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A Paradigm Shift in 340B - How to Protect AND Grow the Program

HCCA 2018 Compliance Institute
Las Vegas, NV

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Your Entertainers on this lovely Sunday afternoon

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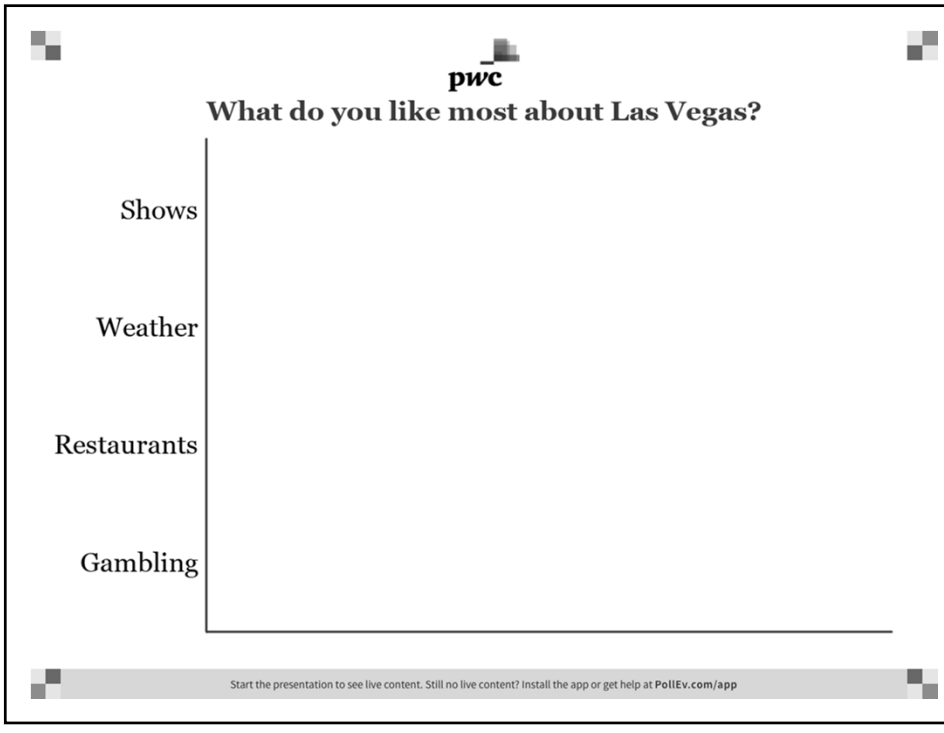
Agenda

340B Compliance Monitoring Utilizing Data Analytics

- Introductions
- Program Background, Overview, & Key Statistics
- 340B Program from 5 Different Stakeholder Viewpoints
  - Manufacturers / Big Pharma
  - Providers / Hospitals
  - Congress / Legislators
  - Regulator / HRSA (under HHS)
  - Patient
- Break
- The Challenges, Risks, Sanctions, Solutions, & Value of Compliance
- Break
- Compliance Monitoring Utilizing Data Analytics
- Q&A

Live Polling: Please text message "timothykrzem636" to phone number 22333 to activate!



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Does your organization participate in the 340B program?

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How concerned are you with 340B Compliance at your organization?

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Who is primarily responsible for 340B Compliance within your organization?

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Learning objectives

- Learn what the 340B program is, how it's grown, where it's going
- Understand why this program is so important from the perspective of its major stakeholder groups
- Learn and see some examples of how providers are leveraging analytics to protect and grow their programs
- Let's get started with a video

340B Drug Discount Program – Background

- Created in 1992, the Program allows certain hospitals and other providers ("covered entities"/ "CE's") to obtain **discounted prices** on "covered outpatient drugs" (prescription drugs and biologics other than vaccines) from drug manufacturers.
- Manufacturers must offer 340B discounts to CE's in order to have their drugs covered under Medicaid. The **discounts are substantial** ranging up to 60% off WAC pricing. The Health Resources and Services Administration (HRSA), which manages the program, estimates that covered entities saved $3.8 billion on outpatient drugs in fiscal year 2013 and utilization continues to expand rapidly.
- Using proprietary calculations, HRSA calculates a **340B ceiling price** for each covered outpatient drug, which represents the maximum price a manufacturer can charge a covered entity for the drug.
- Although the ceiling price calculation is proprietary, it is estimated that, on average, hospitals in the 340B program receive a **minimum discount of 22.5%** of the average sales price for drugs paid under the outpatient prospective payment system (OPPS).

340B Drug Pricing Program

History

- The 340B Drug Discount Program is a U.S. Federal Government Program created under the Veterans Health Care Act of 1992 (VHCA)
  - The Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations ("Covered Entities") at significantly reduced prices
  - CE's include disproportionate share hospitals (DSH), childrens' hospitals and cancer hospitals, sole community hospitals, rural referral centers, & critical access hospitals

Program Intent

The intent of the program is to allow Covered Entities to, "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"*

340B Drug Pricing Program (continued)

Requirements

- The program requires pharmaceutical manufacturers that participate in Medicaid to enter into a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services (HHS)

Pharmaceutical Pricing Agreement (PPA)

- The manufacturer agrees to provide statutorily defined discounts on "covered outpatient drugs" purchased by eligible Covered Entities, so that they can fulfill their mission to serve the nation's underinsured and vulnerable patient populations

