

The Art of combining Data Analytics and Compliance Monitoring: 340B Revealed

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Objectives

- Establish a base for what data analytics is, and how to effectively implement them across the audit and compliance spectrums
- Demonstrate how enhanced ROIs can be achieved by leveraging analytics to continuously monitor your 340B program

Parting thought...

If you're still sampling for 340B audits, you could be leaving millions of dollars on the table.

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What is Data Analytics?

- What you may have heard before...
- Data analytics is the process of **identifying, gathering, validating, analyzing** and **interpreting** various forms of data using computerized tools to provide **meaningful intelligence** to clients.



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Data Analytics in the Audit & Compliance Cycles

	Historical Analysis	Audit Planning	Continuous Monitoring
Analysis Principals	<p>An analysis of risk, audit and issues data backward looking</p>	<p>Analysis of principals coverage against risks and audit plan</p>	<p>Key areas to monitor going forward for the audit organization</p>
Key Questions	<ul style="list-style-type: none"> • What is historical distribution of risk and audit coverage? • Are there patterns in issues between geography and risk? • Is there a correlation between number of issues and hours spend in business lines of an audit? 	<ul style="list-style-type: none"> • What is the current risk and audit coverage distribution? • Are there historical areas with high number of issues and low coverage? • Are there opportunities to shift coverage based on risks? 	<ul style="list-style-type: none"> • What key metrics should be monitored in this area going forward? • How should these metrics be trended and alerted for actions? • What type of actions should be taken?

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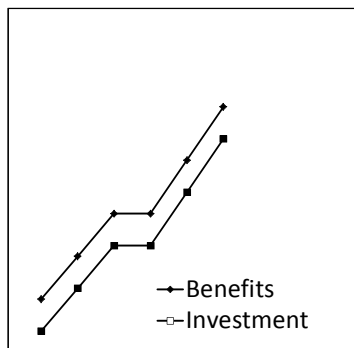
Data Analytics Examples

- University of Tennessee has a losing football season ➡ • Butch Jones might be looking for a new head coaching job
- Service Code 36821 has \$0.00 YTD charges ➡ • Was there an error with how this code was set up?
- Charges for aspirin totaled \$2,000,000 for October 2016 ➡ • Something is wrong!

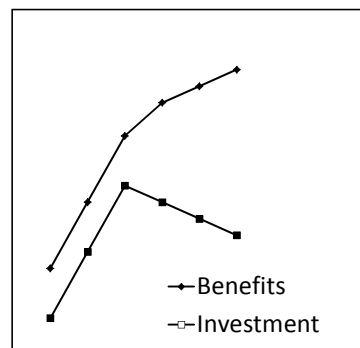
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The Data Analytics ROI

Traditional Auditing
Infrequent use of analytics



Analytics Enabled Auditing
Consistent use of analytics



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340B Compliance Monitoring Utilizing Data Analytics

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340B Drug Discount Program Overview

<p style="text-align: center;">Background</p> <ul style="list-style-type: none"> • Created in 1992 to help poor and uninsured populations • Requires drug manufacturers to provide outpatient drugs to eligible healthcare providers at significantly reduced prices 	<p style="text-align: center;">Eligible Providers</p> <ul style="list-style-type: none"> • Disproportionate Share Hospitals • Children's Hospitals & Cancer Hospitals • Sole Community Hospitals • Rural Referral Centers • Critical Access Hospitals 	<p style="text-align: center;">Key Components</p> <ul style="list-style-type: none"> • Covered Entities (CE) and Contract Pharmacies (CP) • 340B database • Billing modifiers • HRSA/OPA Program Integrity audits • Eligible providers and locations
<p style="text-align: center;">Challenges</p> <ul style="list-style-type: none"> • Disparate systems • Lack of oversight • Quantifying benefits • Monitoring eligibility • Integrating pharmacy & hospital data • Resource allocation 	<p style="text-align: center;">Key Risks</p> <ul style="list-style-type: none"> • Drug diversion • Duplicate discounts • OPA registration • GPO prohibition • Medicaid exclusion • Orphan drugs • Overpayments & repayments 	<p style="text-align: center;">Leading Practices</p> <ul style="list-style-type: none"> • Split-billing vendors (i.e., Sentry, Macro Helix) • Mock recurring audits • Data Analytics • Executive engagement • Engagement with state agency

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Most Recent Regulatory Updates

- The Health Resources and Services Administration (HRSA) on Aug. 28, 2015, released its proposed Omnibus Guidance on the 340B Drug Pricing Program
- Significant proposals from the provider perspective include:
 - Proposed changes to the definition of "patient"
 - Proposed changes to the scope of the definition of "covered outpatient drug"
 - Stronger oversight requirements
 - Proposals to address the prevention of duplicate discounts on drugs furnished to Medicaid managed care patients
 - Covered entities are "expected to" conduct quarterly reviews of contract pharmacies' 340B dispensing records and should reconcile such records against the covered entity's records to ensure there have been no diversions or duplicate discounts.

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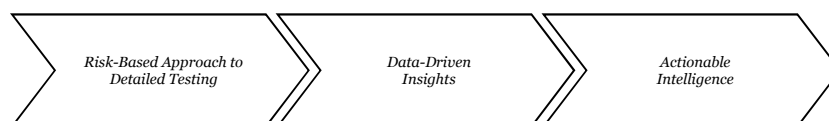
Why Data Analytics, Why Now?

