DEVELOPING AND IMPLEMENTING A 340B PROGRAM COMPLIANCE AUDIT PLAN

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Agenda

- 340B program overview
- Illustrative risk universe and current program landscape
- HRSA and manufacturer audit overview
- Review of internal controls to address program risks
- Considerations for a 340B audit plan
- Taking corrective action: disclosures and repayment
- Closing
- Q&A

Session objectives

- **Review** and understand 340B program history and requirements
- **Learn** about the current landscape of the 340B Program and associated risks
- **Review** elements of a 340B compliance audit program
- **Gain** perspective on applicable internal controls to address program risks

Opening Comments and Perspectives

Auditing vs. monitoring

Monitoring

- Typically defined as activities performed on an **on-going basis**, to measure and detect potential issues of non-compliance as defined by policies, procedures, and standards.
- Performed by department personnel with direction from management who is responsible and accountable for the process and data being measured.

Auditing

- Typically defined as activities performed on a **scheduled basis** to measure and detect observations of non-compliance as defined by policies, procedures, and standards.
- Performed by third parties within or at the direction of the organization (e.g. other departments within the covered entity such as Internal Audit, Compliance, or contracted consultants).

- Monitoring may use some or many of the same tools and techniques deployed in an audit, but
- Monitoring is not auditing, primarily because:
  - Monitoring activities are reported through the management responsible for the operations being monitored.

Auditing vs. monitoring

- While Consisting of Similar Tasks, Auditing and Monitoring are:
  - Separate Concepts
  - Separate Activities
  - Performed by Different Professionals
  - With Different Outcomes
  - And Different Audience Expectations

- Auditing and Monitoring convey and represent different levels of independence.
  - They are not a combined concept as may be inferred from the Federal Sentencing Guidelines and OIG Compliance Program Guidance.
  - Report Accordingly to your Board.
- The Compliance and Internal Audit Functions have similar reporting and accountability structures in serving the Board, but their roles and responsibilities are very different.
- Management is responsible for compliance and controls; corporate compliance and internal audit are not.

340B Program overview

340B Program overview

- The 340B program requires drug manufacturers to provide outpatient drugs to qualified and participating healthcare organizations at significantly reduced prices
- The 340B Program provides the deepest discount on pharmaceuticals in the country, trailing only the Department of Defense and Veterans Healthcare Administration contracts
- Up to 2,048 hospitals and health systems participated as covered entities in 2014[2]
- 340B Entities accounted for over **$7 billion**[1] in drug spend in 2013, roughly **2%** of total spend across the United States

The **Veterans Health Care Act of 1992** requires pharmaceutical manufacturers whose drugs are covered by **Medicaid** to provide discounts on outpatient covered drugs purchased by specific public health services that serve the nation's most vulnerable patient populations.

The program has come under increasing levels of scrutiny since its **expansion after the PPACA in 2010.**

The OIG previously filed reports indicating **inconsistent operational practices** across covered entitles and **limited oversight** by HRSA.

HRSA has attempted to issue formal guidance in the past; however, the guidance left many unanswered questions and "gray" areas.

HRSA released omnibus guidance in August 2015 in an attempt to **clarify existing policy** and provide a framework for program audit & enforcement.

[1] Source: http://www.medpac.gov/documents/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0

[2] http://www.pharmacypracticenews.com/Article/PrintArticle?articleID=27580

340B Program overview

Diversion	Covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity
Duplicate Discount	Covered entity is prohibited from accepting a discount for a drug that would also generate a Medicaid rebate to the State.
GPO Exclusion	DSH hospitals, children's hospitals, and free-standing cancer hospitals may not obtain covered outpatient drugs through a GPO or other group purchasing arrangement.
Orphan Drugs	Free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals may not purchase selected rare disease drugs at 340B prices.