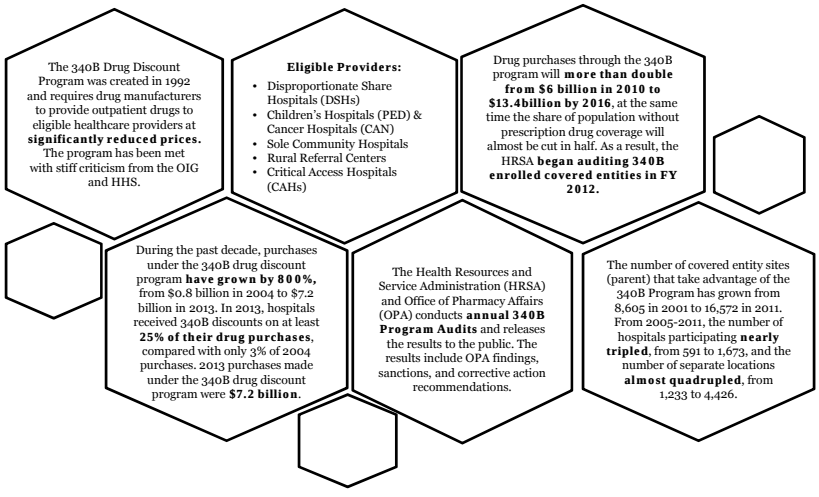
Public Health Services (PHS) Price

- The PHS Price is based on Medicaid Average Manufacturer Price (AMP) minus the Medicaid Unit Rebate Amount (URA)

HRSA's Office of Pharmacy Affairs (OPA)

- Administer the 340B program; responsible for interpreting and implementing the 340B law

340B Drug Discount Program – Key 340B Program Statistics



Various Perspectives

Manufacturers/Big Pharma - I make the drugs, and this program costs me a lot of money. How can I ensure providers are participating in the program correctly?

Providers/Hospitals - I get deep discounts to drugs. How can I ensure compliance in the program, and then grow it?

Congress/Legislators - We originally intended for 340B to "to enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

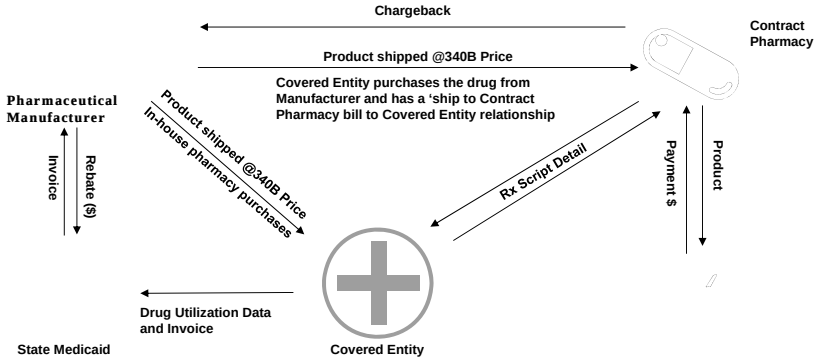
How do we issue renewed guidance to clarify the intent of the program; and to reconcile clear lack of understanding as HRSA audits of CE's routinely identify non-compliance

HRSA/OPA/Regulator - How do I continue to improve my ability to leverage modern technology to scale the breadth, depth and accuracy of my audits to improve CE compliance, and reduce the risks in the program?

Patient - I have no idea what the 340B program is. I just want my drugs cheap(er).

340B Drug Discount Program is Complex

The **340B Drug Discount Program** requires pharmaceutical manufacturers to provide outpatient drugs to eligible health care organizations ("covered entities") at significantly reduced prices. The 340B Program allows covered entities to reduce outpatient drug spend and increase 340B benefit with the goal of increasing patient access to drugs and providing more comprehensive services. To supplement this goal, covered entities may elect to dispense 340B drugs to eligible patients through "contract pharmacies" but are responsible for compliance of their contract pharmacy arrangement(s).



340B – The Challenge for Providers

HRSA, OPA, and Manufacturers are aggressively auditing providers to assess Covered Entity's controls around compliance with the 340B program, including prevention of both duplicate discounts and product diversion. Providers historically have struggled to consolidate eligibility and purchasing data across all Covered Entity and Contract Pharmacy relationships. Failure to implement effective controls could lead to government audit findings, financial penalties, and exclusion from the 340B Drug Discount Program.

01

The Challenge

How can I protect ("be compliant") and grow ("expand CEs, discounts")?

Key Compliance Risks

340B Datasources

Product diversion	***Diversion to ineligible patients.*** Covered entities must not resell or otherwise transfer 340B drugs to ineligible patients.
Duplicate discounts	***Prevent duplicate discounts.*** Manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same claim. Covered entities must accurately report how they bill Medicaid drugs on the Medicaid Exclusion File.
GPO Prohibition	***GPO Violation.*** Covered entities are not permitted to purchase from a GPO contract for to obtain outpatient drugs. Should purchase initially from WAC account, and then replenish through 340B account.

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Which of the following aspects of 340B Compliance are you most concerned with?

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Are you still awake?

