

# **340B Program Update & Recommendations for Monitoring Program Compliance**

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# Speaker Biography



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Ray is a Director in Deloitte & Touche LLP's Business Risk Health Sciences practice. He has 35 years of consulting experience in the healthcare industry. Prior to joining Deloitte, Ray was a Partner in Ernst & Young's Health Science Advisory Service practice where he served as the National co-Director of the Regulatory Reimbursement practice and as the National Director of the Revenue Management.

He has worked with clients on 340B projects for the past 15 years, planning and directing over 50 340B projects for health systems, acute care and children's hospitals. These engagements have included: financial assessments, split billing software system selection, program compliance reviews, program expansion, implementation services and credit and rebill filings. This work has been performed for some of the largest health systems in the country.



# Objectives

-  Provide a brief overview of the Federal 340B Drug Pricing Program requirements
-  Describe the current regulatory landscape
-  Provide recommendations for monitoring program compliance
-  Background on work performed by Ray and his team at UC in 2012-2014 – key assessment findings
-  Q & A



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# Overview of the 340B Program

# 340(b) Program Overview

## 340(b) Program Criteria

1. Hospital must have a Disproportionate Share Adjustment Percentage of 11.75% or greater.
2. Must be owned or operated by a unit of State or local government, a non-profit corporation which is formally granted governmental powers by a unit of State or local government, or a private non-profit hospital which has a contact with a State or local government to provide healthcare services to low income individuals.
3. Must not obtain outpatient drugs covered by 340(b) through a group purchasing organization.

## OPA's Patient Definition

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
3. The individual receives health care service(s) from the covered entity which is consistent with the services(s) for which grant funding or federally-qualified health center look-alike status has been provided to the entity.