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Illustrative 340B Program risk universe

Inventory Management

- Multiple distribution channels
- Drug shortages
- 340B replenishment variability
- Inventory swell and reduced turnover
- Tracking, monitoring, and auditing of inventory
- Non-contract spend volatility
- Accurate fulfillment of prescription orders
- Accuracy of electronic product tracking information (tracking and pedigree)
- Reconciliation of medication transfers (i.e. borrow/loan)

Dispensing

- Drug diversion to non-340B patients
- Clarity and consistency of 340B "patient definition"
- Drug Enforcement Administration (DEA) compliance
- State Board of Pharmacy Regulations
- Replenishment/virtual inventory models
- Uninsured/Charity programs
- Reconciliation of return-to-stock medication
- Patient freedom of choice
- GPO purchasing compliance

Covered Entity/ Vendor Partnership

- High software costs
- Third-party vendor sophistication and performance
- Vendor selection
- Operational contractual terms
- Patient Health Information exchange/data breaches
- Reliance on third-party software systems
- Reliance on third-party product tracking information

Technology

- Complexity and variability of hospital IT systems
- Data Integrity
- Interface issues between hospital and vendor systems
- Downtime procedures
- Billing errors and data loss
- Software maintenance activities

Billing & Reimbursement

- Medicaid carve-in/carve-out
- Managed Medicaid billing compliance
- Reimbursement/Coverage Shifts due to 340B volume
- Payment Collection processes
- Medicaid Payor verification and management
- Payer Auditing Activity
- Variability of 340B prices
- Losses incurred on high-yield prescriptions
- Facility eligibility – integration with Medicare Cost Report

Legal/Regulatory/ Corporate Compliance

- 340B Omnibus Guidance
- DEA Tracking and Pedigree regulations
- MEDPAC cost-sharing recommendation
- Anti-Kick Back regulations
- Patient Records Management/Retention
- Litigation and Dispute Res.
- Antitrust
- Contract compliance
- HRSA, Manufacturer audit requests
- Public disclosure of audit results/reputational risks
- OIG Investigations
- 340B Registration

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Regulatory updates

340B regulatory landscape

MedPac recommendations

The Medicare Payment Advisory Commission backed a controversial proposal to reduce Part B drug payment rates for hospitals participating in the 340B Drug Pricing Program

340B Omnibus Guidance

In 2016, HRSA plans to release final guidance for covered entities enrolled in the 340B Program and drug manufacturers that are required by section 340B of the PHSA to make their drugs available to covered entities under the 340B Program[1]

New regulations

In 2016, HRSA plans to release new regulations related to administrative dispute resolution, civil monetary penalties, and ceiling price calculation.

Contract pharmacies

OIG-issued report in 2014 highlights complications with preventing diversion and inconsistent approaches among covered entities. However, contract pharmacies have continued to expand, including specialty pharmacy programs

Provider-based rules

Changes in provider-based reimbursement and provider-based status may impact 340B registrations

Medicaid

OIG calls for increased transparency of claims. New Managed Medicaid rules set to go into place next year.[2]

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[1]Source: https://www.federalregister.gov/articles/2015/08/28/2015-21246/340b-drug-pricing-program-omnibus-guidance
[2]Source: https://oig.hhs.gov/oei/reports/oei-05-14-00430.asp

Spotlight: Medicaid billing

There have been **increases in state inquiries** relative to potential duplicate discounts

Contract Pharmacy

- HRSA reiterates that contract pharmacies will not dispense 340B drugs to Medicaid Fee-For-Service (FFS) or Managed Care Organizations (MCO) patients (i.e., will be "carve-out"), unless the covered entity obtains Department of Health and Human Services (HHS) approval on a written agreement that describes a system to prevent duplicate discounts.

Medicaid Managed Care

- The guidance adds further complexity in an attempt to prevent Managed Medicaid duplicate discounts. The guidance allows Covered Entities to choose a different carve-in/carve-out election for MCO vs. FFS as well as different elections by covered entity site and by MCO. It also doesn't explicitly require the carve-in/carve-out elections to be made available publicly through the 340B Medicaid Exclusion File.