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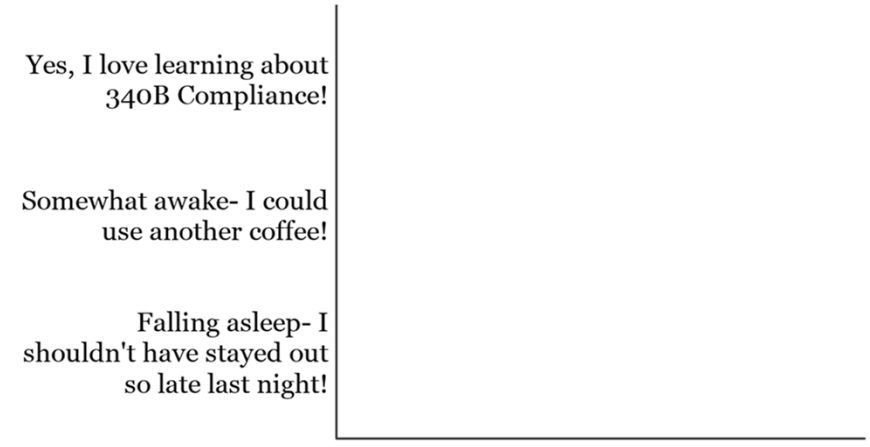

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BREAK – 5 minutes

Stand up, get the blood flowing

Check your Facebook and IG notifications

Read depressing news

Come back

340B Covered Entity Compliance Risks from a Pharma Manufacturer's Perspective

Why should I care?

Product Diversion and Duplicate Discounts can lead to significant revenue erosion for the manufacturer if left unresolved

	Product diversion	**Duplicate discounts**
What is it?	Covered Entities must not resell or otherwise transfer 340B drugs to ineligible patients.	Manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same claim. Covered Entities must accurately report how they bill Medicaid drugs on the OPA Database.
Our Experience	• **Incorrect configuration of split billing software** resulting in ineligible discount purchases spanning years • **Centralized inventory management which incorrectly tracks purchases** between parents and children of registered 340B sites – Example: an outpatient only facility mixing purchases with a mixed use setting resulting in non compliant discount purchases • **Proliferation of contract pharmacies** making it harder to maintain auditable records – covered entity should have visibility into contract pharmacy operations	• **Non compliance activity** can be identified with detailed Medicaid line item level submission data (claims level detail) • **High potential for error** relative to duplicate billing • **Incorrect designation** of carve-in/carve-out status on the Medicaid Exclusion file • **Multiple potential points of failure** - chargeback with Covered Entity, rebate with state Medicaid agency, maintenance in exclusion file
Data Inputs	• 844 Chargeback Data • 867 Sales Data • OPA/HRSA Data Sources • Manufacturer Purchased Third-Party Data	• State Claims Level Detail (CLD) for each State • Medicaid Exclusion File • OPA/HRSA Data Sources • Manufactured Purchased Third-Party Data

340B Drug Discount Program – The Risk

Typical compliance violations that can lead to monetary sanctions or expulsion from the program include:

- Weak or non-existent internal controls as they relate to the administration of the program.
- The existence of product diversion (e.g. inpatient vs. outpatient)
- Duplicate discounts being claimed (340B discount as well as Medicaid rebate).
- Adherence to guidelines defining what is an eligible patient and prescriber.
- Inadequate recertification procedures and eligibility validation.
- Inadequate program recordkeeping and adherence to HRSA guidelines.

Any of the issues noted above may result in financial sanctions and/or expulsion from the 340b Discount Program of which the effects could be significant to a hospital's financial health.

02

The Risk

340B Drug Discount Program – Historical Sanctions

Implications of Non-Compliance with Program Requirements

Discounts derived from participation in the 340B drug discount program can represent as much a 60% of a providers ***outpatient drug spend.***

Program participation requirements included in a HRSA or Manufacturer lead audit can cover the following:

- Product Diversion
- Double Dipping of Program Discount and Medicaid Rebate
- Contract Pharmacy Oversight
- Approved Policies & Procedures
- Maintaining Auditable Records

Sanctions imposed related to non-compliance can range from corrective action plans to financial penalties, to expulsion from the program. Expulsion from the program could have a material long term impact on a providers financial health.

03

The Sanctions for Non-Compliance

340B Drug Discount Program – Historical Sanctions (continued)

Below is an example of some findings under HRSA or Manufacturer lead audits between 2014 and 2016:

Contract Year	2014	2015	2016
Results from HRSA or Manufacturer Initiated Audit			
Pending; Repayment to manufacturers.	4	4	-
Repayment to manufacturers.	52	87	4
Repayment to manufacturers; Termination of contract pharmacies from 340B Program	-	1	-
Termination from the 340B Program*; Repayment to manufacturers.	-	1	-
Termination of contract pharmacy from 340B Program	2	6	1
Termination of contract pharmacy from 340B Program; Repayment to manufacturers.	4	7	-
Termination of covered entity from 340B Program;	-	1	-
Termination of ineligible site from 340B Program	-	1	-
Termination of ineligible site from 340B Program; Repayment to manufacturers.	3	2	-
Removal of Contract Pharmacy	1	-	-

03

The Sanctions for Non-Compliance

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What is your favorite game?

Craps

Blackjack

Roulette

Slots

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How concerned are you with Contract Pharmacy compliance?

