



## **340B Program Outlook: An Auditor's Toolkit for 2018 and beyond**

Session 408 – April 16, 2018

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## **Agenda**

**Introduction**



**Regulatory trends & updates**



**340B operational trends and risk areas**



**Monitoring practices and trends**



**Auditing\* practices and trends**



\*In this context and throughout this document, the term "audit" means a compliance assessment and does not constitute an audit conducted in accordance with generally accepted auditing standards, a test of internal controls, or other attestation or review services in accordance with standards established by the American Institute of Certified Public Accountants ("AICPA"), the Public Company Accounting Oversight Board, or other regulatory body.



**Introduction**

What are we hearing from 340B hospitals?

"How much investment should we make in resources for our 340B program?"

"We are finding a new 340B issue every day! Should I be concerned?"

"Should we report findings to our audit committee and/or board?"

"What compliance concerns do I need to be aware of when we implement a split billing software?"

"What should we be looking for as we monitor our 340B program?"

"Is the government canceling 340B?"

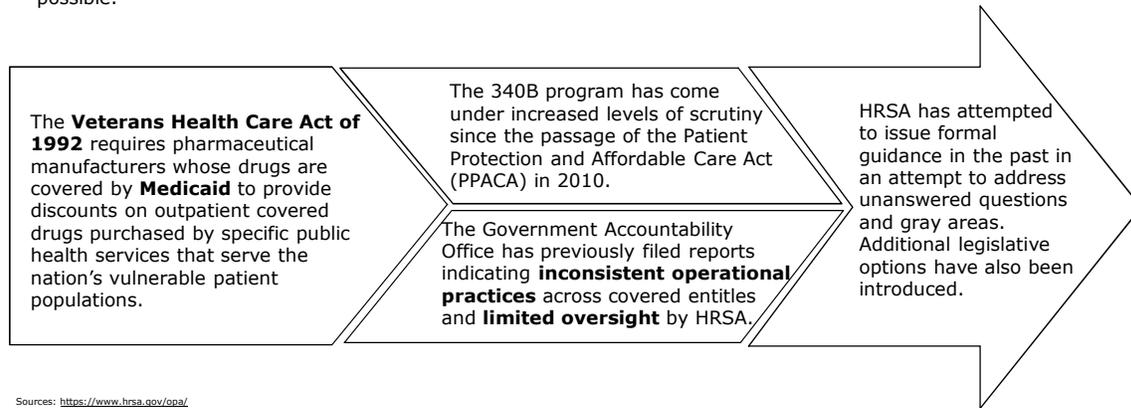
"How do I stay up to date with many the regulatory changes?"

## Introduction

### 340B program overview – Past, present & future

- **The 340B Drug Pricing Program is a government program created in 1992 that requires drug manufacturers to provide outpatient drugs at significantly reduced prices to qualified health care providers. The program is overseen by the Health Resources and Services Administration (HRSA).**

-The stated purpose of the program is to help covered entities stretch scarce federal resources as far as possible.