340B Medicaid Exclusion File Changes

- HRSA does not propose new mechanisms beyond the existing Medicaid Exclusion File to track and prevent Medicaid duplicate discounts.

Spotlight: Specialty pharmacy

Market Consolidation and Competition: Similar to other areas in the healthcare industry, the specialty pharmacy market continues to see growth in mergers and acquisitions. At the same time, larger healthcare organizations continue to evaluate operating health system owned full-service specialty pharmacies.

Complex Regulations: 340B regulations have been in flux over the past few years. This combined with the vendor inefficiencies has potentially contributed to the slow growth of 340B specialty programs. Over the years, The industry has seen more products migrate to the specialty distribution channel; however, 340B specialty program implementations have stalled due to uncertainties surrounding program costs, regulatory scrutiny, and operational challenges.

Increased Drug Spend: Spending on specialty medicines has nearly doubled in the past five years, contributing more than two-thirds of overall medicine spending growth between 2010 and 2015. Increased specialty spending was driven primarily by treatments for hepatitis, autoimmune diseases and oncology, which accounted for $19.3 billion in incrementalspending.[1] Specialty medication costs are expected to reach $192B in 2016 and quadruple to over $400B by 2020.[2]

[1]Source: IMS Health Study: U.S. Drug Spending Growth Reaches 8.5 Percent in 2015
[2]Source:Specialty pharmacy: A unique and growing industry, American Pharmacists Association, Jul 01, 2013

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Latest developments

Unclear if 340B will be addressed in 2016

- HRSA has proposed dates; however the desire to avoid controversial debates and legislation in election year
- New make-up of Congress in 2017

Potential actions in 2017

- 340B likely to be discussed next year in Congress. Greatly different views on what changes are needed.
- Program has bipartisan support

HRSA faces questions on Audits

- HRSA has indicated publically that the organization is auditing against current rules and are not proposed guidelines from the Omnibus Guidance
- HRSA has also indicated that certain manufacturers are sending audit-like letters to covered entities (HRSA must formally approve any manufacturer audit)
- HRSA stated there is no "statute of limitations" for manufactures to come back with payment request

Additional updates

- HRSA continues the stance that its 340B rules apply only to Fee-for-Service Medicaid do not apply to Managed Medicaid.
- Medicaid agencies have until April 2017 to develop policy for Medicaid 340B compliance.
- Differing interpretations regarding the 340B impacts of the CMS off-campus provider-based payment ruling.

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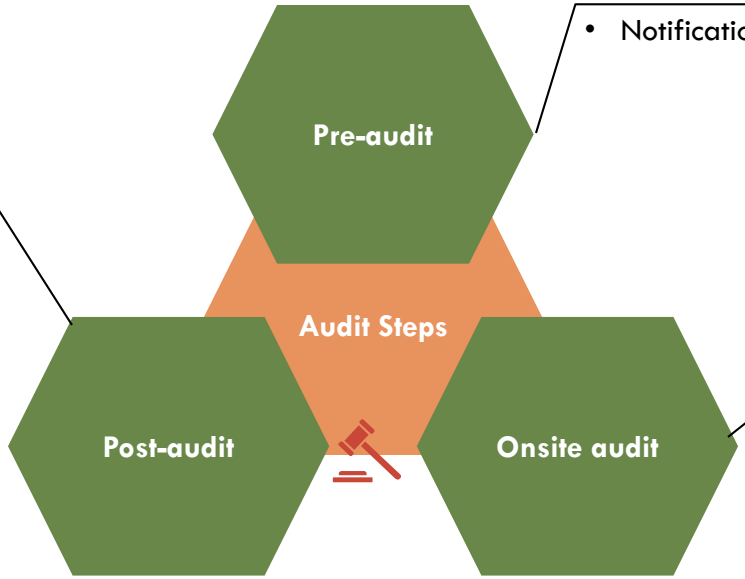
HRSA and manufacturer audits