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Product diversion – What we've seen…

Our experience

- ***Incorrect configuration of split billing software*** resulting in ineligible discount purchases spanning years
- ***Centralized inventory management which incorrectly tracks purchases*** between parents and children of registered 340B sites – Example: an outpatient only facility mixing purchases with a mixed use setting resulting in non compliant discount purchases
- ***Proliferation of contract pharmacies*** making it harder to maintain auditable records – covered entity should have visibility into contract pharmacy operations

HRSA Findings

Prevent diversion to ineligible patients: Covered entities must not resell or otherwise transfer 340B drugs to ineligible patients

Maintain auditable records: documenting compliance with 340B Program requirements. Covered entities are subject to audit by manufacturers or the federal government. Any Covered Entity that fails to comply with 340B Program requirements may be liable to manufacturers for refunds of the discounts obtained

Product Diversion - 340B drugs dispenses:

- To non-patients at contract pharmacies.
- For prescriptions written at ineligible sites by ineligible providers
- Not supported by a medical records
- To inpatients

Duplicate discounts – What we've seen…

Our experience

- Non compliance activity can be identified with detailed Medicaid line item level submission data (claims level detail)
- High potential for error relative to duplicate billing
- Incorrect designation of carve in/carve out status
- Multiple potential points of failure – chargeback with covered entity, rebate with state Medicaid agency, maintenance of information in exclusion file.
- Covered Entity was:
  - Billing Medicaid contrary to information included in the Medicaid Exclusion File
  - Dispensing 340B drugs to Medicaid patients by contract pharmacy, absent arrangement to prevent duplicate discounts.
  - Submitting claims:
    - Without state required NPI numbers.
    - Which were incorrectly coded when provided to the state
    - Without state required UD modifier.
  - Incorrectly listing offsite outpatient facilities on Medicaid Exclusion File.

HRSA Findings

Prevent duplicate discounts. 42 USC 256b(a)(5)(A)(i) prohibits duplicate discounts; that is, 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 OPA database

340B Drug Discount Program – The Solution

- **Policy and Procedure Review** – Conduct and assessment of your programs policies and procedures compared to the 340B rules and regulations as well as industry best practices. Identify any potential gaps in controls that may be exposed under an audit conducted by HRSA.
- **Audit Readiness Assessment (Mock HRSA Audit)** – Conduct an annual audit readiness assessment of the provider 340B program operations.
- **Real Time Monitoring Technology Solution** – Implement a PwC designed web based technology that provides real time monitoring of key performance indicators to assist in identifying potential issues and mitigate risk to the program.

04

The Solution

340B Program Assessment – Options

- Fieldwork, Interviews & Testing
- Policies & Procedures
- Risks, Observations & Recommendations

Policy & Procedure Assessment

Highlights observations, compliance risks & recommendations for ongoing management of 340B Drug Discount Program

- Subject Matter Specialist (SMS)
- Deep pharmacist background
- Familiarity with HRSA & OPA regulations and audits

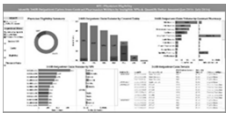
Audit Readiness/Self-Monitoring Program

Policies & Procedures, 340B Database, OPA Registration, Interview Questions, Sample Testing, Data Requests, and self-monitoring plan (i.e., monthly, quarterly)

- Data Infrastructure & Integration
- Data Visualization Tools
- Framework for Continuous Monitoring

Real Time Technology Solution

Data integration across disparate systems to facilitate drill-down sampling & testing. Eligibility, billing & compliance risk metrics are developed to enable continuous monitoring



Policy & Procedure Assessment
Focus Areas & Fieldwork

Program Governance

Assess 340B program oversight and management, analyze the 340B benefits and opportunities available to optimize 340B savings, and develop a self-monitoring protocol for the 340B program.

Covered Entity Eligibility

Confirm covered entity's 340B eligibility and accuracy of current registered information in the OPA website/database.

Drug Diversion

Assess the system and processes in place that prevent the dispensing of 340B drugs to non-340B patients.

Duplicate Discount

Assess the system and processes in place to prevent pharmaceutical companies from providing duplicate discounts.

Group Purchasing Organization ("GPO") Exclusion

Assess the system and processes in place to demonstrate compliance with the GPO exclusion requirement.

Maintaining Readily Auditable Records

Assess the accessibility of records to extract 340B transaction details, including patient demographics to support compliance/audit trail as expected by the OPA.

Audit Readiness Assessment & Self Monitoring

Data analytics and visualization can be leveraged to assess historical performance and overall program effectiveness. Risk metrics and models derived from the program assessment can be used to develop a continuous monitoring strategy to monitor compliance risk in real-time.

Program Assessment

- Integration of organization-wide data and normalization across disparate systems.
- Historical analysis of 340B Program costs, savings, and financial impact.
- Measurement of compliance and identification of process improvement opportunities

Continuous Monitoring

- Apply analytical models, thresholds, and alerts to daily files or real-time (HL7) data feeds.
- Monitor risk and compliance metrics across all Covered Entities and Contract Pharmacies.
- Optimize provider, pharmacy, supplier, and third party relationships.

Benefits

- Prioritization of high-risk areas
- Increased visibility across all Covered Entities & Contract Pharmacies
- Optimization of program compliance and maximization of savings
- Reduced risk of fines and sanctions by regulators and protection against costly reputational damage
- Improved data management, detailed audit trails, and more accurate reporting
- Automated anomaly detection and risk escalation

Audit Readiness Assessment & Self Monitoring Framework

The self-monitoring program can be used as a framework for continuous monitoring and ongoing testing. Data Visualization tools facilitate exception reporting, risk profiling, and proactive analysis of high-risk trends.