- Increased congressional reform and regulatory oversight
- Annual increases in Office of Pharmacy Affairs Audits and manufacturer initiated audits
- 800% growth in purchases over the last decade
- Mandatory self monitoring and annual third party audits
- Affordability of technology, and availability of data, to support proactive transaction monitoring vs. reactive sampling
- Significant opportunities to increase audit coverage, optimize compliance and maximize savings
- Ability to identify potential root causes of diversion and/or double dipping events and institute controls for the long term

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How are providers managing 340B Compliance?

- Covered Entities can leverage **data analytics** to enhance their 340B compliance programs through:
 - Audit readiness / deep dive assessments
 - Self monitoring programs
 - Continuous monitoring solutions
 - Opportunity analyses



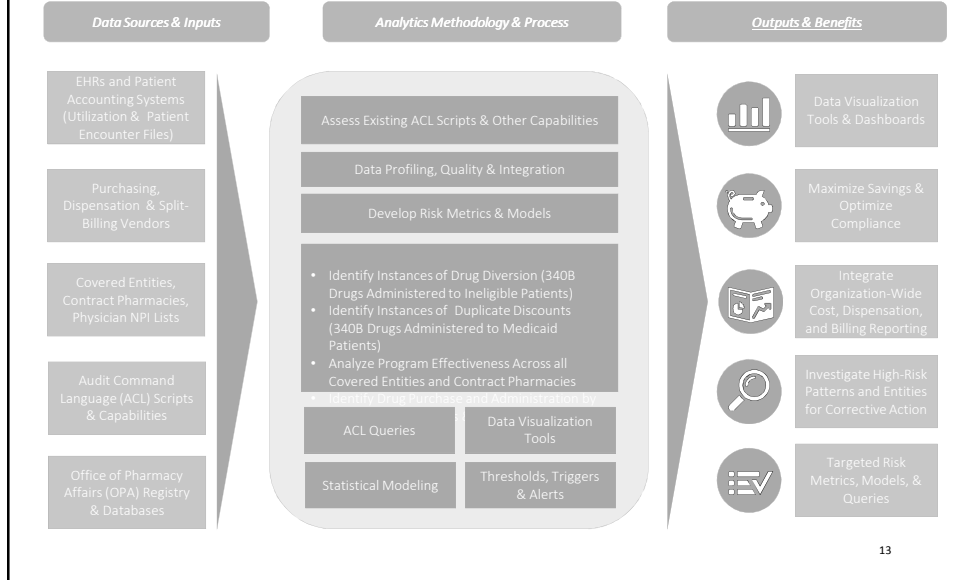
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340B Analytics & Visualization

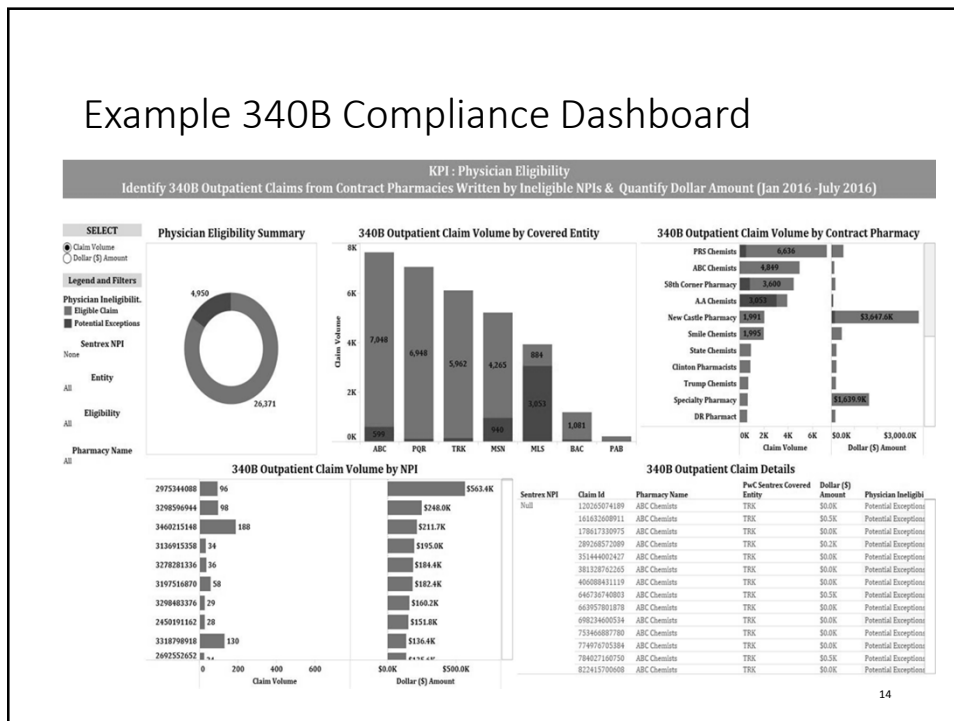
- **Integrate** data from disparate data sources across all entities (encounter, utilization, purchasing, dispensing)
- **Analyze** cost and billing patterns, effectiveness of split-billing software, and other IT systems relevant to the 340B program.
- **Identify** root causes of diversion (site/patient 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.
- Eliminates the need to **extrapolate** localized findings from detailed testing across the entire data population

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Inputs & Outputs



Example 340B Compliance Dashboard



Key Benefits of Utilizing Data Analytics for Managing 340B Compliance

- Data analytics is a tangible capability that, when implemented effectively, can drive significant audit coverage, and business value
- Allows the Covered Entity to review 100% of transactions instead of random sampling
- Enables compliance monitoring of all transactions, while decreasing the costs of compliance
- Ability to identify transactions where 340B replenishment opportunities were potentially overlooked

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Questions?

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