HRSA and manufacturer audit overview

HRSA has the authority to audit covered entities for compliance with 340B Drug Pricing Program (340B Program) requirements (42 USC 256b(a)(5)(C)) and has done so for the past 3 years

- Notification letter from HRSA



- Auditors provide preliminary issues to OPA
- OPA reviews issues found during audit, documents, and addresses concerns
- Entity presents corrective action plan to HRSA
- Results are preliminary until reviewed by OPA
- OPA finalizes report, posts summary on website

- Auditors obtain, review, examine data
- Exit interview, preliminary issues

HRSA Focus Areas:

- 340B Eligibility: 340B registered sites, physician list and eligible patients
- GPO exclusion
- Drug diversion
- Duplicate discounts
- Contract pharmacy compliance
- Contract pharmacy: tracking prescriptions to ensure they originate at an eligible site
- Infusion Centers: validating patient and provider encounters
- Providers: scrutinizing credentialing relationships

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

HRSA and manufacturer audit overview

There have been **increases in manufacturer inquiries** to covered entities

- On-site logistics and documentation requests
- Sample interview topics:

  - Identification of eligible patients and providers
  - Use of 340B drugs and testing for potential diversion.
  - Transfer of drugs between 340B and non 340B sites
  - Medicaid (carved in/out) specific to your state
  - Who does the splitting and how often?

✓	340B policies and procedures with a list of the hospital's 340B clinics
✓	Most recently filed Medicare Cost Report (worksheets S, A, C, and E)
✓	Listing of providers eligible to make 340B drug orders or prescriptions
✓	Listing of 340B purchase orders (PO) made in the six-month period
✓	340B drug orders and prescriptions over a six-month period
✓	Contact with state agency
✓	Listing of any Contract Pharmacies and of location of all 340B drugs

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

HRSA and manufacturer audit overview

Data is analyzed for anomalies and trends, to identify events such as:

Event:	Identified by:	Could indicate:
Spikes in 340B purchases by a covered entity	Analysis of covered entity's chargeback data over time	Diversion
Sustained above average 340B purchase growth rate by a covered entity	Comparison of 340B chargeback growth rate of a covered entity over time against the mean market 340B chargeback growth rate	
Unexpected proportion of 340B purchases to non-340B purchases by a covered entity	Comparison of the 340B chargeback to non-340B sales ratio of a covered entity	
Manufacturer invoiced for Medicaid rebates related to a covered entity that is designated as "carve-in"	Comparison of Medicaid rebate data against the Medicaid exclusion file	Duplicate discounts

- The manufacturer may reach out to the covered entity by letter, phone or email
- Monitoring dialogue may include efforts to:
  - See if the covered entity has a reasonable explanation for identified anomalies and trends
  - Request information and data from the covered entity to compare against manufacturer's data
  - Confirm any cases of diversion and/or duplicate discounts
  - Resolve issues by determining root cause(s), corrective action, and repayment amounts, as applicable

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

HRSA and manufacturer audit overview

The current HRSA audit process sample selections and testing

Sample selection

- For both hospital drug orders and contracted pharmacies (total of 50-100 patient records for each)
- Sample sizes will vary based on size and complexity of the covered entity
- Original list of 25-50 samples of patient records with 340B drug use and replenishment
- Spare list of 25-50 samples
- Additional samples from the top five high use drugs or controlled substances may be requested

Testing

- Tracer a sample of individual medication orders/scripts from dispensing or administration through to drug replenishment.

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

HRSA and manufacturer audit overview

- The table below shows the trend in HRSA audit results over time.