Sample Testing for Hospital-based 340B Operations		
		SAMPLES
Drug Diversion		1 2 3
Patient Eligibility	Medical encounter is documented (Medical record)	
	Patient is outpatient vs. Inpatient (Only outpatients are eligible for 340B	
Provider Eligibility	Provider is responsible for the medical services and maintains medical	
	Provider is employed, contracted or has an agreement with the healthcare facility	
Clinic Eligibility	Patient was seen in a clinic or section of the hospital that is a reimbursable cost center on the most recently filed Medicare Cost report (Above line 118) (Exceptions can be in a form of a medical referral from the covered entity primary care provider)	
Duplicate Discount (Applicable to Medicaid transactions: Obtain a copy of the State Medicaid 34		
Medicaid Carve-in	entity to bill at acquisition cost (340B prices), then verify with accounting/finance that the covered entity billed prescription/transaction as indicated	
	Verify with the OPA database that the service location/pharmacy (NPI/Medicaid Number) is in the Medicaid Exclusion File	
	Optional: Call State Medicaid and verify that a rebate was not requested from the drug manufacturer on the Medicaid prescription/transaction	
OR		
Medicaid Carve-out	Verify that the covered entity bought drug using a WAC pharmacy account to dispense a Medicaid prescription/Transaction (Applicable to DSH 340B covered entities)	
GPO Exclusion (If applicable to covered entity)		
WAC Accounts	Verify the existence of WAC accounts. Interview purchaser on how hospital complies with the GPO exclusion	

- Analyze the **entire data population**
- Develop a **streamlined and risk-based approach** to recurring testing
- Design metrics to adapt to **emerging compliance risks**

Example: Patient received healthcare services from clinics reimbursable on the hospital's most recently filed Medicare cost reports (and registered on the OPA database, for sites outside the hospital's premises)

- ***Identify** Reportable Data Fields (clinic location)*
- ***Validate** Compliance through Continuous Monitoring*
- *Enable **Exception Reporting** & Profiling (by Contract Pharmacy, Provider, Location)*
- ***Prioritize** High-Risk Trends & Anomalies*

Policies & Procedures | Annual and Quarterly Assessments | OPA Registered Information | Software & Third Party Vendors | Contract Pharmacy & Supplier Relationships

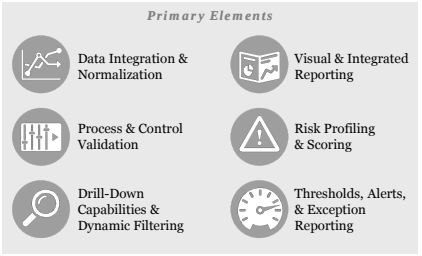
Audit Readiness Assessment & Self Monitoring Framework (continued)

340B Program Management

- Policies & Procedures
- Interview Questions
- Data Sources & Centralized Reporting
- Information Registered on OPA Website
- Custom Dashboards for Key Stakeholders, Locations & Departments
- Risk Scoring & Profiling
- Data-Driven Testing & Detailed Follow-Up
- Drill-Down Control Testing & Reporting
- Resource Allocation & Compliance Program Effectiveness
- Track Drugs from Order to Administration
- Portals, External Links & Knowledge Share
- Risk, Test & Control Matrix

Internal Data

- Registered/Eligible NPIs & Locations
- Data Quality, Completeness & Accuracy
- Matching of Encounter, Utilization & Prescription Files
- Prescription Written-Filled Window
- High Volume & Cost (i.e., Payer, Location,)
- 340B vs. GPO vs. WAC Costs
- Modifiers (i.e., UD, U8)
- Chargemaster (CDM) to National Drug Code (NDC) Crosswalk
- Variation in Utilization & Cost by Physician



External Data

- *OIG Enforcement & Exclusion Database* – Identify prescriptions written by physicians on OIG Exclusion List
- *OpenFDA* – Continuously monitor Adverse Events, Recalls, and Labeling to proactively address high-risk drugs
- *National Drug Code (NDC) Directory* – Validate Accuracy NDC Allocation