## Multiple Issues Surround 340(b)



# Key Dates and Legislation

1992 – 340B Legislation Written into Law

1994 Final Notice – 340B Entity Guidelines

1996 Final Notice – Patient and Entity Eligibility

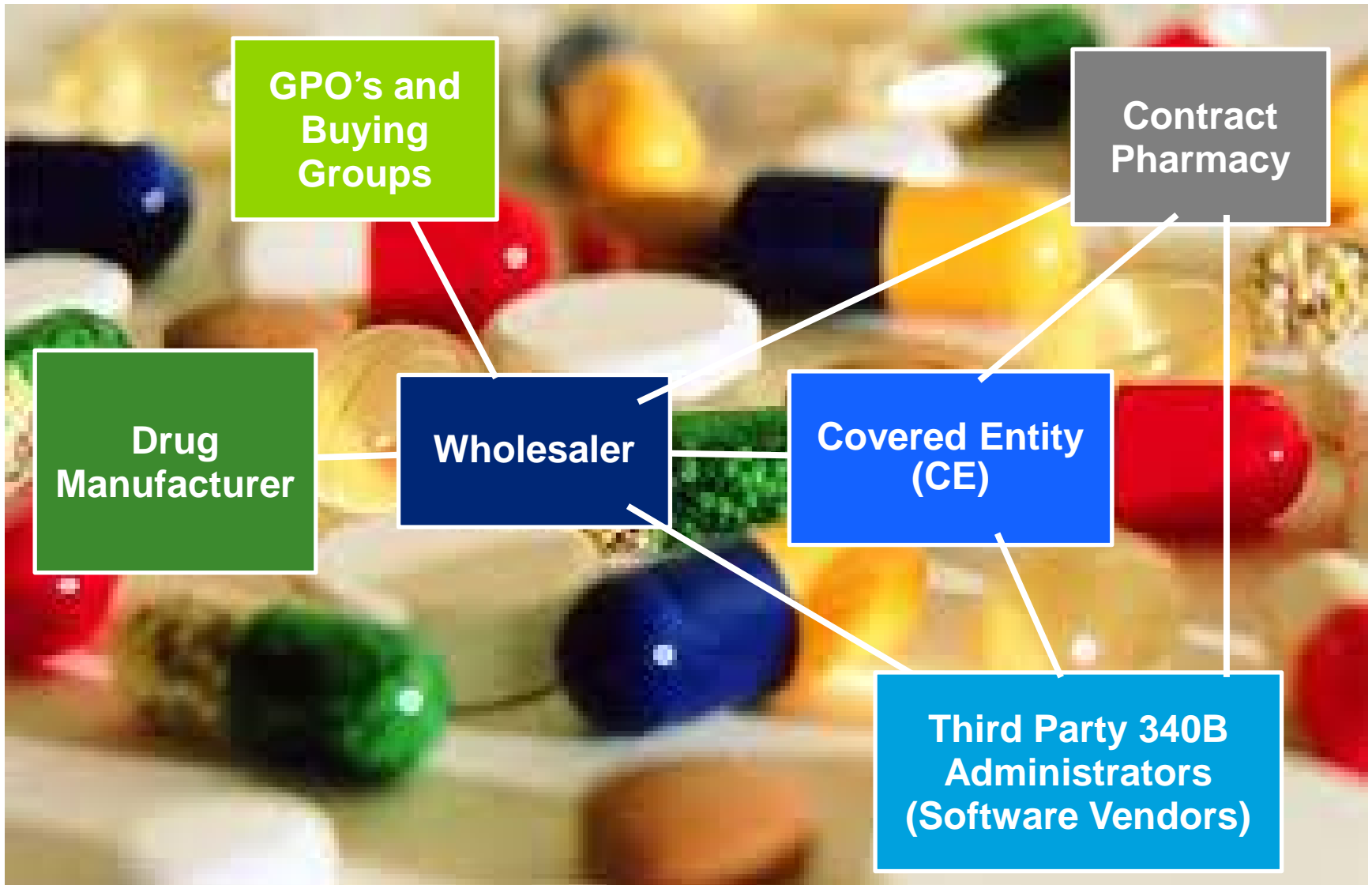
1998 Final Notice – Rebate Option

2010 Final Notice – Contract Pharmacy Services

2014 Mega Regulation ???????



# Active Participants in 340B



# Program Prohibitions

## DUPLICATE DISCOUNT

CE is prohibited from accepting a discount for a drug that would also generate a Medicaid rebate to the State.

## DIVERSION

CE shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

## 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.~~



# Duplicate Discount

- Covered entities may not receive a 340B discount for drugs that are subject to a Medicaid rebate
  - Required to inform HRSA (Medicaid billing number) at the time of 340B enrollment how they plan to handle 340B drugs for Medicaid patients
  - Established by each State Medicaid agency
- State Medicaid program examples:
  - Require covered entities to **carve out Medicaid** patients from 340B so the State can claim the rebate
  - Allow covered entities to use 340B drugs for Medicaid patients, and **reduce Medicaid payment** to the covered entity
  - Allow covered entities to use 340B drugs for Medicaid patients, and pay an **increased dispensing fee**

Source: US Department of Health and Human Services: Health Resources and Services Administration (HRSA). *Clarification of HRSA Audits of 340B Covered Entities. 1-2. 340B Drug Pricing Program Notice Release No. 2012 - 1.1. February 8, 2013.* <http://www.hrsa.gov/opa/programrequirements/policyreleases/auditclarification020813.pdf>

# Diversion

- Drugs must be administered to an **eligible patient**
  1. CE has established a relationship with the individual, such that the CE maintains ***records of the individual's health care***; and
  2. Individual receives health care services from a ***health care professional*** who is either employed by the CE or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the CE; and
  3. Individual receives health care service(s) from the CE which is consistent with the services(s) for which grant funding or federally-qualified health center look-alike status has been provided to the entity.
- Not considered a patient if the only health care service is the dispensing of a drug for **self-administration**
- In 2007, HRSA published proposed guidance to clarify the eligible patient definition. Chose not to issue final guidance at that time.