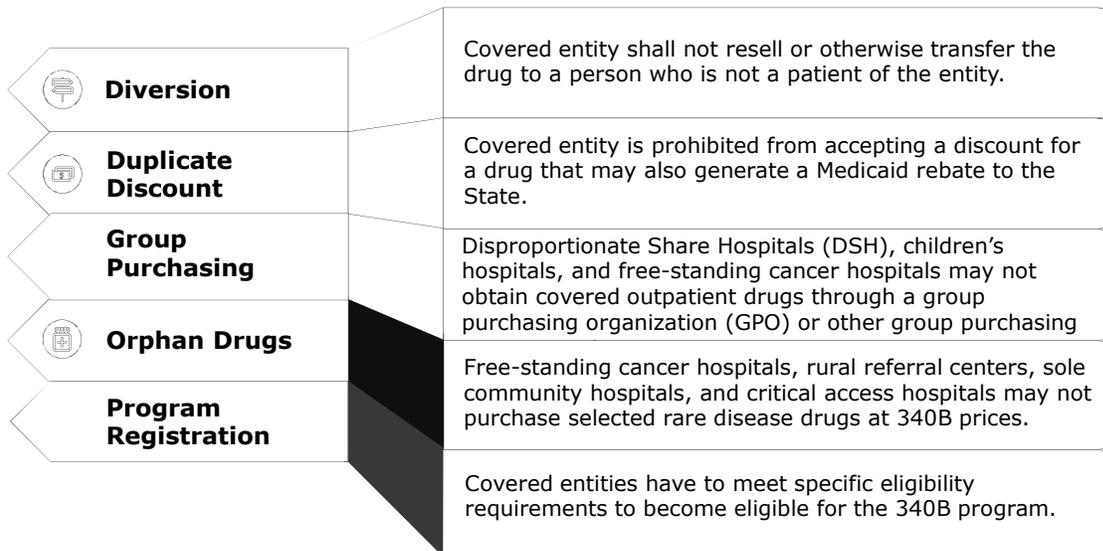


Sources: <https://www.hrsa.gov/opa/>  
<https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf>  
<https://www.healthcare.gov/glossary/patient-protection-and-affordable-care-act/>

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## Introduction

### Example 340B risk areas



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## Regulatory trends & updates

General themes anticipated for 2018 (and beyond)

Program **transparency** has been, and is expected to be, a common theme within legislative hearings as regulators continue to reshape the 340B program.



Covered entities provide services to their patients that may not be possible without the 340B program savings. Thus many entities have begun **documenting** how they are using their savings to better service their communities.



**A lack of clarity** in the regulations, as well as disconnects between legislators, regulators, and program stakeholders, potentially creates additional risks for 340B covered entities.



340B Program legislation has been introduced in both the House of Representatives and the Senate. This is in relation to the new Hospital Outpatient Prospective Payment System (OPPS) guidelines, **reporting requirements**, and facility eligibility.



Sources: <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>  
<https://www.politico.com/states/news/story/2018/02/13/what-to-expect-from-the-budget-hearing-032222>  
<http://www.modernhealthcare.com/article/20180206/NEWS/180209941>

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## Regulatory trends & updates

### Snapshot of current 340B program landscape

#### The Council of Economic Advisers Report

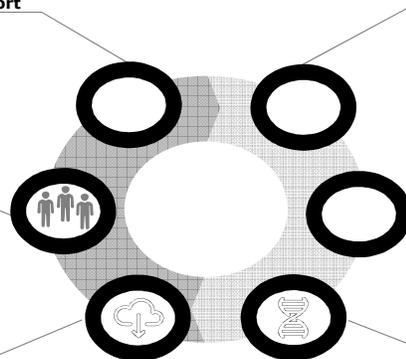
Reports from the White House indicate further suggest for 340B changes. Details of these changes remain unclear but could include more precise eligibility criteria for qualifying hospitals and single agency price control.

#### HRSA and Drug Manufacturer Checks

HRSA has standardized its audit process in hopes of addressing lingering regulatory questions. They have also begun contracting with the Bizzell Group to conduct checks.

#### Energy and Commerce Committee Recommendations

The report recommends increasing HRSA's regulatory authority to improve program integrity, clarify program requirements and monitor and track program use.



#### 340B Oversight Proposal

Senate finance committee chair Orrin Hatch has called for 340B oversight to shift from HRSA to CMS. He claims CMS should have oversight due to their extensive experience with hospitals, drug manufacturers, Medicare, and Medicaid.

#### FY19 Budgetary Impact

FY19 budgetary impact is still unknown; however, initial proposals alter Medicare Part B reimbursement rate for 340B hospitals, redirecting \$1.6 billion in projected savings to other hospital services.

#### American Hospital Association (AHA) Lawsuit

In December 2017, District Judge Contreras dismissed a hospital group's lawsuit against the proposed \$1.6 billion cuts to the 340B program. The hospital group has the opportunity to refile their claim once the payment change goes into effect.