	FY12	FY13	FY14	FY15	FY16
# of Audits Posted	51	94	97	178	76
Findings	63%	78%	80%	75%	62%
No Findings	37%	22%	20%	25%	38%
Repayment	45%	64%	63%	57%	56%
Terminated Sites	0%	3%	3%	2%	1%
Terminated CPs	0%	1%	6%	8%	7%

- Common audit findings include:
  - Diversion issues
  - Duplicate discounts
  - Lack of oversight at contract pharmacies

* Year-to-date as of July 29, 2016

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

HRSA and manufacturer audit overview

- The table below shows the trend in audit results.

Issue	Occurrences	%
Diversion	42	55%
Incorrect 340B database record	28	37%
Duplicate Discounts	20	26%

* Year-to-date as of July 29, 2016

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

Considerations for a 340B independent audit plan

Developing an independent audit plan scope and approach

To provide audit guidelines for the performance of **an annual, independent** audit of the 340B program:

- Online tools available through Apexus
- Address the types of noncompliance that warrant a report to HRSA and/or a manufacturer, records kept, documentation, and plan for corrective action.

- Summarize all activities necessary to perform comprehensive review of 340B compliance at the client.

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Developing an independent audit plan scope and approach

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- How to develop an audit plan based on the new 340B Program guidelines:
  - The auditor will review the processes and internal controls currently in place related to the 340B Drug Pricing Program at 340B DSH Hospital determine the adequacy of the processes and internal controls.
  - Specify the facilities that will be included in the review.

The audit scope will include the following:
• Interview appropriate personnel to gain an understanding of 340B
• Review policies and procedures related to the 340B Program activities to determine whether they are sufficient and whether they support 340B DSH Hospital corporate objectives
• Review how 340B activities are documented and tracked
• Evaluate whether adequate internal controls are in place to monitor and track program compliance related to diversion, duplicate discounts, and GPO exclusion based on samples of patient claims data. Additionally, evaluate whether 340B DSH Hospital is in compliance with program registration requirements
• Review appropriate segregation of duties throughout the 340B program processes

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Illustrative controls to address program risks

The following key processes and sub-processes should be considered in designing relevant controls to effectively manage the 340B program:

Partnerships/ Contracting	Dispensing	Inventory Management	Reimbursement	Finance/ Accounting
Review/understand 340B audit requirements and develop a HRSA and manufacturer audit response plan with 340B covered entity	Education and evaluation of patient definition criteria	Development of 340B formulary	Manage automatic Invoice payment/approval	Periodic Reconciliation and recording of Cost of Good Sold (COGS) and Ending Inventory
Standardize contracts across vendors/covered entities	Periodic review of data transmission between 340B software and pharmacy switch	Development of alternative distribution models	Reconcile invoice price to reimbursement and covered entity dispensing fees	Development of accurate budgeting/forecasting tools that address 340B volume
Community Programs/Store-level engagement	Development of standardized 340B dispensing protocols	Perform routine inventory reconciliation and review 340B purchase history and dispensing data	Identification of excluded payors at go-live	Record and book accurate inventory cost and adjustments (shrink provision, physical inventory, returns, etc.)
Define pharmacy responsibilities in program operations	Develop consistent protocols relating to affected Federal/state regulations, including, but not limited to CMS, DEA, State Board of Pharmacy, etc.	Maintain Inventory Master file for accuracy and completeness	Analyze program performance and routinely monitor/ adjust dispensing fees and/or formulary	Maintain detailed records relating to program operations including but not limited the reporting required by regulations (e.g., quarterly billing statements, status reports of collections, receiving, and dispensing records)
Regularly review/update information on the HRSA 340B Database	Block FFS and MCO payor BINs and participate in retrospective claims analysis	Review/Understand and document compliance with Drug Supply Chain Security Act	Conduct periodic reviews of claims data for potential 340B diversion and/or fraudulent activity	Conduct targeted financial audit activities relative to 340B program performance
Enter into an agreement with a third party to maintain product tracking information	Develop processes to manage, track, and report on the 340B replenishment process	Contract with wholesale distributors to maintain electronic product tracking records for accuracy		