# Covered Drugs

Generally, the 340B Program covers the following outpatient drugs:

- Outpatient prescription drugs
- FDA-approved prescription drugs
- Over-the-counter (OTC) drugs written on a prescription
- Clinic administered drugs within eligible facilities
- FDA-approved insulin
- But NOT Orphan Drugs

The following drugs are not covered:

- Vaccines
- In-patient drugs



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

# GPO Exclusion

- On February 7, 2013, HRSA issued a policy release clarifying its position. Compliance deadline was **April 7, 2013**
  - Hospital subject to the GPO prohibition **may not purchase covered outpatient drugs through a GPO** for any of its covered locations.
  - Opening wholesale acquisition cost (WAC) accounts with their drug wholesalers and overhauling their virtual drug inventory software
  - If found in violation will be considered ineligible and removed from the 340B Program. May be **subject to repayment to manufacturers**
- HRSA extended the compliance deadline to **August 7, 2013**
  - Covered entities unable comply by the extended deadline must immediately notify HRSA and will be terminated from the program
  - Non-compliant hospitals identified by HRSA after the extension will be **involuntarily terminated**

# External Audits to Date

HRSA	Manufacturers
<p><b>FY 2012</b></p> <ul style="list-style-type: none"><li>51 total<ul style="list-style-type: none"><li>45 risk-based</li><li>6 targeted</li></ul></li><li>450 outpatient facilities</li><li>400 contract pharmacies</li></ul> <p><b>FY 2013</b></p> <ul style="list-style-type: none"><li>94 total (estimated)<ul style="list-style-type: none"><li>700 outpatient facilities</li><li>1,930 contract pharmacies</li></ul></li></ul>	<ul style="list-style-type: none"><li>• OPA has received nine audit work plans</li><li>• Allowed eight audits to be conducted by manufacturers</li><li>• OPA has received seven final audit reports</li></ul>

Source: US Department of Health and Human Services: Health Resources and Services Administration (HRSA). Audit Results: Program Update, May 9, 2014.pdf. <http://www.hrsa.gov/opa/updates/140509auditresults.html>.  
Source: US Department of Health and Human Services: Health Resources and Services Administration (HRSA). Program Integrity: FY13 Audit Results, Updated 03/21/2014. <http://www.hrsa.gov/opa/programintegrity/auditresults/fy13results.html>

# HRSA FY13 Audit Results

Only includes audits where the entity has agreed to the HRSA final report

No.	Entity	State	OPA Findings	Sanction	Corrective Action with Completion Date
1	Baptist Memorial Hospital – Desoto	MS	No adverse findings.	None.	N/A
2	Christ Community Health Services, Inc.	TN	No adverse findings.	None.	N/A
3	Citizen’s Baptist Medical Center	AL	Incorrect 340B database record – Incorrect Authorizing Official;	None.	Pending
4	Dell Children’s Medical Center	TX	No adverse findings.	None.	N/A
5	Family Health Services of Cranston	RI	No adverse findings.	None.	N/A
6	Georgia Dept of Public Health	GA	No adverse findings.	None.	N/A
7	Lawrence General Hospital	MA	Diversion – 340B drugs dispensed to inpatients; 340B drug dispensed not supported by a medical record.	Repayment to manufacturers.	Pending
8	Los Angeles County Department of Health Services – USC Medical Center	CA	No adverse findings.	None.	N/A
9	Northeast Alabama Regional Medical Center	AL	No adverse findings.	None.	N/A
10	Reeves County Hospital District	TX	No adverse findings.	None.	N/A
11	Russell Medical Center	AL	No adverse findings.	None.	N/A
12	SeaMar Community Health Centers – Mount Vernon	WA	No adverse findings.	None.	N/A
13	Stokes County Health Department	NC	Incorrect 340B database record – Entity was using contract pharmacies not listed on the 340B database; Incorrect primary contact information.	None.	Pending

# Manufacturer Audits

Patient Protection and Affordable Care Act (ACA) establishes 340B integrity provisions and auditing expectations.

- Implementation of 340B program monitoring activities to assess and monitor covered entity compliance with 340B requirements and identify “**reasonable cause**” to perform 340B audits
- Submission of a “reasonable cause” letter and audit work plan to the OPA for approval
- Retention of an “independent auditor” to perform audits of covered entities





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# Regulatory Landscape



# OIG Report

Issued February 4, 2014 “Contract Pharmacy Arrangements in the 340B Program” (OEI-05-13-00431).

