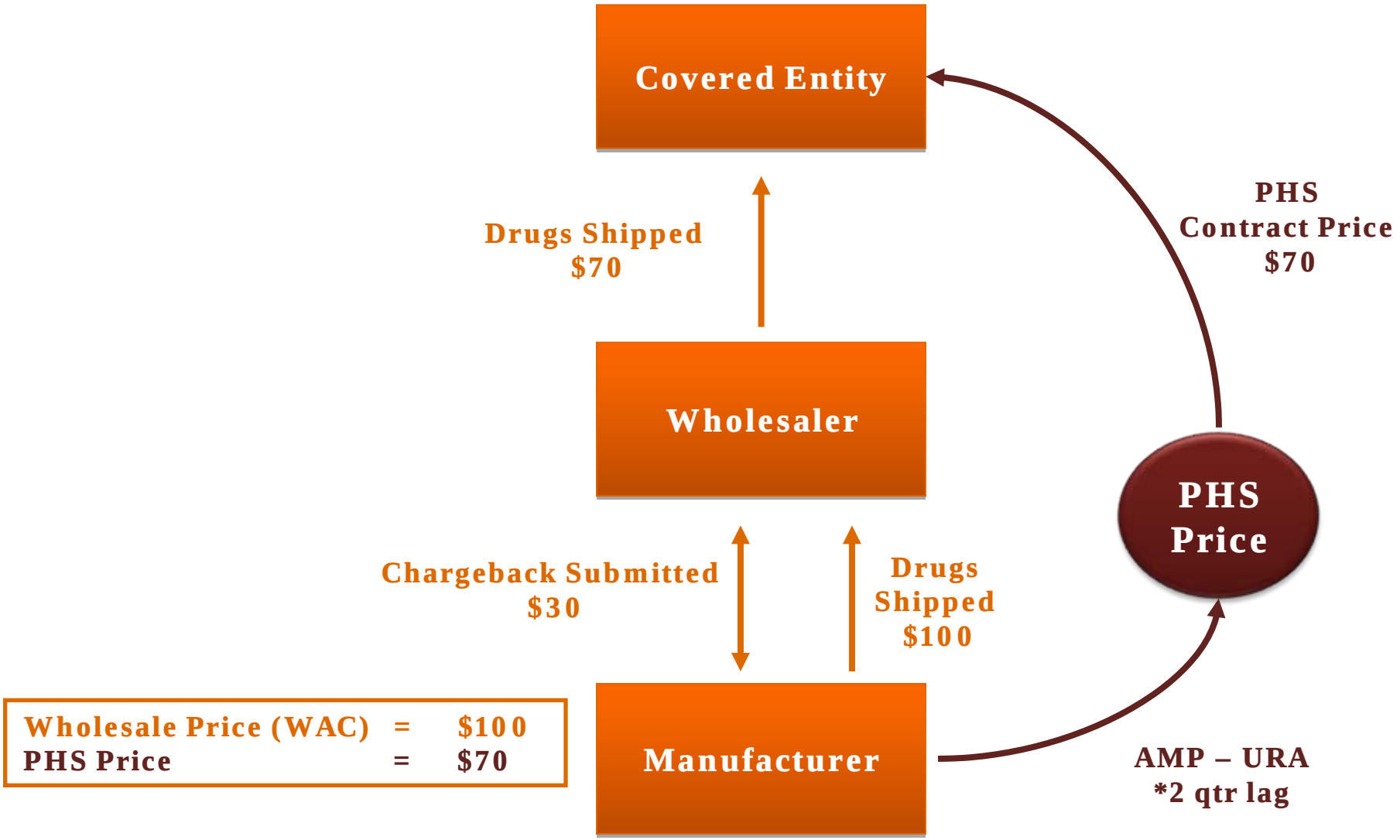
Why does this matter for manufacturers?
Overview of Program Rules

- Manufacturers ***must offer 340B discounts*** to covered entities to have their ***drugs covered under Medicaid***

- Manufacturers are ***prohibited from distributing drugs*** in ways that ***discriminate against covered entities***
  - *i.e. Cannot have minimum purchase requirements*

- If there is drug shortage, manufacturers ***cannot limit drug sales*** to 340B providers ***unless imposing the same limits*** on other providers

How are 340B sales processed?