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340B independent audit plan scope

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Interview appropriate personnel to gain an understanding of 340B

	DETAILED PROCEDURES	Facilities	Performed By	Reviewed By
1.	Conduct interviews with program leadership to understand 340B Program governance and oversight as well as the existence of open-lines of communication between leadership and applicable program stakeholders	HOSPITAL 340B designated facilities	Internal auditor/internal audit manager	Internal audit manager
2.	Conduct interviews with stakeholders from eligible hospitals, clinics, and in-house pharmacies to understand 340B Program operations	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager
3.	Understand applicable controls in place relative to facility eligibility and registration; diversion, duplicate discounts, and the Statutory Prohibition on Group Purchasing Organization Participation	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager
4.	Conduct interviews to understand how the 340B software systems use configuration settings, including inpatient and outpatient status indicators stored in the Sentry software, to control against potential diversion and duplicate discounts	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager

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340B independent audit plan scope

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Review policies and procedures related to the 340B Program activities to determine whether they are sufficient and whether they support 340B DSH Hospital corporate objectives

	DETAILED PROCEDURES	Facilities	Performed By	Reviewed By
1.	Review training and education protocols within policies and assess whether the protocols are being completed and documented	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager
2.	Review 340B Policy to assess the existence of applicable standards related to facility eligibility and registration; diversion, duplicate discounts, and the Statutory Prohibition on Group Purchasing Organization Participation	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager
3.	Review operational procedures related to purchasing, Medicaid billing, and pharmacy operations and assess whether they are consistent with operational practice	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager

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Sample assessment areas

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- Does the health care organization have **written** 340B policies, procedures, or other related documents (i.e., desktop procedures)? Examples include:
  - ✓ Annual OPA recertification Enrolling/removing delivery sites
  - ✓ Updating/reading OPA database
  - ✓ Procurement/inventory management/dispensing; Internal control policy
  - ✓ Monitoring Program
  - ✓ Internal Audit (self-audit – independent of operations) and external audits
  - ✓ Taking corrective action
  - ✓ Designation of staff responsibility for 340B oversight/competency/training
  - ✓ Periodic review/update of 340B policies/procedures; auditable records
- Are staff **informed** and aware of existing policies?
- Do staff **adhere** to existing policies?

Sample policy and procedure components

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- **Patient eligibility:** The healthcare organization has an **established relationship** with the individual, as documented by the covered entity maintaining **records** of the individuals health care?:
  - Sample procedures:
    - Defining and documenting patient eligibility
    - Documenting and assessing patient eligibility sent to and received from contract pharmacies and split-billing software vendors
- **Provider eligibility:** The individual receives health care services from a health care professional who is either employed by the health center or under contractual or other arrangements (e.g., referral for consultation) such that **responsibility for care** provided remains with the health care organization:
  - Sample procedures:
    - Defining/documenting providers eligible to prescribe 340B drugs
    - Documenting referral arrangements
    - Providing/updating provider lists contract pharmacies

Sample policy and procedure components

FOR ILLUSTRATIVE PURPOSES ONLY

- **Duplicate Discounts:** The prevention of Duplicate Discounts for patients covered under Medicaid:
  - Posting/updating OPA **Medicaid Exclusion File**
  - Dispensing 340B drugs to Medicaid FFS beneficiaries
  - Dispensing 340B drugs to Medicaid MCO beneficiaries
  - Medicaid billing/reimbursement
  - Periodic review of state Medicaid 340B policies
- **Group Purchasing (if applicable):** The prevention of purchasing covered outpatient drugs through a GPO contract:
  - Definition of **"covered outpatient drug"**
  - Purchasing controls/separate purchasing accounts
- **Orphan Drugs (if applicable):** The prevention of purchasing specific orphan drugs under the 340B program:
  - Distinction for drugs used for conditions not related to "orphan" designation **("opt-in" vs "opt-out")**
  - Parent site vs. child site designations
  - Purchasing controls/separate purchasing accounts