Main findings:

- **Complications in preventing diversion** – two covered entities may categorize similar types of prescriptions differently
  - **Complications in preventing duplicate discounts** – difficulties identifying beneficiaries covered by Medicaid managed care organizations
  - Many covered entities surveyed chose to **carve out Medicaid claims** altogether thus avoiding the duplicate discount issue
  - Several covered entities do not conduct all of the **oversight activities** that HRSA recommends
  - Some covered entities do not offer **340B discounted drugs to uninsured** patients in their contract pharmacy arrangements
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- **2014 OIG Work Plan Items**

# Status of 340B Mega-Regulation

- April 9, 2014: HRSA sent proposed 340B “mega-reg” to the Office of Management and Budget (OMB) for review prior to its publication in the *Federal Register*
  - OMB review typically takes no more than 90 days
  - 60 days for public comment
- May 22, 2014: PhRMA gave OMB document detailing changes they want to see
  - Limited to "**uninsured indigent individuals**" only
  - **Expansion of 340B contract pharmacy** “beyond any meaningful limits”
  - Opportunities for ‘**arbitrage**’ – difference between the 340B price and the price they charge insurers for patients who have insurance

Source: Drug Discount Monitor



# 340B Mega-Regulation Provisions *(illustrative)*

- **Program intent** – Clearly define the mission of the 340B program, 340B hospitals provide more charity care and discounts on medications to its needy patients
- **Patient eligibility** – clearer and more specific definition of a 340B eligible patient, including referral arrangements
- **Contracted and employed physicians** – a clearer definition of the relationship between physician and covered entity, and who has responsibility for the care of the patient.
- **Contract pharmacy oversight** – may establish a cap on number of contract pharmacy arrangements a covered entity can enter into
- **Independent audits of contract pharmacy** – establishes use of a third party accounting firm as the requirement
- **Covered outpatient drug** – clarification on the definition of covered outpatient drug



# 340B Mega-Regulation Provisions *(illustrative)(cont.)*

- **Medicaid Managed Care Organizations (MCO)** – clarification on HRSA’s guidance stipulating that the statute prohibits covered entities from subjecting manufacturers to duplicate discounts for both Fee-for-Service Medicaid and Medicaid MCO
- **Transparency in 340B prices** – requirement that manufacturers’ 340B ceiling prices be published on the DHHS websites
- **Accurate 340B ceiling price** – verify the accuracy of 340B ceiling prices charged by manufacturers to 340B covered entities, with HRSA/OPA conducting spot checks and/or audits
- **Mandatory manufacturer credit or refund process** – requiring manufacturers to retroactively issue refunds when covered entities were overcharged relevant to underlying Medicaid pricing data
- **Penalties for non-compliance** – regulations implementing penalties for non-compliance and delineating sanctionable events





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# Compliance Monitoring Considerations

# Compliance Program Considerations

- **Develop a resource plan**
  - Identify a **project team**, including executive support, with defined responsibilities for each team member
  - Develop project management **status reporting** and conduct regular meetings
  - For larger hospitals, consider hiring a **dedicated 340B resource**
- **Establish a training program**
  - Ensure all employees are **trained, well-versed**, and understand the rules and compliance requirements
  - Conduct regular staff training and competency assessments
  - Share updates to policies and standard operating procedures
- **Annual review of registered eligible services and sites**
  - Review covered entity's compliance **prior to recertification**
  - Ensure all records and information on the **340B database are kept up-to-date**

# Compliance Program Considerations, (continued)

- **Define auditable prescription capture criteria**
  - Definition for “**Covered Outpatient Drug**” should be consistent with section 1927(k) of the Social Security Act
    - Use a separate GPO and/wholesaler account to purchase drugs that do not meet the definition
  - “Patient” and “Provider” definitions should ensure **appropriate medical record ownership** and **responsibility of care** for captured 340B prescriptions
- **Validate data after making changes to system configuration**
  - Review accuracy of **patient location mapping** and **status indicators**
  - Scrutinize hospital eligible **prescriber list** against established criteria
  - Identify causes of any **accumulation discrepancies** (i.e., excessive positive/negative inventory)