Compliance Considerations of 340B Program

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Key 340B Program Risks

- Failure to Comply with Program Requirements
- Offering 340B Prices to Ineligible Customers
- Revenue Erosion due to Program Misuse

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- **Failure to Comply with Program Requirements**
- **Offering 340B Prices to Ineligible Customers**
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- Accurate 340B Price Calculation and Reporting

Compliance Considerations of 340B Program

Key 340B Program Risks

Failure to Comply with Program Requirements	Offering 340B Prices to Ineligible Customers	Revenue Erosion due to Program Misuse
• Accurate 340B Price Calculation and Reporting	• Membership Maintenance • Chargeback Processing • Refund / Rebill Processes	

Compliance Considerations of 340B Program

Key 340B Program Risks

Failure to Comply with Program Requirements	Offering 340B Prices to Ineligible Customers	Revenue Erosion due to Program Misuse
• Accurate 340B Price Calculation and Reporting	• Membership Maintenance • Chargeback Processing • Refund / Rebill Processes	• Duplicate Discounts • 340B Product Diversion

Remediation of 340B Compliance Risk

Summary of Remediation Activities Previously Discussed

The 340B Opportunity

- Targeting specific high risk covered entities
- Establishing 'reasonable cause'
- Initial communication with Covered Entity

•Executive report – quantification of non compliance findings
•Issues dashboard
•Presentation

Customer and Product Portfolio Risk Assessment → **Audit Planning** → **Fieldwork and Execution** → **Reporting**

- Chargeback analysis
- Wholesaler data analysis
- Product diversion and double dipping profiling
- History of Covered Entity

- Data testing
- 100% coverage
- Process / control validation (i.e. split billing software, end to end testing)
- Root cause identification

When fully integrated, data analytics techniques are fully embedded into all elements of the customer management process

Deliver solutions.. not problems

Types of 340B Analytics

Business profiling and audit intelligence	Profiling quantitative metrics relative to covered entities operations – Example: prior findings, change in designation of carve out status, # contract pharmacies etc.
Risk attribute sampling	Identifying anomalies and patterns – Example: discounted purchases don't align with dispense information
Process and control verification	Diagnosing process and control integrity – Example: is split billing software configured correctly, can system validation checks be manually overridden
Data testing	Testing completeness and integrity of data by integrating disparate data sources – Example: Chargebacks X Wholesales Purchases X Dispenses
Scenario modeling	Modeling of processes using business requirements or independent sources – Example: Quantification of non-compliance – present value cost, weighted average, point in time
Presentation and reporting	Summarizing key 340B compliance issues to stakeholders and operationalizing review on a periodic basis