Sources: <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>  
<https://www.politico.com/states/new-york/newsletters/politico-new-york-health-care/2018/02/12/what-to-expect-from-the-budget-hearing-032722>  
<http://www.modernhealthcare.com/article/20180206/NEWS/180209941>

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## Regulatory trends & updates

There are currently two bills related to 340B that have been proposed in the House of Representatives



**House Bill - HR 4710**

- 340B Protecting Access for the Underserved and Safety-Net Entities Act (**340B PAUSE Act**) introduced by Mr. Bucshon December 12, 2017.
- A **two-year moratorium** on new DSH parent hospitals enrolling in 340B and new child site registrations.
- **New data reporting requirements.**



**House Bill - HR 4392**

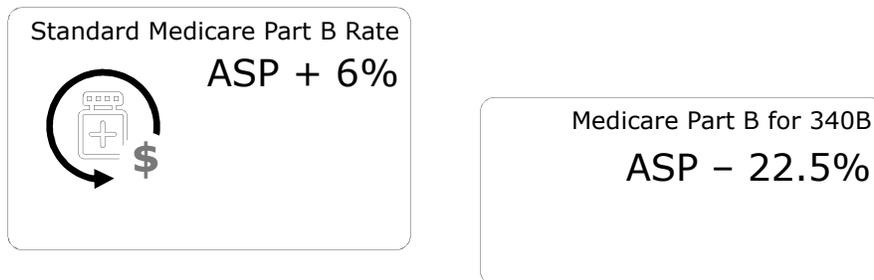
- **Prevent** the implementation of Medicare hospital outpatient **payment changes** for hospitals that purchase drugs under the 340B program.
- Bill was introduced November 14, 2017 by Mr. McKinley.

Sources: <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>  
<https://www.politico.com/states/new-york/newsletters/politico-new-york-health-care/2018/02/12/what-to-expect-from-the-budget-hearing-032722>  
<http://www.modernhealthcare.com/article/20180206/NEWS/180209941>

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## Regulatory trends & updates

### OPPS Rule - Changes to Part B payments for 340B drugs



Under the 2018 OPPS Final Rule, the government will no longer reimburse many 340B-purchased drugs at the standard Part B rate of **Average Sales Price (ASP) plus 6%**, and instead will pay a rate of **ASP minus 22.5%**.

This change has drawn **sharp criticism from hospital organizations** including potential litigation to block the proposed change in December 2017.

There are additional modifier requirements related to the reporting of 340B medications. The **"JG modifier" is used for 340B drugs administered to Medicare Part B patients**. Likewise, there is an **informational "TB modifier"** for medications that are exempt from the 340B payment reduction.

Source: <https://www.federalregister.gov/documents/2017/11/13/2017-23932/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment>

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## Regulatory trends & updates

### Certain drug classes and certain covered entities are exempt from the new OPPS rule changes



#### Exempted Drug Categories

- Drugs that are not separately payable
- Vaccines
- Drugs on "pass-through" status:
  - Certain newer drugs
  - Certain cancer drugs
  - Certain biologics and radiopharmaceuticals
  - Orphan drugs



#### Exempted Entity Types

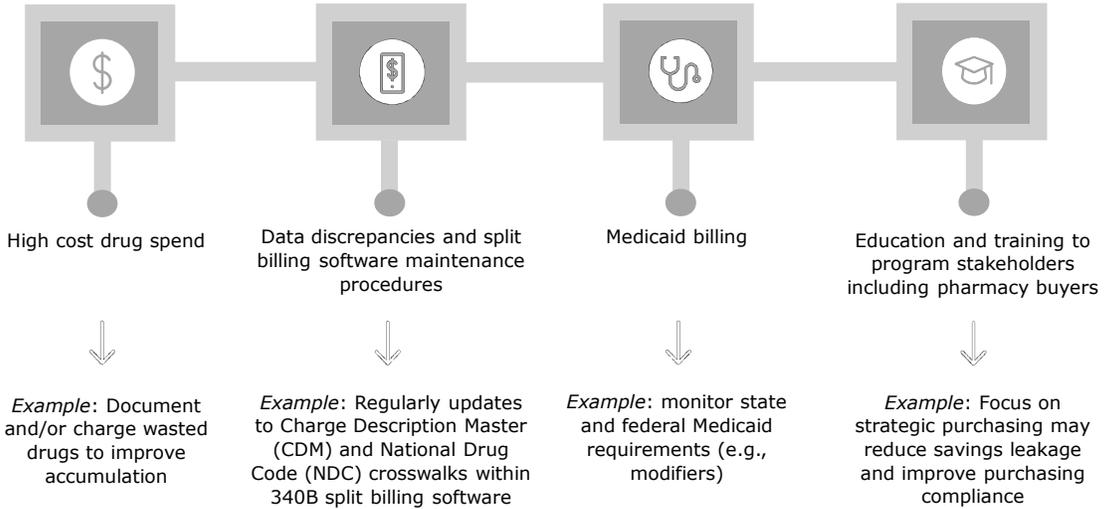
- Rural sole community hospitals (SCHs)
- Children's hospitals
- Prospective Payment System-exempt cancer hospitals
- New (non-excepted) off-campus hospital outpatient departments that are no longer paid under OPPS