# Compliance program considerations, (continued)

- **Maintain accurate records documenting compliance**
  - Develop **policies, procedures and controls** designed to document compliance with the rules regarding diversion, duplicate discounts and GPO exclusion that are **regularly reviewed and updated**
  - Operationalized and reflect actual practice
  - Maintain a **complete “audit trail”** from prescription to pick-up by the patient to replenishment
- **Understand State Medicaid agency’s 340B billing requirements**
  - Review hospital **billing system compliance**
  - Validate accuracy of wholesaler **price catalogs**
  - Obtain confirmation regarding **carving in/ carving out** Medicaid Fee for Service (FFS) and Managed Care Organization (MCO) Medicaid prescriptions for both in-house and contract pharmacy programs



# Compliance program considerations, (continued)

- **Develop specific desktop procedures**
  - Drug processing from **patient/drug presentation to replenishment**
  - Procedures performed by areas such as pharmacy, materials management, IT, patient financial services and reimbursement
  - Outline practices at **specific locations** (i.e., outpatient clinic, mixed-use, contract pharmacy)
- **Conduct routine auditing and monitoring activities**

• Patient eligibility audits	• State Medicaid billing and reimbursement guidelines
• Physician eligibility audits	• Price changes
• Inventory audits	• Changes in purchasing patterns
• Duplicate discount audits	• Contract pharmacy claims

# Example Monitoring Plan

Monitoring Tool – Frequency	Method
<b>Purchasing volume analysis - Monthly</b>	<ul style="list-style-type: none"> <li>• High level review of purchasing volume for each account to ensure purchases have been transacted on the correct account.</li> <li>• Review significant changes in purchase volume.</li> <li>• Variances are corrected, using credit and re-bill if necessary.</li> </ul>
<b>Validation of utilization data in mixed use areas - Monthly</b>	Review 25 patients which the splitting software designated for 340B drug purchase. Check status in the EHR to ensure patient status was outpatient and eligible for 340B purchase.
<b>Eligible drug review in mixed use areas - Monthly</b>	Review 340B drug purchases which are primarily utilized for inpatients. Select 25 drugs and review for appropriate outpatient status and the accumulation is accurate.
<b>Crosswalk review in mixed use areas – Monthly</b>	Review the accuracy of the drug crosswalk for 25 medications.
<b>Drug purchase review in mixed use areas – Monthly</b>	For 10 selected drugs, verify the correct quantity is purchased on the 340B accounts based on the quantity that was processed in the accumulator.
<b>Review of Medicaid billing in mixed use areas – Monthly</b>	Review 10 Medicaid outpatient drug claims for accuracy.
<b>Review of charges versus purchases in mixed use settings - Quarterly</b>	For 30 selected drugs, review 340B eligible patient charges to validate the 340B purchases for the same time period.

# Example Monitoring Plan, cont.

Monitoring Tool – Frequency	Method
<b>Review of eligible 340B prescriptions - Monthly</b>	Assess 340B accumulation for patients with an ineligible plan.
<b>Review of purchases at ineligible sites - Monthly</b>	Review purchases from ineligible locations evaluate that purchases were made under the WAC account.
<b>Physician database for Contract Pharmacies – Monthly</b>	Assess the accuracy of the prescriber database to ensure proper designation.
<b>Prescription Transaction Validation for Contract Pharmacy - Daily</b>	Verify the number of prescriptions filled matches the number of transactions that cross into prescription splitting software.
<b>Review of Insurance Type on Captured Claims – Monthly</b>	Review insurance information for all 340B captured prescriptions from contract pharmacies to ensure no Medicaid prescriptions were replenished with 340B medications.
<b>Patient eligibility review in contract pharmacy - Monthly</b>	Select 30 340B claims to validate that an appropriate record of care exists for that patient in EPIC.
<b>Provider review in contract pharmacy – Monthly</b>	Validate provider information for 30 340B claims to ensure that the provider is currently listed on the eligible prescriber list.
<b>Review of pharmacy invoices - Monthly</b>	Review contract pharmacy purchases against pharmacy invoices to validate payments to pharmacy wholesaler.



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Background on work performed by Ray and his team at UC in 2012-2014 – key assessment findings



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Q & A