Emerging Issues within 340B Program

Emerging Items within the 340B Program

340B Mega rule and other recent guidance

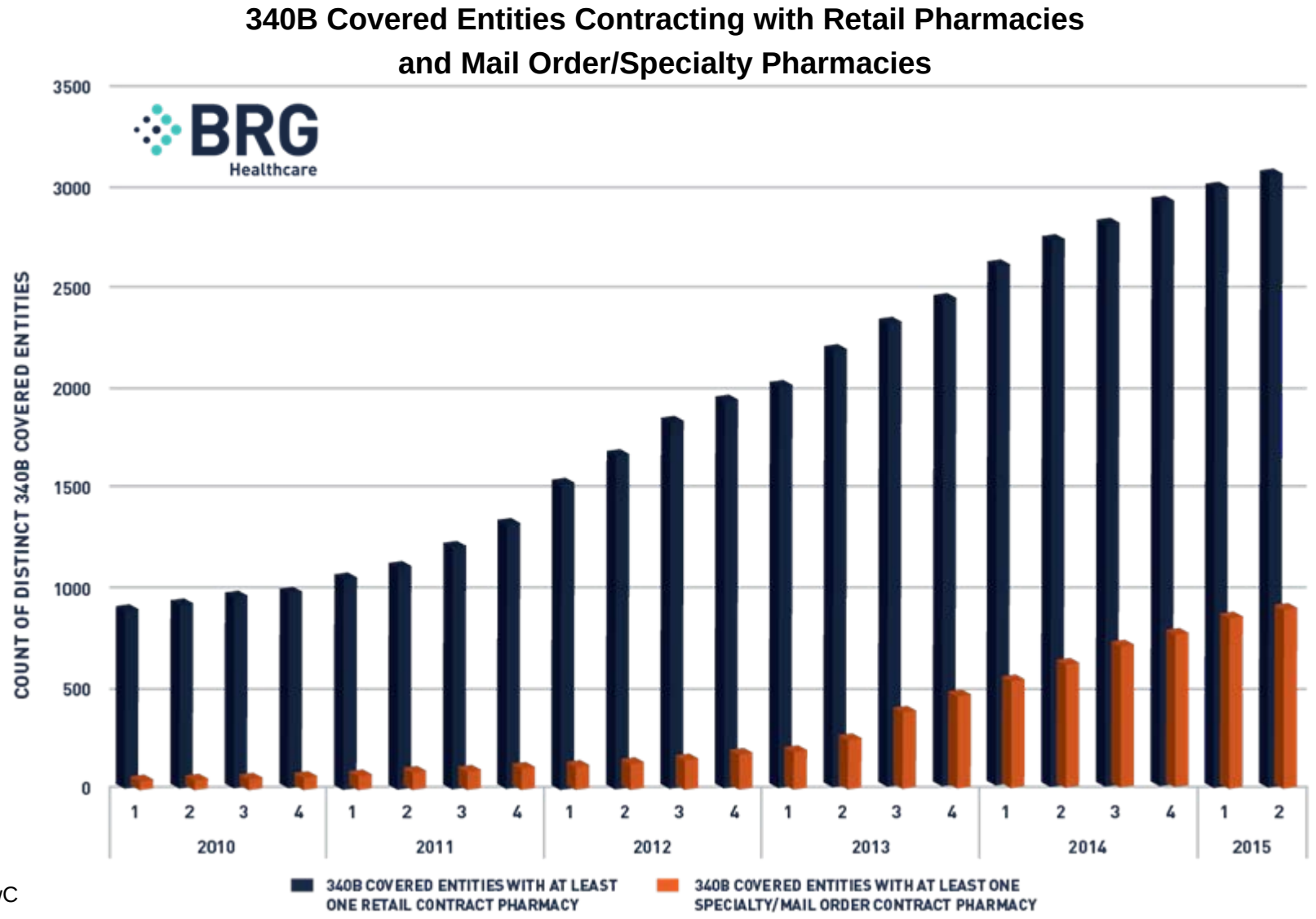
Increase in Contract Pharmacies

Expansion of Specialty Pharmacy Channel

340B Omnibus Guidance & Other Regulations

- Omnibus Guidance creates new requirements for manufacturers:
  - Communications to HRSA regarding limited distribution arrangements
  - Quarterly 340B price reporting and annual recertification process
  - Procedures for issuance of refunds & credits
- The guidance also proposes significant changes to the patient definition:
  - Inpatient prescriptions no longer eligible in contract pharmacy channel
  - Prescription must originate from a 340B eligible location
  - Provider must have a contractual relationship with the covered entity such that the covered entity can bill for the healthcare services of the provider
- Recent CMS guidance also creates an opportunity to offer 340B pricing to covered entities for inpatient utilization without triggering Best Price

Contract Pharmacy Enrollment Trends



Specialty Pharmacy Considerations

- Replenishment order process creates complexity in managing a limited distribution network which is more common with specialty therapeutics and may be critical in terms of proper handling and administration of a drug

- Ability to properly allocate prescriptions to sales representatives is also complicated with replenishment orders and could result in double counting or improper allocation of credit

- Many of the third parties that help administer a specialty distribution and specialty pharmacy network don't fully understand how contract pharmacy arrangements work and may be providing inaccurate information to manufacturers

Conclusion

Conclusion – 340B Program Considerations

What are the type of questions you should be asking your Managed Markets Team?

340B Price Calculations

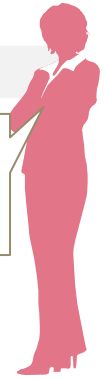
"Do we have formal and documented policies and procedures for our Government Price calculation and reporting requirements including Medicaid and 340B**?**

Membership Maintenance

"How often are we reviewing our 340B customer list to confirm eligibility?"

Refund / Rebills

"What is our process to recoup discounts from customers we determine are 340B ineligible?**"**

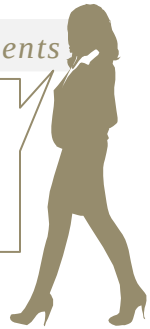


340B Program Misuse

"Do we monitor our 340B sales activity and if so, have we seen any significant changes in the volume of sales through this channel?"

Regulatory Requirements

"Who is responsible for reviewing new guidance / rules from the OPA and have we considered the impact of the Mega Rule?"



Contract Pharmacies

"Do we have an ability to identify the commercial pharmacies that purchase product at 340B prices and how are they validated?

Thank you!

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