<https://www.federalregister.gov/documents/2017/11/13/2017-23932/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment>

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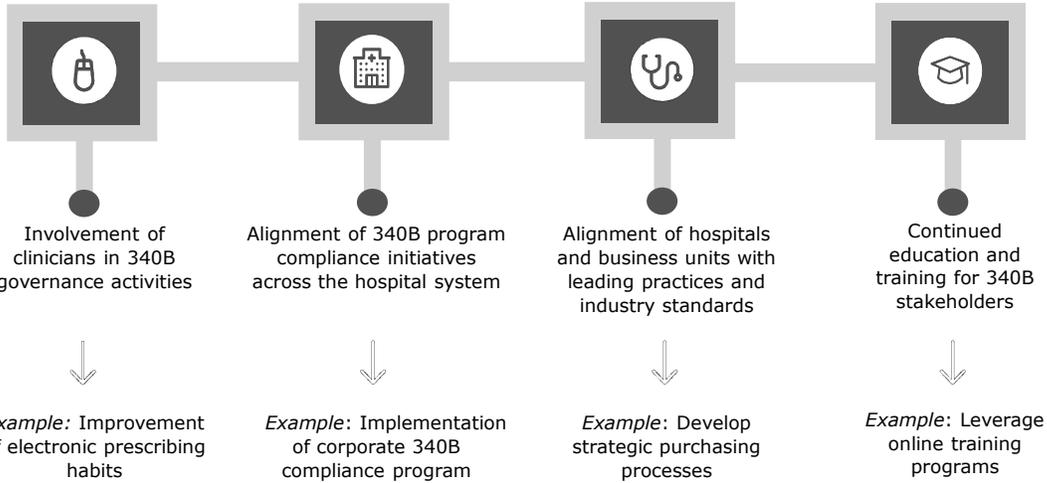
**340B program trends**  
Operational considerations



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<https://www.politico.com/states/new-york/newsletters/politico-new-york-health-care/2018/07/17/what-to-expect-from-the-budget-hearing-032722>  
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## 340B program trends