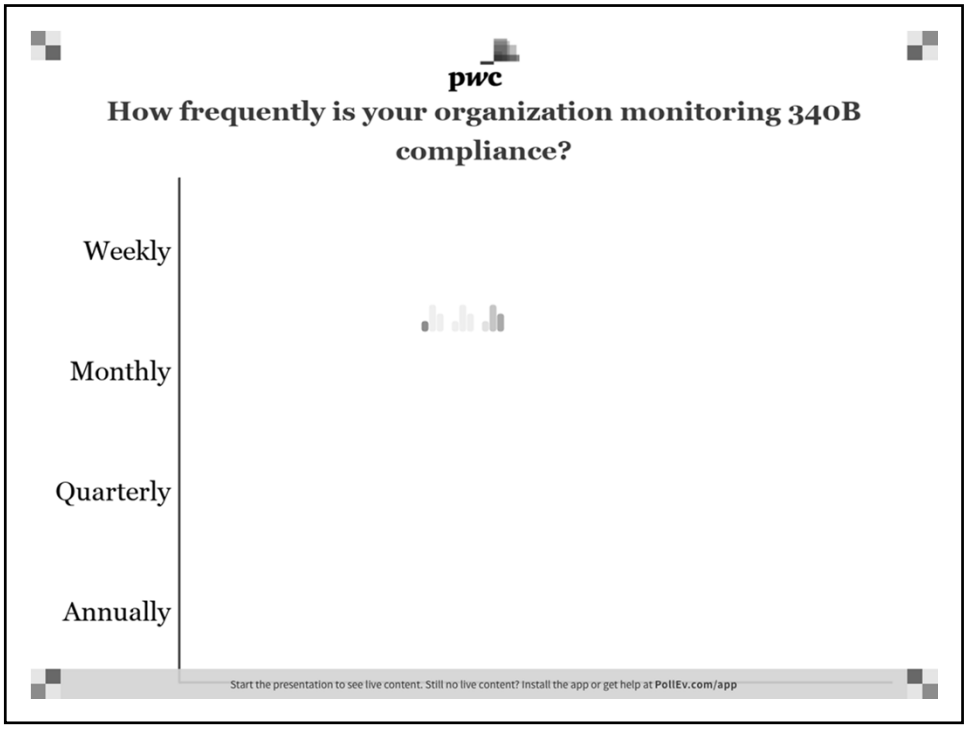
BREAK – 15 minutes

Eat something, you're hungry

Call your kids, they're misbehaving

Yeah you can probably fit in a few hands at the black jack table if you hurry

You will be called on when you get back, be afraid, be very afraid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How frequently is your organization monitoring 340B compliance?
Weekly
Monthly
Quarterly
Annually
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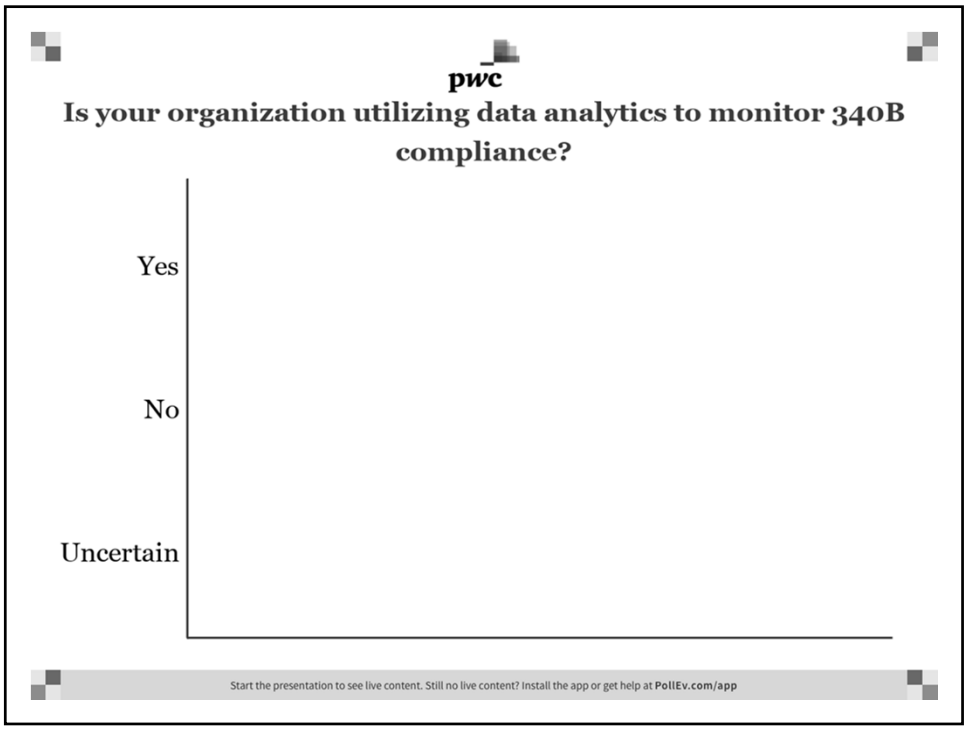
pwc
Is your organization utilizing data analytics to monitor 340B compliance?
Yes
No
Uncertain
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340B Drug Discount Program - The Value

- Mitigate risk of potential adverse findings (under manufacturer or HRSA Audit) related to non-compliance with program terms
- Protect the financial benefits derived from participation in the 340b Discount Program
- Ability to quickly escalate high-risk trends in order to optimize compliance and maximize savings derived from 340B drug purchases.
- Custom dashboards are leveraged to quantify savings and maximize benefits through the 340B Drug Discount Program.
- Insights gained from analytics help providers increase visibility, reduce risk, and streamline program improvement initiatives.

05
The Value of Compliance

Why build Continuous Monitoring for 340B?