340B independent audit plan scope

FOR ILLUSTRATIVE PURPOSES ONLY

Review how 340B activities are **documented and tracked**

	DETAILED PROCEDURES	Facilities	Performed By	Reviewed By
1.	Obtain and review evidence of a sample of monitoring activities established by the Compliance Plan	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager
2.	Confirm monitoring activity is operating as intended in policy and procedures and proper documentation is maintained	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager
3.	Obtain a list of the split billing software system changes performed during the period	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager
4.	Validate system changes followed the relevant policies and procedures and that the appropriate 340B staff were involved	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager

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Review of independent audit plan

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Evaluate whether adequate internal controls are in place to monitor and track program compliance related to diversion, duplicate discounts, and GPO exclusion based on samples of patient claims data. Additionally, evaluate whether 340B DSH Hospital is in compliance with program registration requirements

	DETAILED PROCEDURES	Facilities	Performed By	Reviewed By
1.	Confirm presence of all Covered Entities and accuracy of information	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager
2.	Verify contact information including phone and e-mail information, Medicaid exclusion information, ship to/bill to information, and contract pharmacy information	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager
3.	Review X hospital claims (X high cost medications and X random claims) to assess adherence to 340B patient eligibility and GPO purchasing requirements Assess the following elements of the 30 selected 340B claims: • Billed/accumulated quantity of the drug • Patient status • Location • Authorizing/Ordering provider is 340B-eligible • Purchasing contract is not listed as “GPO”	340B Hospitals	Internal auditor	Internal audit manager
4.	Review X Medicaid outpatient drug claims per facility and assess adherence to state billing guidelines	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager

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Sample documentation

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- **HRSA registration:** Documentation related to the facilities receiving and/or purchasing 340B medications
  - HRSA registration information (i.e., OPA Database)
  - Facility map and/or listing of areas receiving 340B medications
  - Medicare cost report and/or trial balance
- **Contracts (if applicable):** Agreements related to contract pharmacy and the provision of care for low-income patients (i.e., private, non-profit hospitals)
  - For private, non-profit hospitals - contract with a state or local government to provide health care services to low-income individuals who are not entitled to benefits under Medicare or Medicaid
  - For covered entities with contract pharmacies – written contract between covered entity and contract pharmacy that includes the ten (10) elements recommended by HRSA
- **Contract pharmacy (if applicable):** Additional documentation outlining controls in place within contract pharmacies
  - Registration
  - Duplicate discounts
  - Diversion

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Snapshot of metrics

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340B Compliance Monitoring/Sample Testing

Contract Pharmacy (CP)		
Tick Mark	Exception:	Count
{a}	Unable to identify a relevant encounter	1
{b}	Written date did not populate in the Split Billing software	2
{c}	UD modifier not present on prescription	3
{d}	Medicaid billing does not reflect acquisition cost + $7.25	4

Hospital Pharmacy		
Tick Mark	Exception:	Count
{a}	Patient was in deceased status when the drugs were administered	5
{b}	NDC does not match between Split Billing Software and EHR	6
{c}	Drug accumulated in incorrect account (GPO/340B)	7
{e}	Quantity Dispensed does not match between Split Billing Software and EHR	8

Medicaid		
Tick Mark	Exception:	Count
{a}	UD modifier not present prescription	9

Areas	Total Claims Tested	Claims Passed	Percent of Passed Claims
Area 1	100	100	100.00%
Area 2	100	90	90.00%
Area 3	100	80	80.00%
Contract Pharmacy 1	100	70	70.00%
Contract Pharmacy 2	100	60	60.00%
Contract Pharmacy 3	100	50	50.00%
Medicaid	100	40	40.00%
Total Claims	700	490	70.00%