### Governance considerations

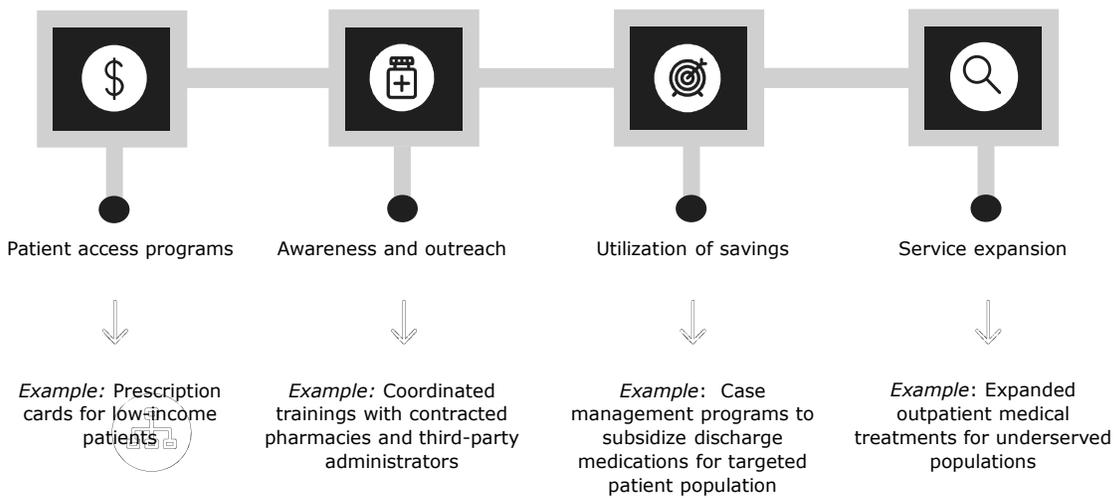


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<https://www.politico.com/states/new-york/newsletters/politico-new-york-health-care/2018/02/12/what-to-expect-from-the-budget-hearing-032722>  
<http://www.modernhealthcare.com/article/20180206/NEWS/180209941>

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## 340B program trends

### Community benefit considerations



Sources: <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>  
<https://www.politico.com/states/new-york/newsletters/politico-new-york-health-care/2018/02/12/what-to-expect-from-the-budget-hearing-032722>  
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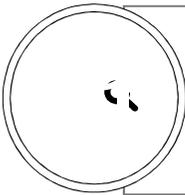
## Monitoring practices and trends

### Compliance 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.



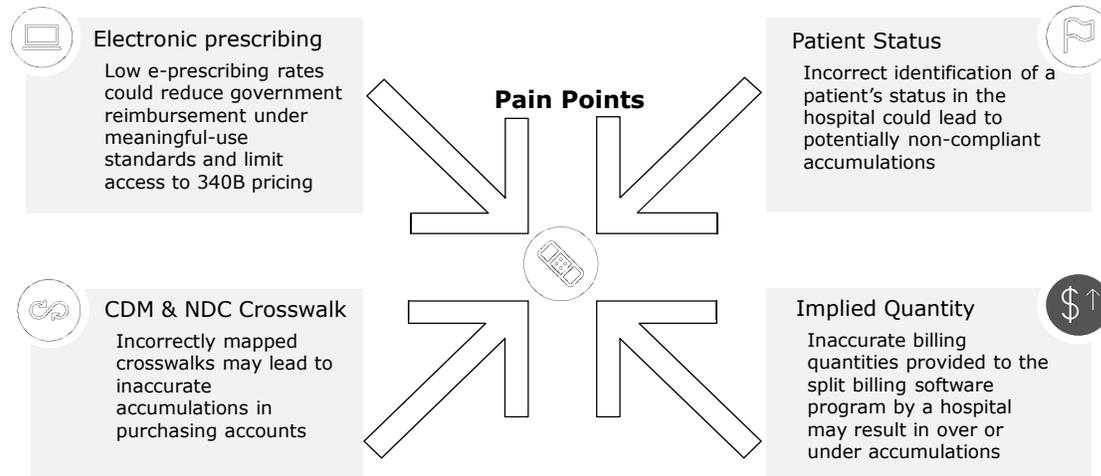
#### Auditing

- Typically defined as activities performed on a **scheduled basis** to measure and detect potential non-compliance as defined by policies, procedures, and standards.
- Performed by third parties within or at the direction of the organization, such as Internal Audit, Compliance, or contracted consultants.