01
The Challenge

- **Remain compliant** with 340B program to **minimize risk of OPA sanctions and repayments to Manufacturers**
- Manage a **scalable compliance program** as the organization continues to grow (e.g. # of Covered Entities, # of Contract Pharmacies)
- Develop a continuous monitoring solution that can **automate compliance while optimizing cost savings**

02
The Opportunity

- **Cost-savings**: Identify additional 340B replenishment opportunities from mismatched patient and/or physician names
- **Reduce Risk:** Identify and remediate potential 340B non-compliance related to drug/product diversion, duplicate discounts and/or GPO prohibition
- **Validate system configuration:** Ensure split-billing software is configured to appropriately classify dispensed drugs as eligible 340B transactions

03
The Benefits

- Improve risk management from **automated continuous monitoring for 100% of transactions**
- **Save money** due to missed 340B replenishment opportunities
- **Reduce** the number of **dedicated FTEs** required to maintain compliance with 340B program
- Access to **customized and interactive dashboards** highlighting key risks and trends across all Covered Entities and Contract Pharmacies within the hospital network

Real Time Technology Solution – Leveraging Data Analytics & Visualization

Given the complexity and fragmentation of data sources relevant to the 340B Drug Discount Program, it is essential for providers to utilize advanced analytics and visualization tools in order to enhance visibility and proactively address high-risk trends across the organization.

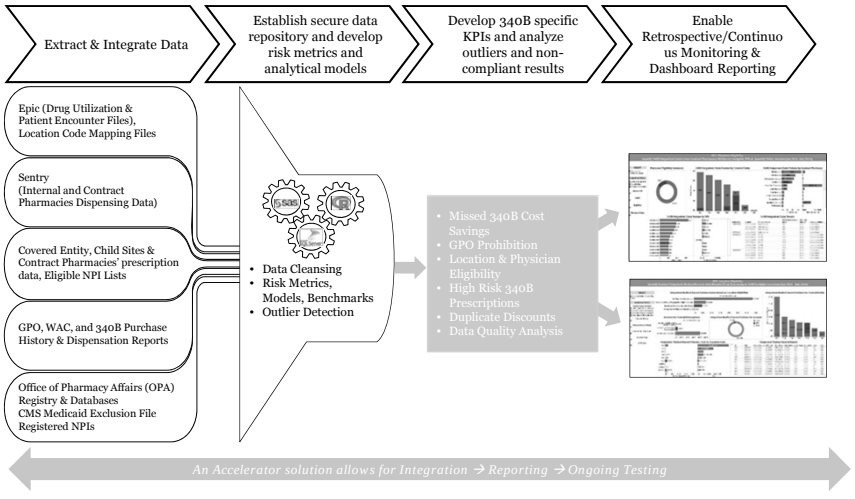
Continuous Monitoring → *Data-Driven Insights* → *Actionable Intelligence*

Primary Elements

- Data Integration & Normalization
- Visual & Integrated Reporting
- Process & Control Validation
- Risk Profiling & Scoring
- Drill-Down Capabilities & Dynamic Filtering
- Thresholds, Alerts, & Exception Reporting

- **Integrate** data from disparate data sources across all entities
- **Analyze** cost and billing patterns, effectiveness of split-billing software, and other IT systems relevant to the 340B program.
- **Identify** root causes of diversion (site/patient eligibility and dual coverage) and duplicate discounts (carve-in, carve-out, contract pharmacy)
- Dynamically **visualize** 340B drug costs and savings across all Covered Entity and Contract Pharmacy locations.
- **Extrapolate** localized findings across the entire data population

340B Insights Analytics Solution – Data Flow



Ways to Manage Highest Risk Areas Using Data Analytics

Compliance

Objective: Allowing providers to assess compliance with the 340B Drug Discount Program on an on-going basis

Compliance Related Dashboards:

- Potential Drug Diversion due to Physician Ineligibility
- Potential Drug Diversion due to Location Ineligibility
- Potential High Risk 340B Prescriptions
- GPO Prohibition
- Duplicate Discounts

Objective: Identification of potential additional 340B replenishment opportunities

Operational Dashboards:

- Assessment of Prescription Aging Algorithm (Prescription Qualification Window)
- 340B Eligible Physician Prescribing Metrics

Operational

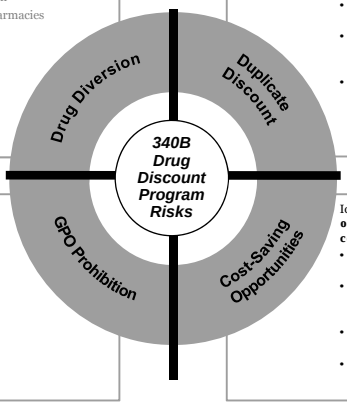
Example Findings from Recent Engagements

Diversion resulting in **non-compliance** due to the following:

- Physician ineligibility
- Errors in split-billing software configuration
- Inaccurate data received from Contract Pharmacies
- Outdated physician roster list
- Location code discrepancies in split billing software data and Medicare cost reports

Duplicate discounts resulting in **non-compliance** due to the following:

- Outdated Medicaid Exclusion File containing incorrect NPIs
- List of Carve-In NPIs not updated to reflect only "Active" or "Participating" Sites maintained by Covered Entity
- New "child site" Covered Entities within the network which have not been properly registered



GPO Prohibition non-compliance due to the following:

- Purchases made on GPO account for outpatient only sites/clinics
- GPO purchase volume higher than inpatient drug dispensing at mixed used sites/clinics