	A	B	C	D	E	F
1	**340B Compliance Monitoring/Sample Testing**					
2						
3		**Selection ID**		**Selection Criteria**		
4		T1		Prescriptions with high profitability		
5		T2		Randomly selected GPO prescriptions		
6		T3		Randomly selected deceased patients		
7		T4		Randomly selected claims		
8						

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Independent audit plan scope

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Review appropriate **segregation of duties** throughout the 340B program processes

	DETAILED PROCEDURES	Facilities	Performed By	Reviewed By
1.	Review program roles and responsibilities as defined within the policy and assess whether they are consistent with operational practice	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager
2.	Review past internal/external audit observations	All 340B Facilities		
3.	Review past internal/external audit observations	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager
4.	Assess any follow up/action items were completed	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager
5.	Obtain documentation relative to the completion of associated corrective action plans	HOSPITAL 340B designated facilities	Internal auditor	Internal audit manager

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Taking Corrective Action

Disclosure of program violations

- HRSA requires disclosure of a material breaches of program non-compliance[1]
- HRSA has indicated that it intends to provide thresholds for materiality, but in the meantime, it recommends that covered entities maintain policies and procedures which define a "material breach"
- Apexus has provided an online tool[2] with examples of threshold indicators, including:
  1. X% of total 340B purchases or impact to any one manufacturer
  2. $X (fixed amount), based upon total outpatient or 340B spend, or impact to any one manufacturer
  3. X% of total 340B inventory (units)
  4. X% of audit sample
  5. X% of prescription volume/prescription sample
  6. Will not self-correct within x months

[1]Source: http://www.hrsa.gov/opa/updates/september2014.html#_ftn1
[2]Source: http://docs.340bpvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf

Repayment

- Covered entity and the manufacturer to work out any necessary financial remedy in good faith[1]
- Repayment may be voluntary or as a result of an audit
- Process between manufacturers and covered entities is still a "work-in-progress":
  - Outdated contact information on the OPA Database
  - Lack of defined timetables
  - Incongruity of repayment calculations
- At the recent 340B Summer Conference, HRSA indicated that it will be providing additional clarity on the repayment process in the future

[1]Source: http://www.hrsa.gov/opa/updates/september2014.html#_ftn1

Closing Comments

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Operational and financial takeaways

- **Financial impact:** Infusion centers and contract pharmacies are typically large drivers of program savings and are areas most affected within the proposed guidance. If changes go into effect as written, **what can organizations do to make up for the lost savings?**

- **Technology:** Certain configurations may already be possible within existing information technology infrastructure (i.e., accumulating/replenishing based on final billed status), while others may require additional investment of time and resources (i.e., excluding "bundled" drugs for Medicaid patients).

- **Audit and monitoring:** Proposed guidelines included detailed expectations for audit and monitoring activities. Most entities perform routine auditing and monitoring, but many lack a formal, structured, and integrated plan.

- Perform a **risk assessment** to analyze the effects of proposed guidance in its current form:
  - Financial – analyze how program savings/ROI is affected
  - Operational – assess additional resource requirements and procedural changes
  - Regulatory – look at at-risk areas based on current standards and findings from recent HRSA audits

- **Propose internal controls** to address risk areas

- Assess the possibility of **immediate corrective action** versus waiting until the guidance is released in final form:
  - Audit and monitoring practices
  - Error reporting procedures
  - Develop a repository for program documentation
  - Software and data infrastructure modifications

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Next steps

Moving toward a new 340B Program landscape

Pivoting in the marketplace

… providers need to take advantage of the changes in the regulatory landscape and pivot in the marketplace.

Compliance

…the rules are complex and massive. Proceed with caution.

Costs

…new Omnibus Guidance may reduce program savings. New opportunities and funding streams need to be explored

Providers and payers

…how they define value, act as purchasers and respond to new incentives will set the stage.

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Questions?

Additional Questions?

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