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

## Monitoring practices and trends

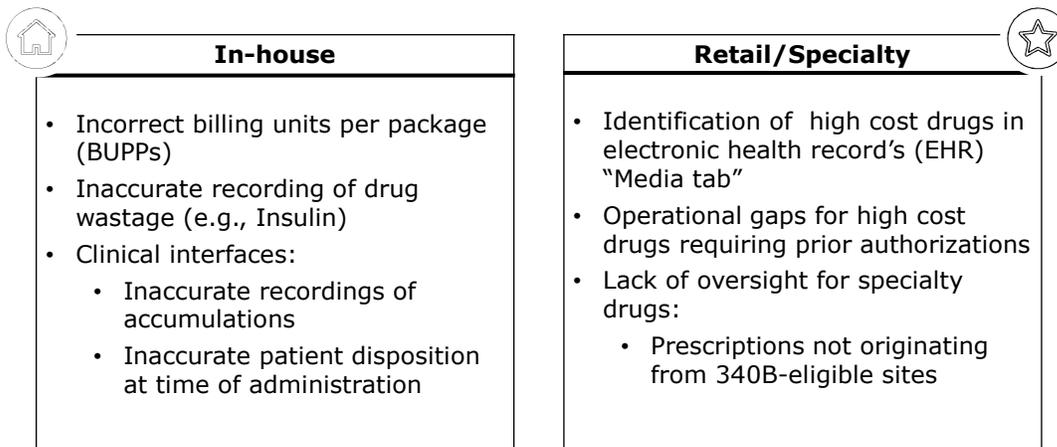
Illustrative listing of issues that could be identified during routine program monitoring at 340B hospitals



## Monitoring practices and trends

Specific focus areas related to “in-house” operations and retail pharmacy usage

As regulatory scrutiny surrounding the 340B program increases, hospitals should perform more than “check-the-box” reviews. Furthermore, the higher drug prices associated with retail pharmacy (i.e., specialty pharmacy) can create additional risks for hospitals. Some common issues are listed below.





## Audit practices and trends

HRSA is now contracting with The Bizzell Group to perform many of the HRSA checks

1

### Pre-audit

- Engagement letter from HRSA indicating selection for audit.
- Auditors conduct an introductory teleconference with entity and schedule opening meeting.
- Document list requested and provided prior to on site visit.

2

### On site

- Auditors review and test data to test policies, procedures, internal controls, compliance and transaction records.
- Auditors are now asking for more detail during checks, including attestations from external checks and validation from states regarding duplicate discounts.
- No preliminary results are presented at the conclusion of visit.

3

### Post-audit

- Auditors forward a preliminary report to Office of Pharmacy Affairs Information System (OPAIS) for review.
- OPAIS reviews the preliminary report, drafts a Final Report and issues the report to the covered entity, with a request for a corrective action plan (CAP), if applicable.

## Audit practices and trends

Snapshot of topics covered during recent HRSA 340B audits

	Topics	Details
	Registration and Paper Work Requested	<ul style="list-style-type: none"> <li>• 340B policies and procedures</li> <li>• Monitoring and auditing activities</li> <li>• Documentation showing evidence of non-profit status and Tax ID information</li> <li>• <b>Evidence of independent audits</b> as they relate to contract pharmacy arrangements</li> <li>• Detailed assessment of Medicare Cost Report</li> </ul>
	Claims Testing	<ul style="list-style-type: none"> <li>• Testing of high cost and randomly selected drugs</li> <li>• Requested evidence of drug order, administration, accumulation</li> <li>• Provider eligibility as it relates to claim (e.g., contractual relationship, evidence from credentialing office including start and end)</li> <li>• Medicaid:               <ul style="list-style-type: none"> <li>• Will want to know CEs processes on how they are handling in <b>AND out of state Medicaid patients</b></li> <li>• Request of UB-04 claim form for Medicaid patients</li> <li>• Evidence showing that CE is billing Medicaid with the appropriate National Provider Identifier number as well as state specific drug pricing/modifier</li> </ul> </li> </ul>

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## Audit practices and trends

Snapshot of topics covered during recent HRSA 340B audits

	Topics	Details
	Walkthroughs and Interviews	<ul style="list-style-type: none"> <li>• Walkthrough of pharmacy facilities and sample child sites</li> <li>• May request talk to persons responsible for drug procurement (e.g., supply chain and buyers)</li> <li>• Inquires on inventory management practices for automated dispensing machines, medicine cabinet locations</li> </ul>

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## Audit practices and trends

### Sample internal controls to assess

01

#### Vendor relationships and contracting

- Standardizing contracts across vendors/covered entities
- Defining procedures to regularly review and update information on the HRSA 340B Database
- Use of third-party software systems to maintain product tracking information

02

#### Medicaid

- For "carve-in" entities develop software controls to remove Medicaid plans through retrospective claims analysis.
- For "carve-out" entities develop automated alerts or emails to be sent to the 340B team in the event that the covered entities NPI or Medicaid number(s) change.