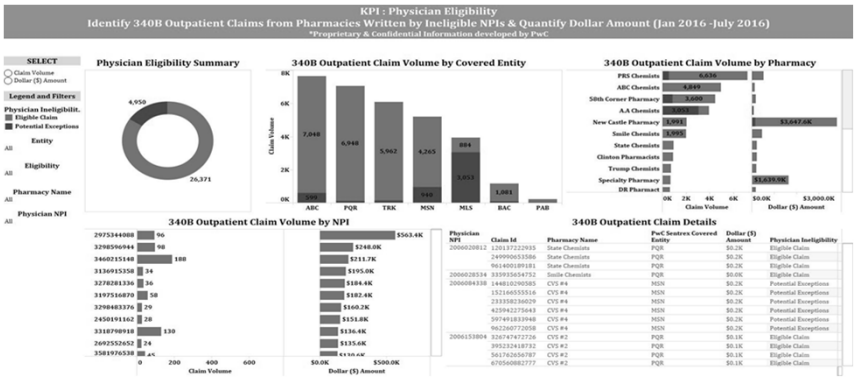
Identification of **lost 340B replenishment opportunities** resulting in potential **cost-savings:**

- Assessment of ineligible prescriptions classified by split-billing software
- Contract Pharmacies with prescriptions filled after established thresholds of # days since patient encounter
- Nuance differences between Covered Entity data and Contract Pharmacy data
- Eligible Physician not included and/or updated timely in split-billing software

Example Dashboards

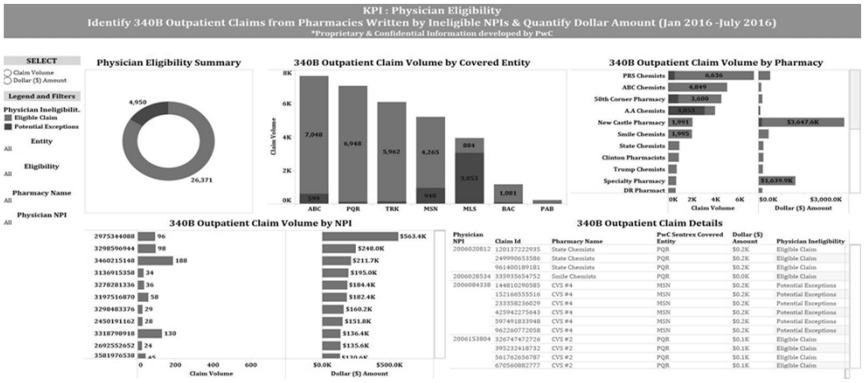
Physician Eligibility

Description of key focus area	Potential benefit
• Identify 340B outpatient claims from contract pharmacies written by ineligible physicians leading to potential drug diversion issues • Identify potential repayments to pharmaceutical manufacturers due to 340B claims written by ineligible physicians	• Identification of potential drug diversion due to physician ineligibility, thus improving compliance • Decreased repayments to Pharmaceutical Manufacturers for scripts written by Ineligible Physicians



High Risk 340B Prescriptions

Description of key focus area	Potential benefit
• Identify high risk 340B prescriptions filled at contract pharmacies	Identify potential drug diversion issues caused due to patient ineligibility at contract pharmacies
• Text Analytics to match patient attributes from patient encounter data and pharmacy data	Identify split billing software limitations with regards to determining patient eligibility



Questions?

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Ryan is a partner with PwC with more than 15 years of experience in healthcare industry and consulting experience working with many of the leading payers and providers across the country. He is a strategic adviser with the ability to outline enterprise data vision supported by strong ROI from tactical data integration projects. He has a history of success at executive level of hospitals, IDN's, AMCs and Health Plans. He has successfully designed and implemented solutions that automate the collection, transformation and presentation of healthcare metrics reducing the cost of data collection and enhancing the value of reporting and analysis.

Tim Krzeminski
Director
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Tim is a Director in PwC's Healthcare Compliance practice with over 13 years of experience specializing in the execution of value-added assessments and monitoring activities across all lines of Healthcare Providers, Pharmaceutical Manufacturers, and their third-party vendors. He is a subject matter specialist in 340B Compliance working with both healthcare providers and pharma manufacturers. Tim has developed and implemented 340B Compliance monitoring programs utilizing data analytics and performed multiple 340B Covered Entity Assessments for providers as part of the proposed annual audit requirements and/or in preparation for HRSA audits. He has also participated in multiple meetings with Captain Pedley and the OPA to discuss content of 340B audit work plans and audit results, spoken about 340B program integrity at multiple conferences including Government Pricing Conferences, the 340B Coalition, and 340B University. Tim has also conducted multiple webinars and authored several whitepapers and blogs on various topics related to 340B program integrity. Tim is a Certified Fraud Examiner, Certified Internal Auditor, and is Certified in Risk Management Assurance.

Policy & Procedure Assessment
Focus Areas & Fieldwork

Program Governance

Assess 340B program oversight and management, analyze the 340B benefits and opportunities available to optimize 340B savings, and develop a self-monitoring protocol for the 340B program.

Covered Entity Eligibility

Confirm covered entity's 340B eligibility and accuracy of current registered information in the OPA website/database.

Drug Diversion

Assess the system and processes in place that prevent the dispensing of 340B drugs to non-340B patients.

Duplicate Discount

Assess the system and processes in place to prevent pharmaceutical companies from providing duplicate discounts.

Group Purchasing Organization ("GPO") Exclusion

Assess the system and processes in place to demonstrate compliance with the GPO exclusion requirement.

Maintaining Readily Auditable Records

Assess the accessibility of records to extract 340B transaction details, including patient demographics to support compliance/audit trail as expected by the OPA.