03

#### Inventory management

- Development of 340B formulary
- 340B controlled substance tracking and monitoring
- Routine inventory reconciliation and review of 340B purchase history and dispensing data
- Routine monitoring of 340B claims against the covered entities GPO exclusion/blacklisted file

04

#### Reimbursement

- Automated invoice reconciliation processes
- Real-time program performance analysis
- Routine monitoring of claims data for potential 340B diversion and/or fraudulent activity

05

#### Finance and accounting

- Develop correct budgeting/forecasting tools that address 340B volume
- Record and book careful inventory cost and adjustments (shrink provision, physical inventory, drug reconciliations, etc.)
- Conduct targeted financial audit activities relative to 340B program performance

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## Audit practices and trends

### Policy and procedure controls

As the 340B program continues to evolve, it is a leading practice to have appropriate controls in place.

Sample controls for 340B Program (not all inclusive; every organization must determine what is appropriate for itself)

- Definitions of "inpatient/outpatient status" and "covered outpatient drug"
- Process to obtain and monitor agreement with applicable county that addresses requirement for 340B program that hospital is committed to serve uninsured and underinsured (if applicable)
- Discharge prescription process and eligibility requirements
- Process for wastage
- Responsibilities, meetings requirements, and documentation for management oversight team
- Education and competency requirements to include self-audits by pharmacists

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## Audit practices and trends

### Policy and procedure controls

As the 340B program continues to evolve, it is a leading practice to have appropriate controls in place.

Sample controls for 340B Program (not all inclusive; every organization must determine what is appropriate for itself)



- Program intent for 340B savings
- Verification and update of information on the OPA database to include contacts and child sites
- Review and monitoring of SureScripts identifiers with active prescribers
- Enrollment for new contract pharmacies
- Process used by contract pharmacies to determine 340B-eligible patients
- Process used by contract pharmacies to filter eligible prescribers
- Define material breach and threshold indicators for issues
- Protocols for HRSA-initiated audits

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## Audit practices and trends

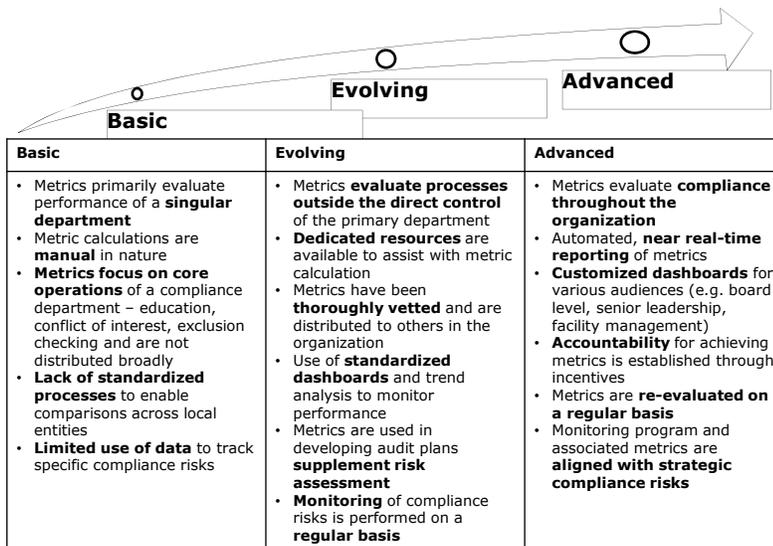
### Sample 340B compliance program maturity model

#### Working toward a leading 340B Compliance Program

- Implement changes that advance the 340B compliance program
- Integrated monitoring as well as cross-functional issue investigation and resolution
- Regular communication to, and involvement with, leadership on 340B issues and metrics
- Adaptive strategies using benchmarked practices

#### Avoiding common pitfalls

- Low levels of awareness and involvement from leadership
- Siloed operations
- Lack of formal 340B compliance program structure
- Limited resource support
- Immature and inconsistent auditing & monitoring
- Reactive vs. proactive



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## Thank You!



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